

## **16.1.13 Optional Appendix**

### **16.1.13.1 Standardized MedDRA Queries (Version 23.0)**

The SMQs included in this section are as follows:

[SMQ Anaphylactic Reaction MedDRA](#)

[SMQ Angioedema MedDRA](#)

[SMQ Arthritis MedDRA](#)

[SMQ Convulsions MedDRA](#)

[SMQ Demyelination MedDRA](#)

[SMQ Hypersensitivity MedDRA](#)

[SMQ Peripheral Neuropathy MedDRA](#)

[SMQ Vasculitis MedDRA](#)

[SMQ Thrombophlebitis MedDRA](#)

[SMQ Cardiomyopathy MedDRA](#)

[SMQ Central nervous system vascular disorders MedDRA](#)

[SMQ Embolic and thrombotic events MedDRA](#)

[SMQ Haematopoietic cytopenias MedDRA](#)

[SMQ Hearing and vestibular disorders MedDRA](#)

[CMQ Autoimmune MedDRA](#)

[CMQ Potential Dermal Filler Reaction post Vaccination MedDRA](#)

### **16.1.13.2 DSMB Charters**

The DSMB Charters included in this section are as follows:

[Charter for the COVID-19 Vaccine Data and Safety Monitoring Board dated 24 Jun 2020](#)

[Charter for the COVID-19 Vaccine Data and Safety Monitoring Board dated 22 Jul 2020](#)

[Charter for the COVID-19 Vaccine Data and Safety Monitoring Board dated 03 Aug 2020](#)

[Charter for the COVID-19 Vaccine Data and Safety Monitoring Board dated 30 Oct 2020](#)

[Analysis Plan for Data Safety Monitoring Board \(DSMB\) Version 2.0 dated 07 Aug 2020](#)

<b>SMQ Export: 23.0 - English</b>			<b>1/15/2021</b>
	Include Inactive PT: No		
<b>English: Anaphylactic reaction (SMQ)</b>			
	<b>English</b>	<b>Code</b>	<b>Level</b>
	Anaphylactic reaction	10002198	PT
	Anaphylactic shock	10002199	PT
	Anaphylactic transfusion reaction	10067113	PT
	Anaphylactoid reaction	10002216	PT
	Anaphylactoid shock	10063119	PT
	Circulatory collapse	10009192	PT
	Dialysis membrane reaction	10076665	PT
	Kounis syndrome	10069167	PT
	Procedural shock	10080894	PT
	Shock	10040560	PT
	Shock symptom	10040581	PT
	Type I hypersensitivity	10045240	PT
	Acute respiratory failure	10001053	PT
	Asthma	10003553	PT
	Bronchial oedema	10056695	PT
	Bronchospasm	10006482	PT
	Cardio-respiratory distress	10049874	PT
	Chest discomfort	10008469	PT
	Choking	10008589	PT
	Choking sensation	10008590	PT
	Circumoral oedema	10052250	PT
	Cough	10011224	PT
	Cough variant asthma	10063076	PT
	Cyanosis	10011703	PT
	Dyspnoea	10013968	PT
	Hyperventilation	10020910	PT
	Irregular breathing	10076213	PT
	Laryngeal dyspnoea	10052390	PT
	Laryngeal oedema	10023845	PT
	Laryngospasm	10023891	PT
	Laryngotracheal oedema	10023893	PT
	Mouth swelling	10075203	PT
	Nasal obstruction	10028748	PT
	Oedema mouth	10030110	PT
	Oropharyngeal oedema	10078783	PT
	Oropharyngeal spasm	10031111	PT
	Oropharyngeal swelling	10031118	PT
	Pharyngeal oedema	10034829	PT
	Pharyngeal swelling	10082270	PT
	Respiratory arrest	10038669	PT
	Respiratory distress	10038687	PT
	Respiratory failure	10038695	PT
	Reversible airways obstruction	10062109	PT
	Sensation of foreign body	10061549	PT
	Sneezing	10041232	PT

	Stridor	10042241	PT
	Swollen tongue	10042727	PT
	Tachypnoea	10043089	PT
	Throat tightness	10043528	PT
	Tongue oedema	10043967	PT
	Tracheal obstruction	10044291	PT
	Tracheal oedema	10044296	PT
	Upper airway obstruction	10067775	PT
	Wheezing	10047924	PT
	Acquired C1 inhibitor deficiency	10081035	PT
	Allergic oedema	10060934	PT
	Angioedema	10002424	PT
	Circumoral swelling	10081703	PT
	Erythema	10015150	PT
	Eye oedema	10052139	PT
	Eye pruritus	10052140	PT
	Eye swelling	10015967	PT
	Eyelid oedema	10015993	PT
	Face oedema	10016029	PT
	Flushing	10016825	PT
	Hereditary angioedema with C1 esterase inhibitor deficiency	10080955	PT
	Injection site urticaria	10022107	PT
	Lip oedema	10024558	PT
	Lip swelling	10024570	PT
	Nodular rash	10075807	PT
	Ocular hyperaemia	10030041	PT
	Oedema	10030095	PT
	Oedema blister	10080039	PT
	Periorbital oedema	10034545	PT
	Periorbital swelling	10056647	PT
	Pruritus	10037087	PT
	Pruritus allergic	10063438	PT
	Rash	10037844	PT
	Rash erythematous	10037855	PT
	Rash pruritic	10037884	PT
	Skin swelling	10053262	PT
	Swelling	10042674	PT
	Swelling face	10042682	PT
	Swelling of eyelid	10042690	PT
	Urticaria	10046735	PT
	Urticaria papular	10046750	PT
	Blood pressure decreased	10005734	PT
	Blood pressure diastolic decreased	10005737	PT
	Blood pressure systolic decreased	10005758	PT
	Cardiac arrest	10007515	PT
	Cardio-respiratory arrest	10007617	PT
	Cardiovascular insufficiency	10065929	PT
	Diastolic hypotension	10066077	PT
	Hypotension	10021097	PT
	Hypotensive crisis	10083659	PT
	Post procedural hypotension	10084013	PT

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Scope	Category	Weight	Status	Addition Version	Last Modified Version
Narrow	A	0	Active	8.1	8.1
Narrow	A	0	Active	8.1	8.1
Narrow	A	0	Active	11.1	11.1
Narrow	A	0	Active	8.1	8.1
Narrow	A	0	Active	8.1	8.1
Narrow	A	0	Active	8.1	8.1
Narrow	A	0	Active	18.1	18.1
Narrow	A	0	Active	12.0	12.0
Narrow	A	0	Active	21.0	21.0
Narrow	A	0	Active	8.1	8.1
Narrow	A	0	Active	8.1	18.1
Narrow	A	0	Active	8.1	8.1
Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	8.1	8.1
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Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	11.0	11.0
Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	8.1	23.0
Broad	B	0	Active	14.1	15.0
Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	18.0	18.1
Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	8.1	8.1
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Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	17.1	17.1
Broad	B	0	Active	12.1	14.0
Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	20.0	20.0
Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	20.0	20.0
Broad	B	0	Active	22.0	22.0
Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	8.1	8.1



Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	14.1	14.1
Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	8.1	8.1
Broad	B	0	Active	11.0	11.0
Broad	B	0	Active	8.1	8.1
Broad	C	0	Active	21.0	21.0
Broad	C	0	Active	8.1	8.1
Broad	C	0	Active	8.1	10.0
Broad	C	0	Active	21.1	21.1
Broad	C	0	Active	8.1	8.1
Broad	C	0	Active	8.1	8.1
Broad	C	0	Active	14.1	14.1
Broad	C	0	Active	8.1	8.1
Broad	C	0	Active	8.1	8.1
Broad	C	0	Active	8.1	8.1
Broad	C	0	Active	21.0	21.0
Broad	C	0	Active	14.1	14.1
Broad	C	0	Active	8.1	9.1
Broad	C	0	Active	8.1	9.1
Broad	C	0	Active	18.0	18.1
Broad	C	0	Active	14.1	14.1
Broad	C	0	Active	8.1	8.1
Broad	C	0	Active	20.1	20.1
Broad	C	0	Active	8.1	8.1
Broad	C	0	Active	8.1	21.1
Broad	C	0	Active	8.1	8.1
Broad	C	0	Active	8.1	8.1
Broad	C	0	Active	8.1	8.1
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Broad	C	0	Active	8.1	8.1
Broad	C	0	Active	8.1	21.1
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Broad	C	0	Active	8.1	8.1
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Broad	D	0	Active	8.1	8.1
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Broad	D	0	Active	8.1	8.1
Broad	D	0	Active	8.1	8.1
Broad	D	0	Active	9.0	9.0
Broad	D	0	Active	9.1	9.1
Broad	D	0	Active	8.1	9.1
Broad	D	0	Active	23.0	23.0
Broad	D	0	Active	23.0	23.0

<b>SMQ Export: 23.0 - English</b>			<b>1/15/2021 1:55:02 PM</b>						
	Include Inactive PT: No								
<b>English: Angioedema (SMQ)</b>									
	<b>English</b>	<b>Code</b>	<b>Level</b>	<b>Scope</b>	<b>Category</b>	<b>Weight</b>	<b>Status</b>	<b>Addition Version</b>	<b>Last Modified Version</b>
	Acquired C1 inhibitor deficiency	10081035	PT	Narrow	A	0	Active	21.0	21.0
	Allergic oedema	10060934	PT	Narrow	A	0	Active	8.1	8.1
	Angioedema	10002424	PT	Narrow	A	0	Active	8.1	10.0
	Circumoral oedema	10052250	PT	Narrow	A	0	Active	8.1	8.1
	Circumoral swelling	10081703	PT	Narrow	A	0	Active	21.1	21.1
	Conjunctival oedema	10010726	PT	Narrow	A	0	Active	8.1	8.1
	Corneal oedema	10011033	PT	Narrow	A	0	Active	8.1	8.1
	Epiglottic oedema	10015029	PT	Narrow	A	0	Active	8.1	8.1
	Eye oedema	10052139	PT	Narrow	A	0	Active	8.1	8.1
	Eye swelling	10015967	PT	Narrow	A	0	Active	8.1	8.1
	Eyelid oedema	10015993	PT	Narrow	A	0	Active	8.1	8.1
	Face oedema	10016029	PT	Narrow	A	0	Active	8.1	8.1
	Gingival oedema	10049305	PT	Narrow	A	0	Active	8.1	8.1
	Gingival swelling	10018291	PT	Narrow	A	0	Active	8.1	8.1
	Gleich's syndrome	10066837	PT	Narrow	A	0	Active	10.0	10.0
	Hereditary angioedema	10019860	PT	Narrow	A	0	Active	8.1	8.1
	Hereditary angioedema with C1 esterase inhibitor deficiency	10080955	PT	Narrow	A	0	Active	21.0	21.0
	Idiopathic angioedema	10073257	PT	Narrow	A	0	Active	16.0	16.0
	Idiopathic urticaria	10021247	PT	Narrow	A	0	Active	8.1	8.1
	Intestinal angioedema	10076229	PT	Narrow	A	0	Active	18.0	18.0
	Laryngeal oedema	10023845	PT	Narrow	A	0	Active	8.1	8.1
	Laryngotracheal oedema	10023893	PT	Narrow	A	0	Active	8.1	8.1
	Limbal swelling	10070492	PT	Narrow	A	0	Active	13.1	14.0
	Lip oedema	10024558	PT	Narrow	A	0	Active	8.1	9.1
	Lip swelling	10024570	PT	Narrow	A	0	Active	8.1	9.1
	Mouth swelling	10075203	PT	Narrow	A	0	Active	17.1	17.1
	Oculorespiratory syndrome	10067317	PT	Narrow	A	0	Active	10.1	10.1
	Oedema mouth	10030110	PT	Narrow	A	0	Active	8.1	8.1
	Oropharyngeal oedema	10078783	PT	Narrow	A	0	Active	20.0	20.0
	Oropharyngeal swelling	10031118	PT	Narrow	A	0	Active	8.1	8.1
	Palatal oedema	10056998	PT	Narrow	A	0	Active	8.1	8.1
	Palatal swelling	10074403	PT	Narrow	A	0	Active	17.0	17.0
	Periorbital oedema	10034545	PT	Narrow	A	0	Active	8.1	8.1
	Periorbital swelling	10056647	PT	Narrow	A	0	Active	8.1	21.1
	Pharyngeal oedema	10034829	PT	Narrow	A	0	Active	8.1	8.1
	Pharyngeal swelling	10082270	PT	Narrow	A	0	Active	22.0	22.0
	Scleral oedema	10057431	PT	Narrow	A	0	Active	8.1	8.1
	Swelling face	10042682	PT	Narrow	A	0	Active	8.1	8.1

Swelling of eyelid	10042690	PT	Narrow	A	0	Active	8.1	21.1
Swollen tongue	10042727	PT	Narrow	A	0	Active	8.1	8.1
Tongue oedema	10043967	PT	Narrow	A	0	Active	8.1	8.1
Tracheal oedema	10044296	PT	Narrow	A	0	Active	8.1	8.1
Urticaria	10046735	PT	Narrow	A	0	Active	8.1	8.1
Urticaria cholinergic	10046740	PT	Narrow	A	0	Active	8.1	8.1
Urticaria chronic	10052568	PT	Narrow	A	0	Active	8.1	8.1
Urticaria papular	10046750	PT	Narrow	A	0	Active	8.1	8.1
Auricular swelling	10003800	PT	Broad	A	0	Active	8.1	8.1
Breast oedema	10006294	PT	Broad	A	0	Active	8.1	8.1
Breast swelling	10006312	PT	Broad	A	0	Active	8.1	8.1
Choking	10008589	PT	Broad	A	0	Active	8.1	8.1
Choking sensation	10008590	PT	Broad	A	0	Active	8.1	8.1
Drug hypersensitivity	10013700	PT	Broad	A	0	Active	8.1	8.1
Ear swelling	10014025	PT	Broad	A	0	Active	8.1	16.1
Endotracheal intubation	10067450	PT	Broad	A	0	Active	10.1	10.1
Gastrointestinal oedema	10058061	PT	Broad	A	0	Active	8.1	8.1
Generalised oedema	10018092	PT	Broad	A	0	Active	8.1	8.1
Genital swelling	10067639	PT	Broad	A	0	Active	10.1	10.1
Hypersensitivity	10020751	PT	Broad	A	0	Active	8.1	8.1
Laryngeal dyspnoea	10052390	PT	Broad	A	0	Active	8.1	8.1
Laryngeal obstruction	10059639	PT	Broad	A	0	Active	8.1	8.1
Localised oedema	10048961	PT	Broad	A	0	Active	8.1	8.1
Nasal obstruction	10028748	PT	Broad	A	0	Active	12.1	14.0
Nasal oedema	10028750	PT	Broad	A	0	Active	8.1	8.1
Nipple oedema	10059012	PT	Broad	A	0	Active	8.1	8.1
Nipple swelling	10058680	PT	Broad	A	0	Active	8.1	8.1
Obstructive airways disorder	10061877	PT	Broad	A	0	Active	8.1	8.1
Oedema	10030095	PT	Broad	A	0	Active	8.1	8.1
Oedema blister	10080039	PT	Broad	A	0	Active	20.1	20.1
Oedema genital	10030104	PT	Broad	A	0	Active	8.1	8.1
Oedema mucosal	10030111	PT	Broad	A	0	Active	8.1	8.1
Oedema neonatal	10061317	PT	Broad	A	0	Active	8.1	8.1
Oedema peripheral	10030124	PT	Broad	A	0	Active	8.1	8.1
Orbital oedema	10031051	PT	Broad	A	0	Active	8.1	8.1
Penile oedema	10066774	PT	Broad	A	0	Active	10.0	10.0
Penile swelling	10034319	PT	Broad	A	0	Active	8.1	8.1
Perinephric oedema	10078818	PT	Broad	A	0	Active	20.0	20.0
Peripheral oedema neonatal	10049779	PT	Broad	A	0	Active	8.1	8.1
Peripheral swelling	10048959	PT	Broad	A	0	Active	8.1	17.1
Reversible airways obstruction	10062109	PT	Broad	A	0	Active	8.1	8.1
Scrotal oedema	10039755	PT	Broad	A	0	Active	8.1	8.1
Scrotal swelling	10039759	PT	Broad	A	0	Active	8.1	8.1
Skin oedema	10058679	PT	Broad	A	0	Active	8.1	8.1

Skin swelling	10053262	PT	Broad	A	0	Active	8.1	8.1
Soft tissue swelling	10076991	PT	Broad	A	0	Active	18.1	18.1
Stridor	10042241	PT	Broad	A	0	Active	8.1	8.1
Suffocation feeling	10042444	PT	Broad	A	0	Active	8.1	8.1
Swelling	10042674	PT	Broad	A	0	Active	8.1	8.1
Therapeutic product cross-reactivity	10079645	PT	Broad	A	0	Active	20.1	20.1
Throat tightness	10043528	PT	Broad	A	0	Active	8.1	8.1
Tracheal obstruction	10044291	PT	Broad	A	0	Active	8.1	8.1
Tracheostomy	10044320	PT	Broad	A	0	Active	8.1	8.1
Type I hypersensitivity	10045240	PT	Broad	A	0	Active	8.1	8.1
Upper airway obstruction	10067775	PT	Broad	A	0	Active	11.0	11.0
Vaginal oedema	10063818	PT	Broad	A	0	Active	8.1	8.1
Visceral oedema	10065768	PT	Broad	A	0	Active	9.0	9.0
Vulval oedema	10047763	PT	Broad	A	0	Active	8.1	8.1
Vulvovaginal swelling	10071211	PT	Broad	A	0	Active	14.1	14.1
Wheezing	10047924	PT	Broad	A	0	Active	8.1	8.1

SMQ Export: 23.0 - English			1/15/2021 1:55:54 PM						
	Include Inactive PT: No								
English: Arthritis (SMQ)									
	English	Code	Level	Scope	Category	Weight	Status	Addition Version	Last Modified Version
	Ankylosing spondylitis	10002556	PT	Narrow	A	0	Active	16.1	16.1
	Arthritis	10003246	PT	Narrow	A	0	Active	16.1	16.1
	Arthritis allergic	10061430	PT	Narrow	A	0	Active	16.1	16.1
	Arthritis bacterial	10053555	PT	Narrow	A	0	Active	16.1	16.1
	Arthritis climacteric	10003251	PT	Narrow	A	0	Active	16.1	16.1
	Arthritis enteropathic	10003253	PT	Narrow	A	0	Active	16.1	16.1
	Arthritis fungal	10060966	PT	Narrow	A	0	Active	16.1	16.1
	Arthritis gonococcal	10003256	PT	Narrow	A	0	Active	16.1	16.1
	Arthritis helminthic	10060967	PT	Narrow	A	0	Active	16.1	16.1
	Arthritis infective	10060968	PT	Narrow	A	0	Active	16.1	16.1
	Arthritis reactive	10003267	PT	Narrow	A	0	Active	16.1	16.1
	Arthritis rubella	10003270	PT	Narrow	A	0	Active	16.1	16.1
	Arthritis salmonella	10003271	PT	Narrow	A	0	Active	16.1	16.1
	Arthritis viral	10003274	PT	Narrow	A	0	Active	16.1	16.1
	Autoimmune arthritis	10071155	PT	Narrow	A	0	Active	16.1	16.1
	Axial spondyloarthritis	10071400	PT	Narrow	A	0	Active	16.1	18.0
	Caplan's syndrome	10065917	PT	Narrow	A	0	Active	16.1	16.1
	Carcinomatous polyarthritis	10069494	PT	Narrow	A	0	Active	16.1	16.1
	Chondrocalcinosis	10061761	PT	Narrow	A	0	Active	16.1	16.1
	Chondrocalcinosis pyrophosphate	10008690	PT	Narrow	A	0	Active	16.1	16.1
	Chondromalacia	10008729	PT	Narrow	A	0	Active	16.1	16.1
	Chondronecrosis	10082974	PT	Narrow	A	0	Active	22.1	22.1
	COPA syndrome	10083948	PT	Narrow	A	0	Active	23.0	23.0
	Diffuse idiopathic skeletal hyperostosis	10080059	PT	Narrow	A	0	Active	20.1	20.1
	Enteropathic spondylitis	10076549	PT	Narrow	A	0	Active	18.1	18.1
	Epidemic polyarthritis	10066919	PT	Narrow	A	0	Active	16.1	16.1
	Facet joint syndrome	10054813	PT	Narrow	A	0	Active	16.1	16.1
	Felty's syndrome	10016386	PT	Narrow	A	0	Active	16.1	16.1
	Gout	10018627	PT	Narrow	A	0	Active	16.1	16.1
	Gouty arthritis	10018634	PT	Narrow	A	0	Active	16.1	16.1
	Gouty tophus	10018641	PT	Narrow	A	0	Active	16.1	16.1
	Haemophilic arthropathy	10065057	PT	Narrow	A	0	Active	16.1	16.1
	Idiopathic condylar resorption	10080457	PT	Narrow	A	0	Active	21.0	21.0
	Immune-mediated arthritis	10083155	PT	Narrow	A	0	Active	22.1	22.1
	Infected gouty tophus	10083459	PT	Narrow	A	0	Active	23.0	23.0
	Infusion site joint infection	10076073	PT	Narrow	A	0	Active	18.0	18.0
	Infusion site joint inflammation	10076074	PT	Narrow	A	0	Active	18.0	18.0
	Injection site joint infection	10074703	PT	Narrow	A	0	Active	17.0	17.0
	Injection site joint inflammation	10064111	PT	Narrow	A	0	Active	16.1	16.1
	Juvenile idiopathic arthritis	10059176	PT	Narrow	A	0	Active	16.1	16.1
	Juvenile psoriatic arthritis	10076674	PT	Narrow	A	0	Active	18.1	18.1

Juvenile spondyloarthritis	10076675	PT	Narrow	A	0	Active	18.1	18.1
Laryngeal rheumatoid arthritis	10059669	PT	Narrow	A	0	Active	16.1	16.1
Medical device site joint infection	10076118	PT	Narrow	A	0	Active	18.0	18.0
Nodal osteoarthritis	10029469	PT	Narrow	A	0	Active	16.1	16.1
Oligoarthritis	10082100	PT	Narrow	A	0	Active	22.0	22.0
Osteoarthritis	10031161	PT	Narrow	A	0	Active	17.1	17.1
Palindromic rheumatism	10033534	PT	Narrow	A	0	Active	16.1	16.1
Paraneoplastic arthritis	10077507	PT	Narrow	A	0	Active	19.0	19.0
Patellofemoral pain syndrome	10049143	PT	Narrow	A	0	Active	16.1	16.1
Periarthritis	10034464	PT	Narrow	A	0	Active	16.1	16.1
Periarthritis calcarea	10064754	PT	Narrow	A	0	Active	16.1	16.1
Plica syndrome	10066850	PT	Narrow	A	0	Active	16.1	16.1
Polyarthritis	10036030	PT	Narrow	A	0	Active	16.1	16.1
Pyogenic sterile arthritis pyoderma gangrenosum and acne syndrome	10072222	PT	Narrow	A	0	Active	16.1	16.1
Rapidly progressive osteoarthritis	10075201	PT	Narrow	A	0	Active	17.1	17.1
Rheumatic disorder	10072736	PT	Narrow	A	0	Active	16.1	16.1
Rheumatic fever	10039054	PT	Narrow	A	0	Active	16.1	16.1
Rheumatoid arthritis	10039073	PT	Narrow	A	0	Active	16.1	16.1
Sacroiliitis	10039361	PT	Narrow	A	0	Active	16.1	16.1
Septic arthritis haemophilus	10040059	PT	Narrow	A	0	Active	16.1	16.1
Septic arthritis neisserial	10040061	PT	Narrow	A	0	Active	16.1	16.1
Septic arthritis staphylococcal	10040063	PT	Narrow	A	0	Active	16.1	16.1
Septic arthritis streptobacillus	10040064	PT	Narrow	A	0	Active	16.1	16.1
Septic arthritis streptococcal	10067323	PT	Narrow	A	0	Active	16.1	16.1
Seronegative arthritis	10062164	PT	Narrow	A	0	Active	16.1	16.1
SLE arthritis	10040968	PT	Narrow	A	0	Active	16.1	16.1
Spinal osteoarthritis	10041591	PT	Narrow	A	0	Active	16.1	16.1
Spondylitis	10061371	PT	Narrow	A	0	Active	16.1	16.1
Still's disease	10042061	PT	Narrow	A	0	Active	16.1	20.0
Synovitis	10042868	PT	Narrow	A	0	Active	16.1	16.1
Temporomandibular joint syndrome	10043220	PT	Narrow	A	0	Active	16.1	16.1
Traumatic arthritis	10048873	PT	Narrow	A	0	Active	16.1	16.1
Vaccination site joint infection	10076173	PT	Narrow	A	0	Active	18.0	18.0
Amyloid arthropathy	10064554	PT	Broad	A	0	Active	16.1	16.1
Ankle arthroplasty	10050195	PT	Broad	A	0	Active	16.1	16.1
Arthralgia	10003239	PT	Broad	A	0	Active	16.1	16.1
Arthrodesis	10061683	PT	Broad	A	0	Active	16.1	16.1
Arthropathy	10003285	PT	Broad	A	0	Active	16.1	16.1
Arthroscopy abnormal	10003412	PT	Broad	A	0	Active	16.1	16.1
Arthrotoxicity	10068323	PT	Broad	A	0	Active	16.1	16.1
Articular calcification	10003422	PT	Broad	A	0	Active	16.1	16.1
Aspiration joint abnormal	10003518	PT	Broad	A	0	Active	16.1	16.1
Cheilectomy	10080886	PT	Broad	A	0	Active	21.0	21.0
Crystal arthropathy	10061419	PT	Broad	A	0	Active	16.1	16.1
Destructive spondyloarthropathy	10078114	PT	Broad	A	0	Active	19.1	19.1
Hip arthroplasty	10020096	PT	Broad	A	0	Active	16.1	16.1
Infusion site joint effusion	10076072	PT	Broad	A	0	Active	18.0	18.0

Infusion site joint erythema	10076077	PT	Broad	A	0	Active	18.0	18.0
Infusion site joint movement impairment	10076075	PT	Broad	A	0	Active	18.0	18.0
Infusion site joint pain	10076076	PT	Broad	A	0	Active	18.0	18.0
Infusion site joint swelling	10076078	PT	Broad	A	0	Active	18.0	18.0
Infusion site joint warmth	10076079	PT	Broad	A	0	Active	18.0	18.0
Injection site joint effusion	10064494	PT	Broad	A	0	Active	16.1	16.1
Injection site joint erythema	10076327	PT	Broad	A	0	Active	18.0	18.0
Injection site joint movement impairment	10053979	PT	Broad	A	0	Active	16.1	16.1
Injection site joint pain	10049261	PT	Broad	A	0	Active	16.1	16.1
Injection site joint swelling	10049260	PT	Broad	A	0	Active	16.1	16.1
Injection site joint warmth	10049262	PT	Broad	A	0	Active	16.1	16.1
Intervertebral discitis	10060738	PT	Broad	A	0	Active	16.1	16.1
Joint abscess	10058981	PT	Broad	A	0	Active	16.1	16.1
Joint adhesion	10058031	PT	Broad	A	0	Active	16.1	16.1
Joint arthroplasty	10057681	PT	Broad	A	0	Active	16.1	16.1
Joint contracture	10023201	PT	Broad	A	0	Active	16.1	16.1
Joint debridement	10076971	PT	Broad	A	0	Active	18.1	18.1
Joint destruction	10023203	PT	Broad	A	0	Active	16.1	16.1
Joint effusion	10023215	PT	Broad	A	0	Active	16.1	16.1
Joint fluid drainage	10066994	PT	Broad	A	0	Active	16.1	16.1
Joint noise	10074329	PT	Broad	A	0	Active	17.0	21.0
Joint range of motion decreased	10048706	PT	Broad	A	0	Active	16.1	16.1
Joint stiffness	10023230	PT	Broad	A	0	Active	16.1	16.1
Joint swelling	10023232	PT	Broad	A	0	Active	16.1	16.1
Joint warmth	10054106	PT	Broad	A	0	Active	16.1	16.1
Knee arthroplasty	10023469	PT	Broad	A	0	Active	16.1	16.1
Musculoskeletal stiffness	10052904	PT	Broad	A	0	Active	16.1	16.1
Neck pain	10028836	PT	Broad	A	0	Active	16.1	16.1
Neuropathic arthropathy	10029326	PT	Broad	A	0	Active	16.1	16.1
Osteoarthritis	10031173	PT	Broad	A	0	Active	16.1	16.1
Periarticular disorder	10048745	PT	Broad	A	0	Active	16.1	16.1
Physical examination of joints abnormal	10083028	PT	Broad	A	0	Active	22.1	22.1
Psoriatic arthropathy	10037162	PT	Broad	A	0	Active	16.1	16.1
Pustulotic arthro-osteitis	10081810	PT	Broad	A	0	Active	22.0	22.0
Rheumatoid nodule removal	10053291	PT	Broad	A	0	Active	16.1	16.1
Shoulder arthroplasty	10049551	PT	Broad	A	0	Active	16.1	16.1
Spinal pain	10072005	PT	Broad	A	0	Active	16.1	16.1
Spondyloarthropathy	10051265	PT	Broad	A	0	Active	16.1	16.1
Swollen joint count	10078912	PT	Broad	A	0	Active	20.0	20.0
Swollen joint count decreased	10079352	PT	Broad	A	0	Active	20.0	20.0
Swollen joint count increased	10079351	PT	Broad	A	0	Active	20.0	20.0
Synovectomy	10042857	PT	Broad	A	0	Active	16.1	16.1
Synovial fluid analysis abnormal	10059526	PT	Broad	A	0	Active	16.1	16.1
Synovial fluid crystal present	10057112	PT	Broad	A	0	Active	16.1	16.1
Synovial fluid protein present	10057114	PT	Broad	A	0	Active	16.1	16.1
Synovial fluid red blood cells positive	10057111	PT	Broad	A	0	Active	16.1	16.1
Synovial fluid white blood cells positive	10050769	PT	Broad	A	0	Active	16.1	16.1

	Synoviorthesis	10048875	PT	Broad	A	0	Active	16.1	16.1
	Tender joint count	10078913	PT	Broad	A	0	Active	20.0	20.0
	Tender joint count decreased	10079354	PT	Broad	A	0	Active	20.0	20.0
	Tender joint count increased	10079353	PT	Broad	A	0	Active	20.0	20.0
	Traumatic arthropathy	10044502	PT	Broad	A	0	Active	16.1	16.1



<b>SMQ Export: 23.0 - English</b>			<b>1/15/2021 1:56:34 PM</b>						
	Include Inactive PT: No								
<b>English: Convulsions (SMQ)</b>									
	English	Code	Level	Scope	Category	Weight	Status	Addition Version	Last Modified Version
	1p36 deletion syndrome	10082398	PT	Narrow	A	0	Active	22.0	22.0
	2-Hydroxyglutaric aciduria	10078971	PT	Narrow	A	0	Active	20.0	20.0
	Acquired epileptic aphasia	10052075	PT	Narrow	A	0	Active	10.0	10.0
	Acute encephalitis with refractory, repetitive partial seizures	10076948	PT	Narrow	A	0	Active	18.1	18.1
	Alcoholic seizure	10056347	PT	Narrow	A	0	Active	10.0	10.0
	Alpers disease	10083857	PT	Narrow	A	0	Active	23.0	23.0
	Aspartate-glutamate-transporter deficiency	10079140	PT	Narrow	A	0	Active	20.0	20.0
	Atonic seizures	10003628	PT	Narrow	A	0	Active	10.0	10.0
	Atypical benign partial epilepsy	10056699	PT	Narrow	A	0	Active	10.0	10.0
	Automatism epileptic	10003831	PT	Narrow	A	0	Active	10.0	10.0
	Autonomic seizure	10049612	PT	Narrow	A	0	Active	10.0	12.0
	Baltic myoclonic epilepsy	10054895	PT	Narrow	A	0	Active	10.0	10.0
	Benign familial neonatal convulsions	10067866	PT	Narrow	A	0	Active	11.0	11.0
	Benign rolandic epilepsy	10070530	PT	Narrow	A	0	Active	13.1	13.1
	Biotinidase deficiency	10071434	PT	Narrow	A	0	Active	14.1	14.1
	CDKL5 deficiency disorder	10083005	PT	Narrow	A	0	Active	22.1	22.1
	CEC syndrome	10083749	PT	Narrow	A	0	Active	23.0	23.0
	Change in seizure presentation	10075606	PT	Narrow	A	0	Active	18.0	18.0
	Clonic convulsion	10053398	PT	Narrow	A	0	Active	10.0	10.0
	Congenital bilateral perisylvian syndrome	10082716	PT	Narrow	A	0	Active	22.1	22.1
	Convulsion in childhood	10052391	PT	Narrow	A	0	Active	10.0	10.0
	Convulsions local	10010920	PT	Narrow	A	0	Active	10.0	10.0
	Convulsive threshold lowered	10010927	PT	Narrow	A	0	Active	10.0	10.0
	CSWS syndrome	10078827	PT	Narrow	A	0	Active	20.0	20.0
	Deja vu	10012177	PT	Narrow	A	0	Active	10.0	10.0
	Double cortex syndrome	10073490	PT	Narrow	A	0	Active	16.0	16.0
	Dreamy state	10013634	PT	Narrow	A	0	Active	10.0	10.0
	Drug withdrawal convulsions	10013752	PT	Narrow	A	0	Active	10.0	10.0
	Early infantile epileptic encephalopathy with burst-suppression	10071545	PT	Narrow	A	0	Active	14.1	14.1
	Eclampsia	10014129	PT	Narrow	A	0	Active	10.0	10.0
	Epilepsy	10015037	PT	Narrow	A	0	Active	10.0	10.0
	Epilepsy surgery	10079824	PT	Narrow	A	0	Active	20.1	20.1
	Epilepsy with myoclonic-atonic seizures	10081179	PT	Narrow	A	0	Active	21.1	21.1
	Epileptic aura	10015049	PT	Narrow	A	0	Active	10.0	10.0
	Epileptic psychosis	10059232	PT	Narrow	A	0	Active	10.0	10.0
	Febrile convulsion	10016284	PT	Narrow	A	0	Active	10.0	10.0
	Febrile infection-related epilepsy syndrome	10079438	PT	Narrow	A	0	Active	20.0	20.0
	Focal dyscognitive seizures	10079424	PT	Narrow	A	0	Active	20.0	20.0
	Frontal lobe epilepsy	10049424	PT	Narrow	A	0	Active	10.0	10.0

Gelastic seizure	10082918	PT	Narrow	A	0	Active	22.1	22.1
Generalised onset non-motor seizure	10083376	PT	Narrow	A	0	Active	23.0	23.0
Generalised tonic-clonic seizure	10018100	PT	Narrow	A	0	Active	10.0	17.1
Glucose transporter type 1 deficiency syndrome	10078727	PT	Narrow	A	0	Active	19.1	19.1
GM2 gangliosidosis	10083933	PT	Narrow	A	0	Active	23.0	23.0
Grey matter heterotopia	10082084	PT	Narrow	A	0	Active	22.0	22.0
Hemimegalencephaly	10078100	PT	Narrow	A	0	Active	19.1	19.1
Hyperglycaemic seizure	10071394	PT	Narrow	A	0	Active	14.1	14.1
Hypocalcaemic seizure	10072456	PT	Narrow	A	0	Active	15.1	15.1
Hypoglycaemic seizure	10048803	PT	Narrow	A	0	Active	10.0	10.0
Hyponatraemic seizure	10073183	PT	Narrow	A	0	Active	16.0	16.0
Idiopathic generalised epilepsy	10071081	PT	Narrow	A	0	Active	14.0	14.0
Infantile spasms	10021750	PT	Narrow	A	0	Active	10.0	10.0
Juvenile myoclonic epilepsy	10071082	PT	Narrow	A	0	Active	14.0	14.0
Lafora's myoclonic epilepsy	10054030	PT	Narrow	A	0	Active	10.0	10.0
Lennox-Gastaut syndrome	10048816	PT	Narrow	A	0	Active	10.0	10.0
Migraine-triggered seizure	10076676	PT	Narrow	A	0	Active	18.1	18.1
Molybdenum cofactor deficiency	10069687	PT	Narrow	A	0	Active	13.0	13.0
Multiple subpial transection	10079825	PT	Narrow	A	0	Active	20.1	20.1
Myoclonic epilepsy	10054859	PT	Narrow	A	0	Active	10.0	10.0
Myoclonic epilepsy and ragged-red fibres	10069825	PT	Narrow	A	0	Active	13.0	13.0
Neonatal epileptic seizure	10082068	PT	Narrow	A	0	Active	22.0	22.0
Neonatal seizure	10082067	PT	Narrow	A	0	Active	22.0	22.0
Partial seizures	10061334	PT	Narrow	A	0	Active	10.0	10.0
Partial seizures with secondary generalisation	10056209	PT	Narrow	A	0	Active	10.0	10.0
Petit mal epilepsy	10034759	PT	Narrow	A	0	Active	10.0	10.0
Polymicrogyria	10073489	PT	Narrow	A	0	Active	16.0	16.0
Post stroke epilepsy	10076982	PT	Narrow	A	0	Active	18.1	18.1
Post stroke seizure	10076981	PT	Narrow	A	0	Active	18.1	18.1
Postictal headache	10052470	PT	Narrow	A	0	Active	10.0	10.0
Postictal paralysis	10052469	PT	Narrow	A	0	Active	10.0	10.0
Postictal psychosis	10070669	PT	Narrow	A	0	Active	13.1	13.1
Postictal state	10048727	PT	Narrow	A	0	Active	10.0	10.0
Post-traumatic epilepsy	10036312	PT	Narrow	A	0	Active	10.0	10.0
Schizencephaly	10073487	PT	Narrow	A	0	Active	16.0	16.0
Seizure	10039906	PT	Narrow	A	0	Active	10.0	18.0
Seizure anoxic	10039907	PT	Narrow	A	0	Active	10.0	10.0
Seizure cluster	10071350	PT	Narrow	A	0	Active	14.1	14.1
Seizure like phenomena	10071048	PT	Narrow	A	0	Active	14.0	14.0
Severe myoclonic epilepsy of infancy	10073677	PT	Narrow	A	0	Active	16.1	16.1
Simple partial seizures	10040703	PT	Narrow	A	0	Active	10.0	10.0
Status epilepticus	10041962	PT	Narrow	A	0	Active	10.0	10.0
Sudden unexplained death in epilepsy	10063894	PT	Narrow	A	0	Active	10.0	10.0
Temporal lobe epilepsy	10043209	PT	Narrow	A	0	Active	10.0	10.0
Tonic clonic movements	10051171	PT	Narrow	A	0	Active	10.0	10.0

	Tonic convulsion	10043994	PT	Narrow	A	0	Active	10.0	10.0
	Tonic posturing	10075125	PT	Narrow	A	0	Active	17.1	17.1
	Topectomy	10073488	PT	Narrow	A	0	Active	16.0	16.0
	Transient epileptic amnesia	10081728	PT	Narrow	A	0	Active	21.1	21.1
	Tuberous sclerosis complex	10080584	PT	Narrow	A	0	Active	21.0	21.0
	Uncinate fits	10045476	PT	Narrow	A	0	Active	10.0	10.0
	Amygdalohippocampectomy	10071707	PT	Broad	A	0	Active	14.1	14.1
	Aura	10003791	PT	Broad	A	0	Active	10.0	10.0
	Corpus callosotomy	10073491	PT	Broad	A	0	Active	16.0	16.0
	Drop attacks	10013643	PT	Broad	A	0	Active	10.0	10.0
	Foaming at mouth	10062654	PT	Broad	A	0	Active	10.0	10.0
	Focal cortical resection	10083272	PT	Broad	A	0	Active	23.0	23.0
	Narcolepsy	10028713	PT	Broad	A	0	Active	10.0	10.0
	Preictal state	10073854	PT	Broad	A	0	Active	16.1	16.1
	Seizure prophylaxis	10081601	PT	Broad	A	0	Active	21.1	21.1
	Tongue biting	10050467	PT	Broad	A	0	Active	10.0	10.0

<b>SMQ Export: 23.0 - English</b>		<b>1/15/2021 1:57:21 PM</b>							
	Include Inactive PT: No								
<b>English: Demyelination (SMQ)</b>									
	<b>English</b>	<b>Code</b>	<b>Level</b>	<b>Scope</b>	<b>Category</b>	<b>Weight</b>	<b>Status</b>	<b>Addition Version</b>	<b>Last Modified Version</b>
	Acute disseminated encephalomyelitis	10000709	PT	Narrow	A	0	Active	11.1	11.1
	Acute haemorrhagic leukoencephalitis	10058994	PT	Narrow	A	0	Active	11.1	11.1
	Anti-myelin-associated glycoprotein associated polyneuropathy	10078324	PT	Narrow	A	0	Active	19.1	19.1
	Autoimmune demyelinating disease	10075688	PT	Narrow	A	0	Active	18.0	18.0
	Chronic inflammatory demyelinating polyradiculoneuropathy	10057645	PT	Narrow	A	0	Active	11.1	11.1
	Clinically isolated syndrome	10071068	PT	Narrow	A	0	Active	14.0	14.0
	Concentric sclerosis	10010252	PT	Narrow	A	0	Active	11.1	11.1
	Demyelinating polyneuropathy	10061811	PT	Narrow	A	0	Active	11.1	11.1
	Demyelination	10012305	PT	Narrow	A	0	Active	11.1	11.1
	Encephalitis periaxialis diffusa	10049020	PT	Narrow	A	0	Active	11.1	11.1
	Encephalomyelitis	10014619	PT	Narrow	A	0	Active	11.1	11.1
	Expanded disability status scale score decreased	10071385	PT	Narrow	A	0	Active	14.1	14.1
	Expanded disability status scale score increased	10071384	PT	Narrow	A	0	Active	14.1	14.1
	Guillain-Barre syndrome	10018767	PT	Narrow	A	0	Active	11.1	11.1
	Hypergammaglobulinaemia benign monoclonal	10020631	PT	Narrow	A	0	Active	11.1	11.1
	Immune-mediated neuropathy	10078963	PT	Narrow	A	0	Active	22.1	22.1
	Leukoencephalomyelitis	10048999	PT	Narrow	A	0	Active	11.1	11.1
	Leukoencephalopathy	10024382	PT	Narrow	A	0	Active	11.1	11.1
	Lewis-Sumner syndrome	10065580	PT	Narrow	A	0	Active	11.1	11.1
	Marburg's variant multiple sclerosis	10067067	PT	Narrow	A	0	Active	11.1	11.1
	Marchiafava-Bignami disease	10026828	PT	Narrow	A	0	Active	11.1	11.1
	MELAS syndrome	10053872	PT	Narrow	A	0	Active	11.1	11.1
	Multiple sclerosis	10028245	PT	Narrow	A	0	Active	11.1	11.1
	Multiple sclerosis relapse	10048393	PT	Narrow	A	0	Active	11.1	11.1
	Multiple sclerosis relapse prophylaxis	10070495	PT	Narrow	A	0	Active	14.0	14.0
	Myelitis transverse	10028527	PT	Narrow	A	0	Active	11.1	11.1
	Myoclonic epilepsy and ragged-red fibres	10069825	PT	Narrow	A	0	Active	13.0	13.0
	Neuromyelitis optica pseudo relapse	10080353	PT	Narrow	A	0	Active	21.0	21.0
	Neuromyelitis optica spectrum disorder	10077875	PT	Narrow	A	0	Active	19.0	19.0
	Neuropathy, ataxia, retinitis pigmentosa syndrome	10062940	PT	Narrow	A	0	Active	11.1	11.1
	Noninfectious myelitis	10071764	PT	Narrow	A	0	Active	15.0	15.0
	Noninfective encephalomyelitis	10074713	PT	Narrow	A	0	Active	17.0	17.0
	Optic neuritis	10030942	PT	Narrow	A	0	Active	11.1	11.1
	Osmotic demyelination syndrome	10069350	PT	Narrow	A	0	Active	12.1	12.1
	Primary progressive multiple sclerosis	10063401	PT	Narrow	A	0	Active	11.1	11.1
	Progressive multifocal leukoencephalopathy	10036807	PT	Narrow	A	0	Active	11.1	11.1
	Progressive multiple sclerosis	10053395	PT	Narrow	A	0	Active	11.1	11.1
	Progressive relapsing multiple sclerosis	10067063	PT	Narrow	A	0	Active	11.1	11.1
	Relapsing multiple sclerosis	10080700	PT	Narrow	A	0	Active	21.0	21.0

Relapsing-remitting multiple sclerosis	10063399	PT	Narrow	A	0	Active	11.1	11.1
Secondary progressive multiple sclerosis	10063400	PT	Narrow	A	0	Active	11.1	11.1
Subacute inflammatory demyelinating polyneuropathy	10081726	PT	Narrow	A	0	Active	21.1	21.1
Toxic leukoencephalopathy	10075528	PT	Narrow	A	0	Active	18.0	18.0
Tumefactive multiple sclerosis	10078556	PT	Narrow	A	0	Active	19.1	19.1
Zika virus associated Guillain Barre syndrome	10081046	PT	Narrow	A	0	Active	21.0	21.0
Anti-interferon antibody negative	10072887	PT	Broad	A	0	Active	16.0	16.0
Anti-interferon antibody positive	10072888	PT	Broad	A	0	Active	16.0	16.0
Anti-myelin-associated glycoprotein antibodies positive	10078318	PT	Broad	A	0	Active	19.1	19.1
Band sensation	10070714	PT	Broad	A	0	Active	13.1	13.1
JC polyomavirus test positive	10070356	PT	Broad	A	0	Active	21.0	21.0
JC virus CSF test positive	10078957	PT	Broad	A	0	Active	21.0	21.0
Lhermitte's sign	10049690	PT	Broad	A	0	Active	11.1	11.1
Myokymia	10028632	PT	Broad	A	0	Active	11.1	11.1
Saccadic eye movement	10053694	PT	Broad	A	0	Active	11.1	11.1
Trigeminal neuralgia	10044652	PT	Broad	A	0	Active	11.1	11.1
Uhthoff's phenomenon	10067485	PT	Broad	A	0	Active	11.1	11.1

<b>SMQ Export: 23.0 - English</b>		<b>1/15/2021 1:58:15 PM</b>							
	Include Inactive PT: No								
<b>English: Hypersensitivity (SMQ)</b>									
	<b>English</b>	<b>Code</b>	<b>Level</b>	<b>Scope</b>	<b>Category</b>	<b>Weight</b>	<b>Status</b>	<b>Addition Version</b>	<b>Last Modified Version</b>
	Acquired C1 inhibitor deficiency	10081035	PT	Narrow	A	0	Active	21.0	21.0
	Acute generalised exanthematous pustulosis	10048799	PT	Narrow	A	0	Active	16.0	16.0
	Administration related reaction	10069773	PT	Narrow	A	0	Active	20.1	20.1
	Administration site dermatitis	10075096	PT	Narrow	A	0	Active	18.1	18.1
	Administration site eczema	10075099	PT	Narrow	A	0	Active	18.1	18.1
	Administration site hypersensitivity	10075102	PT	Narrow	A	0	Active	17.1	17.1
	Administration site rash	10071156	PT	Narrow	A	0	Active	16.0	16.0
	Administration site recall reaction	10075964	PT	Narrow	A	0	Active	18.1	18.1
	Administration site urticaria	10075109	PT	Narrow	A	0	Active	17.1	17.1
	Administration site vasculitis	10075969	PT	Narrow	A	0	Active	18.0	18.0
	Allergic bronchitis	10052613	PT	Narrow	A	0	Active	16.0	16.0
	Allergic colitis	10059447	PT	Narrow	A	0	Active	16.0	16.0
	Allergic cough	10053779	PT	Narrow	A	0	Active	16.0	16.0
	Allergic cystitis	10051394	PT	Narrow	A	0	Active	16.0	16.0
	Allergic eosinophilia	10075185	PT	Narrow	A	0	Active	17.1	17.1
	Allergic gastroenteritis	10075308	PT	Narrow	A	0	Active	17.1	17.1
	Allergic hepatitis	10071198	PT	Narrow	A	0	Active	16.0	16.0
	Allergic keratitis	10057380	PT	Narrow	A	0	Active	16.0	16.0
	Allergic oedema	10060934	PT	Narrow	A	0	Active	16.0	16.0
	Allergic otitis externa	10075072	PT	Narrow	A	0	Active	17.1	17.1
	Allergic otitis media	10061557	PT	Narrow	A	0	Active	16.0	16.0
	Allergic pharyngitis	10050639	PT	Narrow	A	0	Active	16.0	16.0
	Allergic reaction to excipient	10078853	PT	Narrow	A	0	Active	20.0	20.0
	Allergic respiratory disease	10063532	PT	Narrow	A	0	Active	16.0	16.0
	Allergic respiratory symptom	10063527	PT	Narrow	A	0	Active	16.0	16.0
	Allergic sinusitis	10049153	PT	Narrow	A	0	Active	16.0	16.0
	Allergic stomatitis	10079554	PT	Narrow	A	0	Active	20.1	20.1
	Allergic transfusion reaction	10066173	PT	Narrow	A	0	Active	16.0	16.0
	Allergy alert test positive	10075479	PT	Narrow	A	0	Active	18.0	18.0
	Allergy test positive	10056352	PT	Narrow	A	0	Active	16.0	16.0
	Allergy to immunoglobulin therapy	10074079	PT	Narrow	A	0	Active	16.1	16.1
	Allergy to surgical sutures	10077279	PT	Narrow	A	0	Active	19.0	19.0
	Allergy to vaccine	10055048	PT	Narrow	A	0	Active	16.0	16.0
	Anal eczema	10078682	PT	Narrow	A	0	Active	19.1	22.1
	Anaphylactic reaction	10002198	PT	Narrow	A	0	Active	16.0	16.0
	Anaphylactic shock	10002199	PT	Narrow	A	0	Active	16.0	16.0
	Anaphylactic transfusion reaction	10067113	PT	Narrow	A	0	Active	16.0	16.0
	Anaphylactoid reaction	10002216	PT	Narrow	A	0	Active	16.0	16.0
	Anaphylactoid shock	10063119	PT	Narrow	A	0	Active	16.0	16.0

Anaphylaxis treatment	10002222	PT	Narrow	A	0	Active	16.0	16.0
Angioedema	10002424	PT	Narrow	A	0	Active	16.0	16.0
Antiallergic therapy	10064059	PT	Narrow	A	0	Active	16.0	16.0
Antiendomysial antibody positive	10065514	PT	Narrow	A	0	Active	16.0	16.0
Anti-neutrophil cytoplasmic antibody positive vasculitis	10050894	PT	Narrow	A	0	Active	16.0	16.0
Application site dermatitis	10003036	PT	Narrow	A	0	Active	16.0	16.0
Application site eczema	10050099	PT	Narrow	A	0	Active	16.0	16.0
Application site hypersensitivity	10063683	PT	Narrow	A	0	Active	16.0	16.0
Application site rash	10003054	PT	Narrow	A	0	Active	16.0	16.0
Application site recall reaction	10076024	PT	Narrow	A	0	Active	18.1	18.1
Application site urticaria	10050104	PT	Narrow	A	0	Active	16.0	16.0
Application site vasculitis	10076027	PT	Narrow	A	0	Active	18.0	18.0
Arthritis allergic	10061430	PT	Narrow	A	0	Active	16.0	16.0
Aspirin-exacerbated respiratory disease	10075084	PT	Narrow	A	0	Active	17.1	17.1
Atopic cough	10081492	PT	Narrow	A	0	Active	21.1	21.1
Atopy	10003645	PT	Narrow	A	0	Active	16.0	16.0
Blepharitis allergic	10005149	PT	Narrow	A	0	Active	16.0	16.0
Blood immunoglobulin E abnormal	10005589	PT	Narrow	A	0	Active	16.0	16.0
Blood immunoglobulin E increased	10005591	PT	Narrow	A	0	Active	16.0	16.0
Bromoderma	10006404	PT	Narrow	A	0	Active	16.0	16.0
Bronchospasm	10006482	PT	Narrow	A	0	Active	16.0	16.0
Bullous haemorrhagic dermatosis	10083809	PT	Narrow	A	0	Active	23.0	23.0
Catheter site dermatitis	10073992	PT	Narrow	A	0	Active	16.1	16.1
Catheter site eczema	10073995	PT	Narrow	A	0	Active	16.1	16.1
Catheter site hypersensitivity	10073998	PT	Narrow	A	0	Active	16.1	16.1
Catheter site rash	10052271	PT	Narrow	A	0	Active	16.0	16.0
Catheter site urticaria	10052272	PT	Narrow	A	0	Active	16.0	16.0
Catheter site vasculitis	10074014	PT	Narrow	A	0	Active	16.1	16.1
Chronic eosinophilic rhinosinusitis	10071399	PT	Narrow	A	0	Active	16.0	16.0
Chronic hyperplastic eosinophilic sinusitis	10071380	PT	Narrow	A	0	Active	16.0	16.0
Circulatory collapse	10009192	PT	Narrow	A	0	Active	16.0	16.0
Circumoral oedema	10052250	PT	Narrow	A	0	Active	16.0	16.0
Circumoral swelling	10081703	PT	Narrow	A	0	Active	21.1	21.1
Conjunctival oedema	10010726	PT	Narrow	A	0	Active	16.0	16.0
Conjunctivitis allergic	10010744	PT	Narrow	A	0	Active	16.0	16.0
Contact stomatitis	10067510	PT	Narrow	A	0	Active	16.0	16.0
Contrast media allergy	10066973	PT	Narrow	A	0	Active	16.0	16.0
Contrast media reaction	10010836	PT	Narrow	A	0	Active	16.0	16.0
Corneal oedema	10011033	PT	Narrow	A	0	Active	16.0	16.0
Cutaneous vasculitis	10011686	PT	Narrow	A	0	Active	16.0	16.0
Dennie-Morgan fold	10062918	PT	Narrow	A	0	Active	16.0	16.0
Dermatitis	10012431	PT	Narrow	A	0	Active	16.0	16.0
Dermatitis acneiform	10012432	PT	Narrow	A	0	Active	16.0	16.0
Dermatitis allergic	10012434	PT	Narrow	A	0	Active	16.0	16.0
Dermatitis atopic	10012438	PT	Narrow	A	0	Active	16.0	16.0

Dermatitis bullous	10012441	PT	Narrow	A	0	Active	16.0	16.0
Dermatitis contact	10012442	PT	Narrow	A	0	Active	16.0	16.0
Dermatitis exfoliative	10012455	PT	Narrow	A	0	Active	16.0	16.0
Dermatitis exfoliative generalised	10012456	PT	Narrow	A	0	Active	16.0	16.0
Dermatitis herpetiformis	10012468	PT	Narrow	A	0	Active	16.0	16.0
Dermatitis infected	10012470	PT	Narrow	A	0	Active	16.0	16.0
Dermatitis psoriasiform	10058675	PT	Narrow	A	0	Active	16.0	16.0
Device allergy	10072867	PT	Narrow	A	0	Active	19.0	19.0
Dialysis membrane reaction	10076665	PT	Narrow	A	0	Active	18.1	18.1
Distributive shock	10070559	PT	Narrow	A	0	Active	16.0	16.0
Documented hypersensitivity to administered product	10076470	PT	Narrow	A	0	Active	18.0	18.0
Drug eruption	10013687	PT	Narrow	A	0	Active	16.0	16.0
Drug hypersensitivity	10013700	PT	Narrow	A	0	Active	16.0	16.0
Drug provocation test	10074350	PT	Narrow	A	0	Active	17.0	17.0
Drug reaction with eosinophilia and systemic symptoms	10073508	PT	Narrow	A	0	Active	16.0	16.0
Eczema	10014184	PT	Narrow	A	0	Active	16.0	16.0
Eczema infantile	10014198	PT	Narrow	A	0	Active	16.0	16.0
Eczema nummular	10014201	PT	Narrow	A	0	Active	16.0	16.0
Eczema vaccinatum	10066042	PT	Narrow	A	0	Active	16.0	16.0
Eczema vesicular	10058681	PT	Narrow	A	0	Active	16.0	16.0
Eczema weeping	10055182	PT	Narrow	A	0	Active	16.0	16.0
Encephalitis allergic	10056387	PT	Narrow	A	0	Active	16.0	16.0
Encephalopathy allergic	10014627	PT	Narrow	A	0	Active	16.0	16.0
Eosinophilic granulomatosis with polyangiitis	10078117	PT	Narrow	A	0	Active	19.1	19.1
Epidermal necrosis	10059284	PT	Narrow	A	0	Active	16.0	16.0
Epidermolysis	10053177	PT	Narrow	A	0	Active	16.0	16.0
Epidermolysis bullosa	10014989	PT	Narrow	A	0	Active	16.0	16.0
Epiglottic oedema	10015029	PT	Narrow	A	0	Active	16.0	16.0
Erythema multiforme	10015218	PT	Narrow	A	0	Active	16.0	16.0
Erythema nodosum	10015226	PT	Narrow	A	0	Active	16.0	16.0
Exfoliative rash	10064579	PT	Narrow	A	0	Active	16.0	16.0
Eye allergy	10015907	PT	Narrow	A	0	Active	16.0	16.0
Eye oedema	10052139	PT	Narrow	A	0	Active	16.0	16.0
Eye swelling	10015967	PT	Narrow	A	0	Active	16.0	16.0
Eyelid oedema	10015993	PT	Narrow	A	0	Active	16.0	16.0
Face oedema	10016029	PT	Narrow	A	0	Active	16.0	16.0
Fixed eruption	10016741	PT	Narrow	A	0	Active	16.0	20.0
Giant papillary conjunctivitis	10018258	PT	Narrow	A	0	Active	16.0	16.0
Gingival oedema	10049305	PT	Narrow	A	0	Active	16.0	16.0
Gingival swelling	10018291	PT	Narrow	A	0	Active	16.0	16.0
Gleich's syndrome	10066837	PT	Narrow	A	0	Active	16.0	16.0
Haemorrhagic urticaria	10059499	PT	Narrow	A	0	Active	16.0	16.0
Hand dermatitis	10058898	PT	Narrow	A	0	Active	16.0	16.0
Henoch-Schonlein purpura	10019617	PT	Narrow	A	0	Active	16.0	16.0
Henoch-Schonlein purpura nephritis	10069440	PT	Narrow	A	0	Active	16.0	16.0



Heparin-induced thrombocytopenia	10062506	PT	Narrow	A	0	Active	16.0	16.0
Hereditary angioedema	10019860	PT	Narrow	A	0	Active	16.0	16.0
Hereditary angioedema with C1 esterase inhibitor deficiency	10080955	PT	Narrow	A	0	Active	21.0	21.0
Hypersensitivity	10020751	PT	Narrow	A	0	Active	16.0	16.0
Hypersensitivity myocarditis	10081004	PT	Narrow	A	0	Active	21.0	21.0
Hypersensitivity pneumonitis	10081988	PT	Narrow	A	0	Active	22.0	22.0
Hypersensitivity vasculitis	10020764	PT	Narrow	A	0	Active	16.0	17.0
Idiopathic urticaria	10021247	PT	Narrow	A	0	Active	16.0	16.0
Immediate post-injection reaction	10067142	PT	Narrow	A	0	Active	16.0	16.0
Immune thrombocytopenia	10083842	PT	Narrow	A	0	Active	23.0	23.0
Immune tolerance induction	10070581	PT	Narrow	A	0	Active	16.0	16.0
Implant site dermatitis	10063855	PT	Narrow	A	0	Active	16.0	16.0
Implant site hypersensitivity	10063858	PT	Narrow	A	0	Active	16.0	16.0
Implant site rash	10063786	PT	Narrow	A	0	Active	16.0	16.0
Implant site urticaria	10063787	PT	Narrow	A	0	Active	16.0	16.0
Incision site dermatitis	10073168	PT	Narrow	A	0	Active	16.0	16.0
Incision site rash	10073411	PT	Narrow	A	0	Active	16.0	16.0
Infusion related hypersensitivity reaction	10082742	PT	Narrow	A	0	Active	22.1	22.1
Infusion related reaction	10051792	PT	Narrow	A	0	Active	20.1	20.1
Infusion site dermatitis	10065458	PT	Narrow	A	0	Active	16.0	16.0
Infusion site eczema	10074850	PT	Narrow	A	0	Active	17.0	17.0
Infusion site hypersensitivity	10065471	PT	Narrow	A	0	Active	16.0	16.0
Infusion site rash	10059830	PT	Narrow	A	0	Active	16.0	16.0
Infusion site recall reaction	10076085	PT	Narrow	A	0	Active	18.1	18.1
Infusion site urticaria	10065490	PT	Narrow	A	0	Active	16.0	16.0
Infusion site vasculitis	10074851	PT	Narrow	A	0	Active	17.0	17.0
Injection related reaction	10071152	PT	Narrow	A	0	Active	20.1	20.1
Injection site dermatitis	10022056	PT	Narrow	A	0	Active	16.0	16.0
Injection site eczema	10066221	PT	Narrow	A	0	Active	18.0	18.0
Injection site hypersensitivity	10022071	PT	Narrow	A	0	Active	16.0	16.0
Injection site rash	10022094	PT	Narrow	A	0	Active	16.0	16.0
Injection site recall reaction	10066797	PT	Narrow	A	0	Active	18.1	18.1
Injection site urticaria	10022107	PT	Narrow	A	0	Active	16.0	16.0
Injection site vasculitis	10067995	PT	Narrow	A	0	Active	16.0	16.0
Instillation site hypersensitivity	10073612	PT	Narrow	A	0	Active	18.0	18.0
Instillation site rash	10073622	PT	Narrow	A	0	Active	18.0	18.0
Instillation site urticaria	10073627	PT	Narrow	A	0	Active	18.0	18.0
Interstitial granulomatous dermatitis	10067972	PT	Narrow	A	0	Active	16.0	16.0
Intestinal angioedema	10076229	PT	Narrow	A	0	Active	18.0	18.0
Iodine allergy	10052098	PT	Narrow	A	0	Active	16.0	16.0
Kaposi's varicelliform eruption	10051891	PT	Narrow	A	0	Active	16.0	16.0
Kounis syndrome	10069167	PT	Narrow	A	0	Active	16.0	16.0
Laryngeal oedema	10023845	PT	Narrow	A	0	Active	16.0	16.0
Laryngitis allergic	10064866	PT	Narrow	A	0	Active	16.0	16.0
Laryngospasm	10023891	PT	Narrow	A	0	Active	16.0	16.0

Laryngotracheal oedema	10023893	PT	Narrow	A	0	Active	16.0	16.0
Limbal swelling	10070492	PT	Narrow	A	0	Active	16.0	16.0
Lip oedema	10024558	PT	Narrow	A	0	Active	16.0	16.0
Lip swelling	10024570	PT	Narrow	A	0	Active	16.0	16.0
Mast cell degranulation present	10076606	PT	Narrow	A	0	Active	18.1	18.1
Medical device site dermatitis	10075572	PT	Narrow	A	0	Active	18.0	18.0
Medical device site eczema	10075575	PT	Narrow	A	0	Active	18.0	18.0
Medical device site hypersensitivity	10075579	PT	Narrow	A	0	Active	18.0	18.0
Medical device site rash	10075585	PT	Narrow	A	0	Active	18.0	18.0
Medical device site recall reaction	10076140	PT	Narrow	A	0	Active	18.1	18.1
Medical device site urticaria	10075588	PT	Narrow	A	0	Active	18.0	18.0
Mouth swelling	10075203	PT	Narrow	A	0	Active	17.1	17.1
Mucocutaneous rash	10056671	PT	Narrow	A	0	Active	16.0	16.0
Multiple allergies	10028164	PT	Narrow	A	0	Active	16.0	16.0
Nephritis allergic	10029120	PT	Narrow	A	0	Active	16.0	16.0
Nikolsky's sign	10029415	PT	Narrow	A	0	Active	16.0	16.0
Nodular rash	10075807	PT	Narrow	A	0	Active	18.0	18.1
Nutritional supplement allergy	10084049	PT	Narrow	A	0	Active	23.0	23.0
Oculomucocutaneous syndrome	10030081	PT	Narrow	A	0	Active	16.0	16.0
Oculorespiratory syndrome	10067317	PT	Narrow	A	0	Active	16.0	16.0
Oedema mouth	10030110	PT	Narrow	A	0	Active	16.0	16.0
Oral allergy syndrome	10068355	PT	Narrow	A	0	Active	16.0	16.0
Oropharyngeal blistering	10067950	PT	Narrow	A	0	Active	16.0	16.0
Oropharyngeal oedema	10078783	PT	Narrow	A	0	Active	20.0	20.0
Oropharyngeal spasm	10031111	PT	Narrow	A	0	Active	16.0	16.0
Oropharyngeal swelling	10031118	PT	Narrow	A	0	Active	16.0	16.0
Palatal oedema	10056998	PT	Narrow	A	0	Active	16.0	16.0
Palatal swelling	10074403	PT	Narrow	A	0	Active	17.0	17.0
Palisaded neutrophilic granulomatous dermatitis	10068809	PT	Narrow	A	0	Active	16.0	17.1
Palpable purpura	10056872	PT	Narrow	A	0	Active	16.0	16.0
Pathergy reaction	10074332	PT	Narrow	A	0	Active	17.0	17.0
Perioral dermatitis	10034541	PT	Narrow	A	0	Active	16.0	21.0
Periorbital oedema	10034545	PT	Narrow	A	0	Active	16.0	16.0
Periorbital swelling	10056647	PT	Narrow	A	0	Active	16.0	21.1
Pharyngeal oedema	10034829	PT	Narrow	A	0	Active	16.0	16.0
Pharyngeal swelling	10082270	PT	Narrow	A	0	Active	22.0	22.0
Procedural shock	10080894	PT	Narrow	A	0	Active	21.0	21.0
Pruritus allergic	10063438	PT	Narrow	A	0	Active	16.0	16.0
Radioallergosorbent test positive	10037789	PT	Narrow	A	0	Active	16.0	16.0
Rash	10037844	PT	Narrow	A	0	Active	16.0	16.0
Rash erythematous	10037855	PT	Narrow	A	0	Active	16.0	16.0
Rash follicular	10037857	PT	Narrow	A	0	Active	16.0	16.0
Rash macular	10037867	PT	Narrow	A	0	Active	16.0	16.0
Rash maculo-papular	10037868	PT	Narrow	A	0	Active	16.0	16.0
Rash maculovesicular	10050004	PT	Narrow	A	0	Active	16.0	16.0

Rash morbilliform	10037870	PT	Narrow	A	0	Active	16.0	16.0
Rash neonatal	10037871	PT	Narrow	A	0	Active	16.0	16.0
Rash papulosquamous	10037879	PT	Narrow	A	0	Active	16.0	16.0
Rash pruritic	10037884	PT	Narrow	A	0	Active	16.0	16.0
Rash pustular	10037888	PT	Narrow	A	0	Active	16.0	16.0
Rash rubelliform	10057984	PT	Narrow	A	0	Active	16.0	16.0
Rash scarlatiniform	10037890	PT	Narrow	A	0	Active	16.0	16.0
Rash vesicular	10037898	PT	Narrow	A	0	Active	16.0	16.0
Reaction to azo-dyes	10037973	PT	Narrow	A	0	Active	16.0	16.0
Reaction to colouring	10037974	PT	Narrow	A	0	Active	16.0	16.0
Reaction to excipient	10079925	PT	Narrow	A	0	Active	20.1	20.1
Reaction to food additive	10037977	PT	Narrow	A	0	Active	22.0	22.0
Reaction to preservatives	10064788	PT	Narrow	A	0	Active	16.0	16.0
Red man syndrome	10038192	PT	Narrow	A	0	Active	16.0	16.0
Rhinitis allergic	10039085	PT	Narrow	A	0	Active	16.0	16.0
Scleral oedema	10057431	PT	Narrow	A	0	Active	16.0	16.0
Scleritis allergic	10051126	PT	Narrow	A	0	Active	16.0	16.0
Scrotal dermatitis	10083260	PT	Narrow	A	0	Active	23.0	23.0
Scrotal oedema	10039755	PT	Narrow	A	0	Active	16.0	16.0
Serum sickness	10040400	PT	Narrow	A	0	Active	16.0	16.0
Serum sickness-like reaction	10040402	PT	Narrow	A	0	Active	16.0	16.0
Shock	10040560	PT	Narrow	A	0	Active	16.0	16.0
Shock symptom	10040581	PT	Narrow	A	0	Active	16.0	18.1
SJS-TEN overlap	10083164	PT	Narrow	A	0	Active	22.1	22.1
Skin necrosis	10040893	PT	Narrow	A	0	Active	16.0	16.0
Skin reaction	10040914	PT	Narrow	A	0	Active	16.0	16.0
Skin test positive	10040934	PT	Narrow	A	0	Active	16.0	16.0
Solar urticaria	10041307	PT	Narrow	A	0	Active	16.0	16.0
Solvent sensitivity	10041316	PT	Narrow	A	0	Active	16.0	16.0
Stevens-Johnson syndrome	10042033	PT	Narrow	A	0	Active	16.0	16.0
Stoma site hypersensitivity	10074509	PT	Narrow	A	0	Active	17.0	17.0
Stoma site rash	10059071	PT	Narrow	A	0	Active	17.0	17.0
Swelling face	10042682	PT	Narrow	A	0	Active	16.0	16.0
Swelling of eyelid	10042690	PT	Narrow	A	0	Active	16.0	21.1
Swollen tongue	10042727	PT	Narrow	A	0	Active	16.0	16.0
Symmetrical drug-related intertriginous and flexural exanthema	10078325	PT	Narrow	A	0	Active	19.1	19.1
Therapeutic product cross-reactivity	10079645	PT	Narrow	A	0	Active	20.1	20.1
Tongue oedema	10043967	PT	Narrow	A	0	Active	16.0	16.0
Toxic epidermal necrolysis	10044223	PT	Narrow	A	0	Active	16.0	16.0
Toxic skin eruption	10057970	PT	Narrow	A	0	Active	16.0	16.0
Tracheal oedema	10044296	PT	Narrow	A	0	Active	16.0	16.0
Type I hypersensitivity	10045240	PT	Narrow	A	0	Active	16.0	16.0
Type II hypersensitivity	10054000	PT	Narrow	A	0	Active	16.0	16.0
Type III immune complex mediated reaction	10053614	PT	Narrow	A	0	Active	16.0	16.0
Type IV hypersensitivity reaction	10053613	PT	Narrow	A	0	Active	16.0	16.0

Urticaria	10046735	PT	Narrow	A	0	Active	16.0	16.0
Urticaria cholinergic	10046740	PT	Narrow	A	0	Active	16.0	16.0
Urticaria chronic	10052568	PT	Narrow	A	0	Active	16.0	16.0
Urticaria contact	10046742	PT	Narrow	A	0	Active	16.0	16.0
Urticaria papular	10046750	PT	Narrow	A	0	Active	16.0	16.0
Urticaria physical	10046751	PT	Narrow	A	0	Active	16.0	16.0
Urticaria pigmentosa	10046752	PT	Narrow	A	0	Active	16.0	16.0
Urticaria vesiculosa	10046755	PT	Narrow	A	0	Active	16.0	16.0
Urticarial dermatitis	10082290	PT	Narrow	A	0	Active	22.0	22.0
Urticarial vasculitis	10048820	PT	Narrow	A	0	Active	16.0	19.0
Vaccination site dermatitis	10069477	PT	Narrow	A	0	Active	16.0	16.0
Vaccination site eczema	10076161	PT	Narrow	A	0	Active	18.1	18.1
Vaccination site exfoliation	10069489	PT	Narrow	A	0	Active	16.0	16.0
Vaccination site hypersensitivity	10068880	PT	Narrow	A	0	Active	16.0	16.0
Vaccination site rash	10069482	PT	Narrow	A	0	Active	16.0	16.0
Vaccination site recall reaction	10076188	PT	Narrow	A	0	Active	18.1	18.1
Vaccination site urticaria	10069622	PT	Narrow	A	0	Active	16.0	16.0
Vaccination site vasculitis	10076191	PT	Narrow	A	0	Active	18.1	18.1
Vaccination site vesicles	10069623	PT	Narrow	A	0	Active	16.0	16.0
Vaginal ulceration	10046943	PT	Narrow	A	0	Active	16.0	16.0
Vasculitic rash	10047111	PT	Narrow	A	0	Active	16.0	16.0
Vernal keratoconjunctivitis	10081000	PT	Narrow	A	0	Active	21.0	21.0
Vessel puncture site rash	10077117	PT	Narrow	A	0	Active	18.1	18.1
Vessel puncture site vesicles	10077813	PT	Narrow	A	0	Active	19.0	19.0
Vulval eczema	10066273	PT	Narrow	A	0	Active	16.0	22.1
Vulval ulceration	10047768	PT	Narrow	A	0	Active	16.0	16.0
Vulvovaginal rash	10071588	PT	Narrow	A	0	Active	16.0	16.0
Vulvovaginal ulceration	10050181	PT	Narrow	A	0	Active	16.0	16.0
Vulvovaginitis allergic	10080783	PT	Narrow	A	0	Active	21.0	21.0
Acute respiratory failure	10001053	PT	Broad	A	0	Active	16.0	16.0
Administration site photosensitivity reaction	10075961	PT	Broad	A	0	Active	18.0	18.0
Airway remodelling	10075289	PT	Broad	A	0	Active	17.1	17.1
Allergy to chemicals	10061626	PT	Broad	A	0	Active	16.0	16.0
Allergy to fermented products	10054929	PT	Broad	A	0	Active	16.0	16.0
Alpha tumour necrosis factor increased	10059982	PT	Broad	A	0	Active	16.0	16.0
Alveolitis	10001889	PT	Broad	A	0	Active	16.0	16.0
Antibody test abnormal	10061425	PT	Broad	A	0	Active	16.0	16.0
Antibody test positive	10061427	PT	Broad	A	0	Active	16.0	16.0
Anti-insulin antibody increased	10053815	PT	Broad	A	0	Active	16.0	16.0
Anti-insulin antibody positive	10053814	PT	Broad	A	0	Active	16.0	16.0
Anti-insulin receptor antibody increased	10068226	PT	Broad	A	0	Active	16.0	16.0
Anti-insulin receptor antibody positive	10068225	PT	Broad	A	0	Active	16.0	16.0
Application site photosensitivity reaction	10058730	PT	Broad	A	0	Active	18.0	18.0
Asthma	10003553	PT	Broad	A	0	Active	16.0	16.0
Asthma late onset	10003559	PT	Broad	A	0	Active	16.0	16.0

Asthma-chronic obstructive pulmonary disease overlap syndrome	10077005	PT	Broad	A	0	Active	18.1	18.1
Asthmatic crisis	10064823	PT	Broad	A	0	Active	16.0	16.0
Auricular swelling	10003800	PT	Broad	A	0	Active	16.0	16.0
Blister	10005191	PT	Broad	A	0	Active	16.0	16.0
Blister rupture	10073385	PT	Broad	A	0	Active	16.0	16.1
Blood immunoglobulin A abnormal	10005584	PT	Broad	A	0	Active	16.0	16.0
Blood immunoglobulin A increased	10005586	PT	Broad	A	0	Active	16.0	16.0
Blood immunoglobulin D increased	10063244	PT	Broad	A	0	Active	16.0	16.0
Blood immunoglobulin G abnormal	10005594	PT	Broad	A	0	Active	16.0	16.0
Blood immunoglobulin G increased	10005596	PT	Broad	A	0	Active	16.0	16.0
Blood immunoglobulin M abnormal	10005599	PT	Broad	A	0	Active	16.0	16.0
Blood immunoglobulin M increased	10005601	PT	Broad	A	0	Active	16.0	16.0
Bronchial hyperreactivity	10066091	PT	Broad	A	0	Active	16.0	16.0
Bronchial oedema	10056695	PT	Broad	A	0	Active	16.0	16.0
Bullous impetigo	10006563	PT	Broad	A	0	Active	16.0	16.0
Caffeine allergy	10074895	PT	Broad	A	0	Active	17.1	17.1
Capillaritis	10068406	PT	Broad	A	0	Active	16.0	16.0
Charcot-Leyden crystals	10008413	PT	Broad	A	0	Active	16.0	16.0
Cheilitis	10008417	PT	Broad	A	0	Active	22.0	22.0
Childhood asthma	10081274	PT	Broad	A	0	Active	21.1	21.1
Choking	10008589	PT	Broad	A	0	Active	16.0	16.0
Choking sensation	10008590	PT	Broad	A	0	Active	16.0	16.0
Complement factor C1 decreased	10051552	PT	Broad	A	0	Active	16.0	20.1
Complement factor C2 decreased	10051555	PT	Broad	A	0	Active	16.0	20.1
Complement factor C3 decreased	10050981	PT	Broad	A	0	Active	16.0	20.1
Complement factor C4 decreased	10050983	PT	Broad	A	0	Active	16.0	20.1
Complement factor decreased	10061048	PT	Broad	A	0	Active	16.0	20.1
Conjunctivitis	10010741	PT	Broad	A	0	Active	16.0	16.0
Corneal exfoliation	10064489	PT	Broad	A	0	Active	16.0	16.0
Cough variant asthma	10063076	PT	Broad	A	0	Active	16.0	23.0
Cytokine release syndrome	10052015	PT	Broad	A	0	Active	17.0	17.0
Cytokine storm	10050685	PT	Broad	A	0	Active	17.0	17.0
Ear swelling	10014025	PT	Broad	A	0	Active	16.0	16.1
Eosinophil count abnormal	10061125	PT	Broad	A	0	Active	16.0	16.0
Eosinophil count increased	10014945	PT	Broad	A	0	Active	16.0	16.0
Eosinophil percentage abnormal	10058133	PT	Broad	A	0	Active	16.0	16.0
Eosinophil percentage increased	10052222	PT	Broad	A	0	Active	16.0	16.0
Eosinophilia	10014950	PT	Broad	A	0	Active	16.0	16.0
Eosinophilia myalgia syndrome	10014952	PT	Broad	A	0	Active	16.0	16.0
Eosinophilic bronchitis	10065563	PT	Broad	A	0	Active	16.0	16.0
Eosinophilic oesophagitis	10064212	PT	Broad	A	0	Active	16.0	16.0
Eosinophilic pneumonia	10014962	PT	Broad	A	0	Active	16.0	16.0
Eosinophilic pneumonia acute	10052832	PT	Broad	A	0	Active	16.0	16.0
Eosinophilic pneumonia chronic	10052833	PT	Broad	A	0	Active	16.0	16.0
Erythema	10015150	PT	Broad	A	0	Active	16.0	16.0

Flushing	10016825	PT	Broad	A	0	Active	16.0	16.0
Gastrointestinal oedema	10058061	PT	Broad	A	0	Active	16.0	16.0
Generalised oedema	10018092	PT	Broad	A	0	Active	16.0	16.0
Genital rash	10018175	PT	Broad	A	0	Active	16.0	16.0
Genital swelling	10067639	PT	Broad	A	0	Active	16.0	16.0
Haemolytic transfusion reaction	10067122	PT	Broad	A	0	Active	16.0	16.0
HLA marker study positive	10067937	PT	Broad	A	0	Active	16.0	16.0
Human anti-hamster antibody increased	10082107	PT	Broad	A	0	Active	22.0	22.0
Human anti-hamster antibody positive	10082109	PT	Broad	A	0	Active	22.0	22.0
Immune complex level increased	10064650	PT	Broad	A	0	Active	16.0	16.0
Immunoglobulins abnormal	10021497	PT	Broad	A	0	Active	16.0	16.0
Immunoglobulins increased	10021500	PT	Broad	A	0	Active	16.0	16.0
Immunology test abnormal	10061214	PT	Broad	A	0	Active	16.0	16.0
Implant site photosensitivity	10073415	PT	Broad	A	0	Active	18.0	18.0
Infusion site photosensitivity reaction	10065486	PT	Broad	A	0	Active	18.0	18.0
Injection site panniculitis	10083040	PT	Broad	A	0	Active	22.1	22.1
Injection site photosensitivity reaction	10053396	PT	Broad	A	0	Active	18.0	18.0
Interstitial lung disease	10022611	PT	Broad	A	0	Active	16.0	16.0
Laryngeal dyspnoea	10052390	PT	Broad	A	0	Active	16.0	16.0
Laryngeal obstruction	10059639	PT	Broad	A	0	Active	16.0	16.0
Leukotriene increased	10064663	PT	Broad	A	0	Active	16.0	16.0
Lip exfoliation	10064482	PT	Broad	A	0	Active	16.0	16.0
Localised oedema	10048961	PT	Broad	A	0	Active	16.0	16.0
Macrophage inflammatory protein-1 alpha increased	10083049	PT	Broad	A	0	Active	22.1	22.1
Mechanical urticaria	10068773	PT	Broad	A	0	Active	16.0	16.0
Medical device site photosensitivity reaction	10076137	PT	Broad	A	0	Active	18.0	18.0
Mesenteric panniculitis	10063031	PT	Broad	A	0	Active	16.0	16.0
Monocyte chemotactic protein-2 increased	10083043	PT	Broad	A	0	Active	22.1	22.1
Mouth ulceration	10028034	PT	Broad	A	0	Active	16.0	16.0
Mucocutaneous ulceration	10028084	PT	Broad	A	0	Active	16.0	16.0
Mucosa vesicle	10028103	PT	Broad	A	0	Active	16.0	16.0
Mucosal erosion	10061297	PT	Broad	A	0	Active	16.0	16.0
Mucosal exfoliation	10064486	PT	Broad	A	0	Active	16.0	16.0
Mucosal necrosis	10067993	PT	Broad	A	0	Active	16.0	16.0
Mucosal ulceration	10028124	PT	Broad	A	0	Active	16.0	16.0
Nasal crease	10078581	PT	Broad	A	0	Active	19.1	19.1
Necrotising panniculitis	10062579	PT	Broad	A	0	Active	16.0	16.0
Neurodermatitis	10029263	PT	Broad	A	0	Active	16.0	16.0
Neutralising antibodies positive	10064980	PT	Broad	A	0	Active	16.0	16.0
Noninfective conjunctivitis	10074701	PT	Broad	A	0	Active	17.0	17.0
Non-neutralising antibodies positive	10064982	PT	Broad	A	0	Active	16.0	16.0
Occupational asthma	10070836	PT	Broad	A	0	Active	16.0	16.0
Occupational dermatitis	10030012	PT	Broad	A	0	Active	16.0	16.1
Oedema mucosal	10030111	PT	Broad	A	0	Active	16.0	16.0
Oral mucosal exfoliation	10064487	PT	Broad	A	0	Active	16.0	16.0

Orbital oedema	10031051	PT	Broad	A	0	Active	16.0	16.0
Panniculitis	10033675	PT	Broad	A	0	Active	16.0	16.0
Penile exfoliation	10064485	PT	Broad	A	0	Active	16.0	16.0
Penile oedema	10066774	PT	Broad	A	0	Active	16.0	16.0
Penile rash	10082571	PT	Broad	A	0	Active	22.1	22.1
Penile swelling	10034319	PT	Broad	A	0	Active	16.0	16.0
Perineal rash	10075364	PT	Broad	A	0	Active	17.1	17.1
Perivascular dermatitis	10064986	PT	Broad	A	0	Active	16.0	16.0
Photosensitivity reaction	10034972	PT	Broad	A	0	Active	16.0	16.0
Pneumonitis	10035742	PT	Broad	A	0	Active	16.0	16.0
Prurigo	10037083	PT	Broad	A	0	Active	16.0	16.0
Pruritus	10037087	PT	Broad	A	0	Active	16.0	16.0
Pulmonary eosinophilia	10037382	PT	Broad	A	0	Active	16.0	16.0
Reactive airways dysfunction syndrome	10070832	PT	Broad	A	0	Active	16.0	16.0
Respiratory arrest	10038669	PT	Broad	A	0	Active	16.0	16.0
Respiratory distress	10038687	PT	Broad	A	0	Active	16.0	16.0
Respiratory failure	10038695	PT	Broad	A	0	Active	16.0	16.0
Respiratory tract oedema	10070774	PT	Broad	A	0	Active	16.0	16.0
Reversible airways obstruction	10062109	PT	Broad	A	0	Active	16.0	16.0
Rhinitis perennial	10039094	PT	Broad	A	0	Active	16.0	16.0
Scrotal exfoliation	10081178	PT	Broad	A	0	Active	21.1	21.1
Scrotal swelling	10039759	PT	Broad	A	0	Active	16.0	16.0
Seasonal allergy	10048908	PT	Broad	A	0	Active	16.0	16.0
Septal panniculitis	10056876	PT	Broad	A	0	Active	16.0	16.0
Skin erosion	10040840	PT	Broad	A	0	Active	16.0	16.0
Skin exfoliation	10040844	PT	Broad	A	0	Active	16.0	16.0
Skin oedema	10058679	PT	Broad	A	0	Active	16.0	16.0
Skin swelling	10053262	PT	Broad	A	0	Active	16.0	16.0
Sneezing	10041232	PT	Broad	A	0	Active	16.0	16.0
Status asthmaticus	10041961	PT	Broad	A	0	Active	16.0	16.0
Stomatitis	10042128	PT	Broad	A	0	Active	16.0	16.0
Streptokinase antibody increased	10053797	PT	Broad	A	0	Active	16.0	16.0
Stridor	10042241	PT	Broad	A	0	Active	16.0	16.0
Suffocation feeling	10042444	PT	Broad	A	0	Active	16.0	16.0
Sunscreen sensitivity	10083629	PT	Broad	A	0	Active	23.0	23.0
Throat tightness	10043528	PT	Broad	A	0	Active	16.0	16.0
Tongue exfoliation	10064488	PT	Broad	A	0	Active	16.0	16.0
Tracheal obstruction	10044291	PT	Broad	A	0	Active	16.0	16.0
Tracheostomy	10044320	PT	Broad	A	0	Active	16.0	16.0
Transplantation associated food allergy	10075008	PT	Broad	A	0	Active	17.1	17.1
Upper airway obstruction	10067775	PT	Broad	A	0	Active	16.0	16.0
Vaccination site photosensitivity reaction	10076186	PT	Broad	A	0	Active	18.0	18.0
Vaginal oedema	10063818	PT	Broad	A	0	Active	16.0	16.0
Visceral oedema	10065768	PT	Broad	A	0	Active	16.0	16.0
Vulval oedema	10047763	PT	Broad	A	0	Active	16.0	16.0

	Vulvovaginal exfoliation	10083435	PT	Broad	A	0	Active	23.0	23.0
	Vulvovaginal swelling	10071211	PT	Broad	A	0	Active	16.0	16.0
	Wheezing	10047924	PT	Broad	A	0	Active	16.0	16.0



<b>SMQ Export: 23.0 - English</b>		<b>1/15/2021 1:59:01 PM</b>							
	Include Inactive PT: No								
<b>English: Peripheral neuropathy (SMQ)</b>									
	English	Code	Level	Scope	Category	Weight	Status	Addition Version	Last Modified Version
	Acute painful neuropathy of rapid glycaemic control	10072909	PT	Narrow	A	0	Active	16.0	16.0
	Acute polyneuropathy	10066699	PT	Narrow	A	0	Active	9.1	9.1
	Amyotrophy	10002027	PT	Narrow	A	0	Active	8.1	8.1
	Angiopathic neuropathy	10079036	PT	Narrow	A	0	Active	20.0	20.0
	Anti-myelin-associated glycoprotein associated polyneuropathy	10078324	PT	Narrow	A	0	Active	19.1	19.1
	Autoimmune neuropathy	10070439	PT	Narrow	A	0	Active	13.0	13.0
	Axonal neuropathy	10003882	PT	Narrow	A	0	Active	8.1	10.1
	Biopsy peripheral nerve abnormal	10004846	PT	Narrow	A	0	Active	8.1	8.1
	Decreased vibratory sense	10067502	PT	Narrow	A	0	Active	12.1	12.1
	Demyelinating polyneuropathy	10061811	PT	Narrow	A	0	Active	8.1	8.1
	Guillain-Barre syndrome	10018767	PT	Narrow	A	0	Active	8.1	8.1
	Immune-mediated neuropathy	10078963	PT	Narrow	A	0	Active	20.0	22.1
	Ischaemic neuropathy	10051307	PT	Narrow	A	0	Active	8.1	8.1
	Joint position sense decreased	10081223	PT	Narrow	A	0	Active	21.1	21.1
	Loss of proprioception	10057332	PT	Narrow	A	0	Active	8.1	8.1
	Miller Fisher syndrome	10049567	PT	Narrow	A	0	Active	8.1	8.1
	Multifocal motor neuropathy	10065579	PT	Narrow	A	0	Active	9.0	9.0
	Myelopathy	10028570	PT	Narrow	A	0	Active	8.1	8.1
	Nerve conduction studies abnormal	10029175	PT	Narrow	A	0	Active	8.1	8.1
	Neuralgia	10029223	PT	Narrow	A	0	Active	8.1	8.1
	Neuritis	10029240	PT	Narrow	A	0	Active	8.1	8.1
	Neuronal neuropathy	10071579	PT	Narrow	A	0	Active	14.1	14.1
	Neuropathic muscular atrophy	10075469	PT	Narrow	A	0	Active	18.0	18.0
	Neuropathy peripheral	10029331	PT	Narrow	A	0	Active	8.1	21.0
	Notalgia paraesthetica	10072643	PT	Narrow	A	0	Active	15.1	15.1
	Paroxysmal extreme pain disorder	10081856	PT	Narrow	A	0	Active	22.0	22.0
	Peripheral motor neuropathy	10034580	PT	Narrow	A	0	Active	8.1	8.1
	Peripheral nervous system function test abnormal	10034591	PT	Narrow	A	0	Active	8.1	8.1
	Peripheral sensorimotor neuropathy	10056673	PT	Narrow	A	0	Active	8.1	8.1
	Peripheral sensory neuropathy	10034620	PT	Narrow	A	0	Active	8.1	8.1
	Polyneuropathy	10036105	PT	Narrow	A	0	Active	8.1	8.1
	Polyneuropathy chronic	10064135	PT	Narrow	A	0	Active	13.1	13.1
	Polyneuropathy idiopathic progressive	10036111	PT	Narrow	A	0	Active	8.1	8.1
	Radiation neuropathy	10068886	PT	Narrow	A	0	Active	12.0	12.0
	Sensorimotor disorder	10062162	PT	Narrow	A	0	Active	8.1	8.1
	Sensory disturbance	10040026	PT	Narrow	A	0	Active	8.1	8.1
	Sensory loss	10040030	PT	Narrow	A	0	Active	8.1	8.1
	Small fibre neuropathy	10073928	PT	Narrow	A	0	Active	16.1	16.1
	Tick paralysis	10077336	PT	Narrow	A	0	Active	19.0	19.0

Toxic neuropathy	10067722	PT	Narrow	A	0	Active	10.1	10.1
Anti-ganglioside antibody positive	10072516	PT	Broad	A	0	Active	15.1	15.1
Anti-myelin-associated glycoprotein antibodies positive	10078318	PT	Broad	A	0	Active	19.1	19.1
Areflexia	10003084	PT	Broad	A	0	Active	8.1	8.1
Autonomic failure syndrome	10056339	PT	Broad	A	0	Active	8.1	8.1
Autonomic neuropathy	10061666	PT	Broad	A	0	Active	8.1	8.1
Burning feet syndrome	10070237	PT	Broad	A	0	Active	13.0	13.0
Burning sensation	10006784	PT	Broad	A	0	Active	8.1	8.1
Decreased nasolabial fold	10076861	PT	Broad	A	0	Active	18.1	18.1
Dysaesthesia	10013886	PT	Broad	A	0	Active	8.1	8.1
Electromyogram abnormal	10014431	PT	Broad	A	0	Active	8.1	8.1
Formication	10017062	PT	Broad	A	0	Active	8.1	8.1
Gait disturbance	10017577	PT	Broad	A	0	Active	8.1	8.1
Genital hypoaesthesia	10068912	PT	Broad	A	0	Active	12.0	12.0
Hereditary motor and sensory neuropathy	10077306	PT	Broad	A	0	Active	19.0	19.0
Hypoaesthesia	10020937	PT	Broad	A	0	Active	8.1	8.1
Hyporeflexia	10021089	PT	Broad	A	0	Active	8.1	8.1
Hypotonia	10021118	PT	Broad	A	0	Active	8.1	8.1
Mononeuritis	10027910	PT	Broad	A	0	Active	13.0	13.0
Mononeuropathy	10062203	PT	Broad	A	0	Active	13.0	13.0
Mononeuropathy multiplex	10027918	PT	Broad	A	0	Active	8.1	8.1
Motor dysfunction	10061296	PT	Broad	A	0	Active	8.1	8.1
Muscle atrophy	10028289	PT	Broad	A	0	Active	8.1	8.1
Muscular weakness	10028372	PT	Broad	A	0	Active	8.1	8.1
Nerve degeneration	10056677	PT	Broad	A	0	Active	8.1	8.1
Neuromuscular pain	10074313	PT	Broad	A	0	Active	17.0	17.0
Neuromuscular toxicity	10062284	PT	Broad	A	0	Active	8.1	8.1
Neuromyopathy	10029323	PT	Broad	A	0	Active	8.1	8.1
Neuropathy vitamin B12 deficiency	10079953	PT	Broad	A	0	Active	20.1	20.1
Neuropathy vitamin B6 deficiency	10029332	PT	Broad	A	0	Active	13.1	13.1
Neurotoxicity	10029350	PT	Broad	A	0	Active	8.1	8.1
Paraesthesia	10033775	PT	Broad	A	0	Active	8.1	8.1
Paraesthesia ear	10052433	PT	Broad	A	0	Active	8.1	18.1
Peripheral nerve lesion	10067633	PT	Broad	A	0	Active	13.0	13.0
Peripheral nerve palsy	10058530	PT	Broad	A	0	Active	8.1	8.1
Peripheral nerve paresis	10071663	PT	Broad	A	0	Active	14.1	14.1
Peroneal nerve palsy	10034701	PT	Broad	A	0	Active	8.1	8.1
Phrenic nerve paralysis	10064964	PT	Broad	A	0	Active	8.1	8.1
Skin burning sensation	10054786	PT	Broad	A	0	Active	8.1	8.1
Synkinesis	10078747	PT	Broad	A	0	Active	20.0	20.0
Temperature perception test decreased	10068015	PT	Broad	A	0	Active	11.0	11.0
Tinel's sign	10052492	PT	Broad	A	0	Active	8.1	8.1
Ulnar neuritis	10045380	PT	Broad	A	0	Active	8.1	13.0

<b>SMQ Export: 23.0 - English</b>			<b>1/15/2021 1:59:48 PM</b>						
	Include Inactive PT: No								
<b>English: Vasculitis (SMQ)</b>									
	<b>English</b>	<b>Code</b>	<b>Level</b>	<b>Scope</b>	<b>Category</b>	<b>Weight</b>	<b>Status</b>	<b>Addition Version</b>	<b>Last Modified Version</b>
	Acute haemorrhagic oedema of infancy	10070599	PT	Narrow	A	0	Active	13.1	13.1
	Administration site vasculitis	10075969	PT	Narrow	A	0	Active	18.0	18.0
	Anti-neutrophil cytoplasmic antibody positive vasculitis	10050894	PT	Narrow	A	0	Active	12.0	12.0
	Aortitis	10002921	PT	Narrow	A	0	Active	12.0	12.0
	Application site vasculitis	10076027	PT	Narrow	A	0	Active	18.0	18.0
	Arteritis	10003230	PT	Narrow	A	0	Active	12.0	12.0
	Arteritis coronary	10003232	PT	Narrow	A	0	Active	12.0	12.0
	Behcet's syndrome	10004213	PT	Narrow	A	0	Active	12.0	12.0
	Capillaritis	10068406	PT	Narrow	A	0	Active	12.0	12.0
	Central nervous system vasculitis	10081778	PT	Narrow	A	0	Active	21.1	21.1
	Cerebral arteritis	10008087	PT	Narrow	A	0	Active	12.0	12.0
	Chronic pigmented purpura	10072726	PT	Narrow	A	0	Active	15.1	15.1
	Cogan's syndrome	10056667	PT	Narrow	A	0	Active	12.0	12.0
	Cutaneous vasculitis	10011686	PT	Narrow	A	0	Active	12.0	12.0
	Diabetic arteritis	10077357	PT	Narrow	A	0	Active	19.0	19.0
	Diffuse vasculitis	10012978	PT	Narrow	A	0	Active	12.0	12.0
	Eosinophilic granulomatosis with polyangiitis	10078117	PT	Narrow	A	0	Active	19.1	19.1
	Erythema induratum	10015213	PT	Narrow	A	0	Active	12.0	12.0
	Granulomatosis with polyangiitis	10072579	PT	Narrow	A	0	Active	15.1	15.1
	Haemorrhagic vasculitis	10071252	PT	Narrow	A	0	Active	14.1	14.1
	Henoch-Schonlein purpura	10019617	PT	Narrow	A	0	Active	12.0	12.0
	Henoch-Schonlein purpura nephritis	10069440	PT	Narrow	A	0	Active	12.1	12.1
	Hypersensitivity vasculitis	10020764	PT	Narrow	A	0	Active	12.0	17.0
	Infusion site vasculitis	10074851	PT	Narrow	A	0	Active	17.0	17.0
	Injection site vasculitis	10067995	PT	Narrow	A	0	Active	12.0	12.0
	Kawasaki's disease	10023320	PT	Narrow	A	0	Active	12.0	12.0
	Langerhans' cell histiocytosis	10069698	PT	Narrow	A	0	Active	13.0	13.0
	Lupus vasculitis	10058143	PT	Narrow	A	0	Active	12.0	12.0
	MAGIC syndrome	10078132	PT	Narrow	A	0	Active	19.1	19.1
	Medical device site vasculitis	10076146	PT	Narrow	A	0	Active	18.0	18.0
	Microscopic polyangiitis	10063344	PT	Narrow	A	0	Active	12.0	12.0
	Nodular vasculitis	10029491	PT	Narrow	A	0	Active	12.0	12.0
	Ocular vasculitis	10066926	PT	Narrow	A	0	Active	12.0	12.0
	Polyarteritis nodosa	10036024	PT	Narrow	A	0	Active	12.0	12.0
	Polymyalgia rheumatica	10036099	PT	Narrow	A	0	Active	12.0	12.0
	Pseudovasculitis	10065255	PT	Narrow	A	0	Active	12.0	12.0
	Pulmonary vasculitis	10037457	PT	Narrow	A	0	Active	12.0	12.0

Radiation vasculitis	10074671	PT	Narrow	A	0	Active	17.0	17.0
Renal arteritis	10038373	PT	Narrow	A	0	Active	12.0	12.0
Renal vasculitis	10038546	PT	Narrow	A	0	Active	12.0	12.0
Retinal vasculitis	10038905	PT	Narrow	A	0	Active	12.0	12.0
Rheumatoid vasculitis	10048628	PT	Narrow	A	0	Active	12.0	12.0
Segmented hyalinising vasculitis	10067527	PT	Narrow	A	0	Active	12.0	12.0
Takayasu's arteritis	10043097	PT	Narrow	A	0	Active	12.0	12.0
Temporal arteritis	10043207	PT	Narrow	A	0	Active	12.0	12.0
Thromboangiitis obliterans	10043540	PT	Narrow	A	0	Active	12.0	12.0
Type 2 lepra reaction	10070517	PT	Narrow	A	0	Active	13.1	13.1
Urticarial vasculitis	10048820	PT	Narrow	A	0	Active	12.0	19.0
Vaccination site vasculitis	10076191	PT	Narrow	A	0	Active	18.0	18.0
Vascular purpura	10047097	PT	Narrow	A	0	Active	12.0	12.0
Vasculitic rash	10047111	PT	Narrow	A	0	Active	12.0	12.0
Vasculitis	10047115	PT	Narrow	A	0	Active	12.0	12.0
Vasculitis gastrointestinal	10048319	PT	Narrow	A	0	Active	12.0	12.0
Vasculitis necrotising	10047124	PT	Narrow	A	0	Active	12.0	12.0
Viral vasculitis	10056281	PT	Narrow	A	0	Active	12.0	12.0
Antibody test abnormal	10061425	PT	Broad	A	0	Active	12.0	12.0
Antibody test positive	10061427	PT	Broad	A	0	Active	12.0	12.0
Anti-glomerular basement membrane disease	10081981	PT	Broad	A	0	Active	22.0	22.0
Antineutrophil cytoplasmic antibody increased	10060138	PT	Broad	A	0	Active	12.0	12.0
Antineutrophil cytoplasmic antibody positive	10060136	PT	Broad	A	0	Active	12.0	12.0
Blood viscosity increased	10051293	PT	Broad	A	0	Active	12.0	12.0
Cryoglobulinaemia	10011474	PT	Broad	A	0	Active	12.0	12.0
Cryoglobulins present	10011478	PT	Broad	A	0	Active	12.0	12.0
Goodpasture's syndrome	10018620	PT	Broad	A	0	Active	12.0	12.0
Palpable purpura	10056872	PT	Broad	A	0	Active	12.0	12.0
Plasma viscosity abnormal	10035468	PT	Broad	A	0	Active	12.0	12.0

SMQ Export: 23.0 - English		4/21/2021 9:36:12 PM							
	Include Inactive PT: No								
English: Thrombophlebitis (SMQ)									
	English	Code	Level	Scope	Category	Weight	Status	Addition Version	Last Modified Version
	Pelvic venous thrombosis	10034272	PT	Narrow	A	0	Active	10.1	10.1
	Thrombophlebitis	10043570	PT	Narrow	A	0	Active	10.1	10.1
	Thrombophlebitis migrans	10043581	PT	Narrow	A	0	Active	10.1	10.1
	Thrombophlebitis neonatal	10043586	PT	Narrow	A	0	Active	10.1	10.1
	Thrombophlebitis septic	10043593	PT	Narrow	A	0	Active	10.1	10.1
	Thrombophlebitis superficial	10043595	PT	Narrow	A	0	Active	14.1	14.1
	Administration site phlebitis	10075960	PT	Broad	A	0	Active	18.0	18.0
	Application site phlebitis	10076022	PT	Broad	A	0	Active	18.0	18.0
	Brachiocephalic vein thrombosis	10063363	PT	Broad	A	0	Active	10.1	19.1
	Catheter site phlebitis	10052269	PT	Broad	A	0	Active	18.0	18.0
	Cerebral venous thrombosis	10008138	PT	Broad	A	0	Active	10.1	10.1
	Chemical phlebitis	10067560	PT	Broad	A	0	Active	10.1	22.0
	Deep vein thrombosis	10051055	PT	Broad	A	0	Active	10.1	10.1
	Deep vein thrombosis postoperative	10066881	PT	Broad	A	0	Active	10.1	10.1
	Implant site phlebitis	10063784	PT	Broad	A	0	Active	18.0	18.0
	Infusion site phlebitis	10053663	PT	Broad	A	0	Active	18.0	18.0
	Injection site phlebitis	10022090	PT	Broad	A	0	Active	18.0	18.0
	Injection site thrombosis	10022104	PT	Broad	A	0	Active	10.1	10.1
	Mahler sign	10075428	PT	Broad	A	0	Active	17.1	17.1
	Medical device site phlebitis	10076136	PT	Broad	A	0	Active	18.0	18.0
	Mesenteric vein thrombosis	10027402	PT	Broad	A	0	Active	10.1	10.1
	Periphlebitis	10057267	PT	Broad	A	0	Active	10.1	10.1
	Phlebitis	10034879	PT	Broad	A	0	Active	10.1	10.1
	Phlebitis deep	10034897	PT	Broad	A	0	Active	10.1	10.1
	Phlebitis infective	10056627	PT	Broad	A	0	Active	10.1	10.1
	Portal vein phlebitis	10036205	PT	Broad	A	0	Active	10.1	10.1
	Portosplenomesenteric venous thrombosis	10077623	PT	Broad	A	0	Active	19.0	19.0
	Post thrombotic syndrome	10048591	PT	Broad	A	0	Active	10.1	10.1
	Postpartum venous thrombosis	10036300	PT	Broad	A	0	Active	10.1	10.1
	Retinal vein thrombosis	10038908	PT	Broad	A	0	Active	10.1	10.1
	Septic phlebitis	10056518	PT	Broad	A	0	Active	10.1	10.1
	Stoma site phlebitis	10074513	PT	Broad	A	0	Active	18.0	18.0
	Thrombosis	10043607	PT	Broad	A	0	Active	10.1	10.1
	Thrombosis prophylaxis	10043634	PT	Broad	A	0	Active	10.1	10.1

	Vaccination site phlebitis	10076185	PT	Broad	A	0	Active	18.0	18.0
	Varicophlebitis	10056717	PT	Broad	A	0	Active	10.1	10.1
	Varicose ulceration	10046995	PT	Broad	A	0	Active	10.1	10.1
	Vascular access site thrombosis	10078675	PT	Broad	A	0	Active	19.1	19.1
	Vena cava thrombosis	10047195	PT	Broad	A	0	Active	10.1	10.1
	Vessel puncture site phlebitis	10074993	PT	Broad	A	0	Active	17.1	17.1
	Vessel puncture site thrombosis	10070649	PT	Broad	A	0	Active	13.1	13.1
	Visceral venous thrombosis	10077829	PT	Broad	A	0	Active	19.0	19.0

SMQ Export: 23.0 - English		4/21/2021 9:32:36 PM							
	Include Inactive PT: No								
English: Cardiomyopathy (SMQ)									
	English	Code	Level	Scope	Category	Weight	Status	Addition Version	Last Modified Version
	Atrial septal defect acquired	10003665	PT	Narrow	A	0	Active	11.1	11.1
	Biopsy heart abnormal	10004780	PT	Narrow	A	0	Active	11.1	11.1
	Cardiac amyloidosis	10007509	PT	Narrow	A	0	Active	11.1	11.1
	Cardiac hypertrophy	10007572	PT	Narrow	A	0	Active	11.1	11.1
	Cardiac iron overload	10080569	PT	Narrow	A	0	Active	21.0	21.0
	Cardiac sarcoidosis	10007604	PT	Narrow	A	0	Active	11.1	11.1
	Cardiac septal hypertrophy	10057576	PT	Narrow	A	0	Active	11.1	15.1
	Cardiomyopathy	10007636	PT	Narrow	A	0	Active	11.1	11.1
	Cardiomyopathy acute	10048377	PT	Narrow	A	0	Active	11.1	11.1
	Cardiomyopathy alcoholic	10007637	PT	Narrow	A	0	Active	11.1	11.1
	Cardiomyopathy neonatal	10050111	PT	Narrow	A	0	Active	11.1	11.1
	Cardiotoxicity	10048610	PT	Narrow	A	0	Active	11.1	11.1
	Chagas' cardiomyopathy	10080484	PT	Narrow	A	0	Active	21.0	21.0
	Congestive cardiomyopathy	10056370	PT	Narrow	A	0	Active	11.1	11.1
	Diabetic cardiomyopathy	10012647	PT	Narrow	A	0	Active	12.0	12.0
	Ejection fraction abnormal	10014331	PT	Narrow	A	0	Active	11.1	11.1
	Ejection fraction decreased	10050528	PT	Narrow	A	0	Active	11.1	11.1
	Eosinophilic myocarditis	10014961	PT	Narrow	A	0	Active	11.1	11.1
	Giant cell myocarditis	10083635	PT	Narrow	A	0	Active	23.0	23.0
	HIV cardiomyopathy	10069658	PT	Narrow	A	0	Active	12.1	12.1
	Hypertensive cardiomyopathy	10058222	PT	Narrow	A	0	Active	11.1	11.1
	Hypertrophic cardiomyopathy	10020871	PT	Narrow	A	0	Active	11.1	11.1
	Ischaemic cardiomyopathy	10048858	PT	Narrow	A	0	Active	11.1	11.1
	Metabolic cardiomyopathy	10070909	PT	Narrow	A	0	Active	14.0	14.0
	Myocardial calcification	10054122	PT	Narrow	A	0	Active	11.1	11.1
	Myocardial fibrosis	10028594	PT	Narrow	A	0	Active	11.1	11.1
	Myocardial haemorrhage	10048849	PT	Narrow	A	0	Active	11.1	11.1
	Non-obstructive cardiomyopathy	10049813	PT	Narrow	A	0	Active	11.1	11.1
	Obesity cardiomyopathy	10081007	PT	Narrow	A	0	Active	21.0	21.0
	Peripartum cardiomyopathy	10049430	PT	Narrow	A	0	Active	11.1	11.1
	Pulmonary arterial wedge pressure increased	10037329	PT	Narrow	A	0	Active	11.1	11.1
	Restrictive cardiomyopathy	10038748	PT	Narrow	A	0	Active	11.1	11.1
	Right ventricular ejection fraction decreased	10075337	PT	Narrow	A	0	Active	17.1	19.0
	Stress cardiomyopathy	10066286	PT	Narrow	A	0	Active	11.1	11.1
	Tachycardia induced cardiomyopathy	10074269	PT	Narrow	A	0	Active	16.1	16.1
	Thyrotoxic cardiomyopathy	10075043	PT	Narrow	A	0	Active	17.1	17.1

Toxic cardiomyopathy	10083657	PT	Narrow	A	0	Active	23.0	23.0
Ventricular septal defect acquired	10047299	PT	Narrow	A	0	Active	11.1	11.1
Viral cardiomyopathy	10068767	PT	Narrow	A	0	Active	12.0	12.0
Abnormal precordial movement	10077162	PT	Broad	A	0	Active	18.1	18.1
Acquired cardiac septal defect	10000533	PT	Broad	A	0	Active	11.1	11.1
Acute left ventricular failure	10063081	PT	Broad	A	0	Active	11.1	11.1
Alcohol septal ablation	10072744	PT	Broad	A	0	Active	15.1	15.1
Arrhythmia	10003119	PT	Broad	A	0	Active	11.1	11.1
Arrhythmia supraventricular	10003130	PT	Broad	A	0	Active	11.1	11.1
Artificial heart implant	10072066	PT	Broad	A	0	Active	15.0	15.0
Ascites	10003445	PT	Broad	A	0	Active	11.1	11.1
Atrial enlargement	10079340	PT	Broad	A	0	Active	20.0	20.0
Atrial hypertrophy	10048623	PT	Broad	A	0	Active	11.1	11.1
Atrial pressure increased	10049785	PT	Broad	A	0	Active	11.1	11.1
Autoimmune myocarditis	10064539	PT	Broad	A	0	Active	11.1	11.1
Bendopnoea	10077819	PT	Broad	A	0	Active	19.0	19.0
Blood pressure diastolic abnormal	10005736	PT	Broad	A	0	Active	11.1	11.1
Blood pressure diastolic decreased	10005737	PT	Broad	A	0	Active	11.1	11.1
Blood pressure diastolic increased	10005739	PT	Broad	A	0	Active	11.1	11.1
Blood pressure fluctuation	10005746	PT	Broad	A	0	Active	11.1	11.1
Blood pressure inadequately controlled	10051128	PT	Broad	A	0	Active	11.1	11.1
Blood pressure systolic abnormal	10005757	PT	Broad	A	0	Active	11.1	11.1
Blood pressure systolic decreased	10005758	PT	Broad	A	0	Active	11.1	11.1
Blood pressure systolic increased	10005760	PT	Broad	A	0	Active	11.1	11.1
Cardiac aneurysm	10007513	PT	Broad	A	0	Active	11.1	11.1
Cardiac arrest	10007515	PT	Broad	A	0	Active	11.1	11.1
Cardiac contractility modulation therapy	10077454	PT	Broad	A	0	Active	19.0	19.0
Cardiac device reprogramming	10081886	PT	Broad	A	0	Active	22.0	22.0
Cardiac dysfunction	10079751	PT	Broad	A	0	Active	20.1	20.1
Cardiac electrophysiologic study abnormal	10061808	PT	Broad	A	0	Active	11.1	11.1
Cardiac failure	10007554	PT	Broad	A	0	Active	11.1	11.1
Cardiac failure acute	10007556	PT	Broad	A	0	Active	11.1	11.1
Cardiac failure chronic	10007558	PT	Broad	A	0	Active	17.1	17.1
Cardiac failure congestive	10007559	PT	Broad	A	0	Active	11.1	11.1
Cardiac function test abnormal	10058479	PT	Broad	A	0	Active	11.1	11.1
Cardiac imaging procedure abnormal	10053453	PT	Broad	A	0	Active	11.1	11.1
Cardiac index abnormal	10007576	PT	Broad	A	0	Active	11.1	11.1
Cardiac index decreased	10007577	PT	Broad	A	0	Active	11.1	11.1
Cardiac index increased	10007578	PT	Broad	A	0	Active	11.1	11.1
Cardiac monitoring abnormal	10053440	PT	Broad	A	0	Active	11.1	11.1
Cardiac operation	10061026	PT	Broad	A	0	Active	11.1	11.1
Cardiac output decreased	10007595	PT	Broad	A	0	Active	11.1	11.1



Cardiac pseudoaneurysm	10048974	PT	Broad	A	0	Active	11.1	11.1
Cardiac resynchronisation therapy	10059862	PT	Broad	A	0	Active	14.0	14.0
Cardiac ventricular scarring	10076898	PT	Broad	A	0	Active	18.1	18.1
Cardiac ventriculogram abnormal	10053447	PT	Broad	A	0	Active	11.1	11.1
Cardiac ventriculogram left abnormal	10053499	PT	Broad	A	0	Active	11.1	11.1
Cardiac ventriculogram right abnormal	10053444	PT	Broad	A	0	Active	11.1	11.1
Cardiomegaly	10007632	PT	Broad	A	0	Active	11.1	11.1
Cardiothoracic ratio increased	10007646	PT	Broad	A	0	Active	11.1	11.1
Cardiovascular disorder	10007649	PT	Broad	A	0	Active	11.1	11.1
Cardiovascular function test abnormal	10007651	PT	Broad	A	0	Active	11.1	11.1
Chest pain	10008479	PT	Broad	A	0	Active	11.1	11.1
Chest X-ray abnormal	10008499	PT	Broad	A	0	Active	11.1	11.1
Computerised tomogram thorax abnormal	10057799	PT	Broad	A	0	Active	11.1	11.1
Coxsackie carditis	10011254	PT	Broad	A	0	Active	11.1	11.1
Coxsackie myocarditis	10011258	PT	Broad	A	0	Active	11.1	11.1
Cytomegalovirus myocarditis	10056261	PT	Broad	A	0	Active	11.1	11.1
Decreased ventricular preload	10050905	PT	Broad	A	0	Active	11.1	11.1
Diastolic dysfunction	10052337	PT	Broad	A	0	Active	14.1	14.1
Dilatation atrial	10013002	PT	Broad	A	0	Active	11.1	11.1
Dilatation ventricular	10013012	PT	Broad	A	0	Active	11.1	11.1
Directional Doppler flow tests abnormal	10013048	PT	Broad	A	0	Active	11.1	11.1
Dyspnoea	10013968	PT	Broad	A	0	Active	11.1	11.1
ECG signs of ventricular hypertrophy	10050998	PT	Broad	A	0	Active	18.0	18.0
Echocardiogram abnormal	10061593	PT	Broad	A	0	Active	11.1	11.1
Electrocardiogram abnormal	10014363	PT	Broad	A	0	Active	11.1	11.1
Electrocardiogram change	10061116	PT	Broad	A	0	Active	11.1	11.1
Electrocardiogram PR segment depression	10081493	PT	Broad	A	0	Active	21.1	21.1
Electrocardiogram U wave inversion	10062314	PT	Broad	A	0	Active	20.1	20.1
Endocardial fibroelastosis	10014663	PT	Broad	A	0	Active	11.1	11.1
Enterovirus myocarditis	10075553	PT	Broad	A	0	Active	22.1	22.1
External counterpulsation	10067876	PT	Broad	A	0	Active	11.1	11.1
Gonococcal heart disease	10078670	PT	Broad	A	0	Active	19.1	19.1
Heart and lung transplant	10056409	PT	Broad	A	0	Active	11.1	11.1
Heart transplant	10019314	PT	Broad	A	0	Active	11.1	11.1
Hepatomegaly	10019842	PT	Broad	A	0	Active	11.1	11.1
Hyperdynamic left ventricle	10068359	PT	Broad	A	0	Active	11.1	11.1
Hypersensitivity myocarditis	10081004	PT	Broad	A	0	Active	21.0	21.0
Immune-mediated myocarditis	10082606	PT	Broad	A	0	Active	22.1	22.1
Implantable cardiac monitor replacement	10082009	PT	Broad	A	0	Active	22.0	22.0
Increased ventricular preload	10050900	PT	Broad	A	0	Active	11.1	11.1
Intracardiac pressure increased	10079904	PT	Broad	A	0	Active	20.1	20.1
Irregular breathing	10076213	PT	Broad	A	0	Active	18.0	18.1

	Labile blood pressure	10023533	PT	Broad	A	0	Active	11.1	11.1
	Left atrial dilatation	10067286	PT	Broad	A	0	Active	11.1	11.1
	Left atrial enlargement	10051860	PT	Broad	A	0	Active	11.1	19.1
	Left atrial volume abnormal	10082367	PT	Broad	A	0	Active	22.0	22.0
	Left atrial volume decreased	10082368	PT	Broad	A	0	Active	22.0	22.0
	Left atrial volume increased	10082369	PT	Broad	A	0	Active	22.0	22.0
	Left ventricular dilatation	10050043	PT	Broad	A	0	Active	11.1	19.1
	Left ventricular dysfunction	10049694	PT	Broad	A	0	Active	21.0	21.0
	Left ventricular end-diastolic pressure decreased	10060089	PT	Broad	A	0	Active	11.1	11.1
	Left ventricular enlargement	10050581	PT	Broad	A	0	Active	11.1	19.1
	Left ventricular failure	10024119	PT	Broad	A	0	Active	11.1	11.1
	Left ventricular heave	10052348	PT	Broad	A	0	Active	11.1	14.0
	Lung opacity	10081792	PT	Broad	A	0	Active	21.1	22.1
	Lupus myocarditis	10066391	PT	Broad	A	0	Active	11.1	11.1
	Lyme carditis	10078417	PT	Broad	A	0	Active	19.1	19.1
	Magnetic resonance imaging thoracic abnormal	10083143	PT	Broad	A	0	Active	22.1	22.1
	Malarial myocarditis	10054123	PT	Broad	A	0	Active	11.1	11.1
	Mental status changes	10048294	PT	Broad	A	0	Active	11.1	11.1
	Multiple gated acquisition scan abnormal	10028212	PT	Broad	A	0	Active	11.1	11.1
	Myocardiac abscess	10058440	PT	Broad	A	0	Active	11.1	11.1
	Myocardial necrosis marker increased	10075211	PT	Broad	A	0	Active	17.1	17.1
	Myocarditis	10028606	PT	Broad	A	0	Active	11.1	11.1
	Myocarditis bacterial	10065218	PT	Broad	A	0	Active	11.1	11.1
	Myocarditis helminthic	10065219	PT	Broad	A	0	Active	11.1	11.1
	Myocarditis infectious	10066857	PT	Broad	A	0	Active	11.1	11.1
	Myocarditis meningococcal	10028612	PT	Broad	A	0	Active	11.1	11.1
	Myocarditis mycotic	10059026	PT	Broad	A	0	Active	11.1	11.1
	Myocarditis post infection	10064550	PT	Broad	A	0	Active	11.1	11.1
	Myocarditis septic	10028615	PT	Broad	A	0	Active	11.1	11.1
	Myocarditis syphilitic	10028616	PT	Broad	A	0	Active	11.1	11.1
	Myocarditis toxoplasmal	10028617	PT	Broad	A	0	Active	11.1	11.1
	Myoglobinaemia	10058735	PT	Broad	A	0	Active	11.1	11.1
	Myoglobinuria	10028629	PT	Broad	A	0	Active	11.1	11.1
	Nocturia	10029446	PT	Broad	A	0	Active	11.1	11.1
	Oedema	10030095	PT	Broad	A	0	Active	11.1	11.1
	Orthostatic hypotension	10031127	PT	Broad	A	0	Active	11.1	11.1
	Palpitations	10033557	PT	Broad	A	0	Active	11.1	11.1
	Papillary muscle disorder	10061330	PT	Broad	A	0	Active	11.1	11.1
	Papillary muscle haemorrhage	10059164	PT	Broad	A	0	Active	11.1	11.1
	Radiation myocarditis	10076389	PT	Broad	A	0	Active	18.0	18.0
	Right atrial dilatation	10067282	PT	Broad	A	0	Active	11.1	11.1
	Right atrial enlargement	10058227	PT	Broad	A	0	Active	11.1	19.1

Right atrial pressure increased	10067283	PT	Broad	A	0	Active	11.1	11.1
Right ventricle outflow tract obstruction	10064195	PT	Broad	A	0	Active	11.1	11.1
Right ventricular dilatation	10074222	PT	Broad	A	0	Active	16.1	19.1
Right ventricular enlargement	10050582	PT	Broad	A	0	Active	11.1	19.1
Right ventricular heave	10070955	PT	Broad	A	0	Active	14.0	14.0
Right ventricular systolic pressure decreased	10060237	PT	Broad	A	0	Active	11.1	11.1
Scan myocardial perfusion abnormal	10061501	PT	Broad	A	0	Active	11.1	11.1
Sudden cardiac death	10049418	PT	Broad	A	0	Active	11.1	11.1
Sudden death	10042434	PT	Broad	A	0	Active	11.1	11.1
Surgical ventricular restoration	10078218	PT	Broad	A	0	Active	19.1	19.1
Syncope	10042772	PT	Broad	A	0	Active	11.1	11.1
Systolic anterior motion of mitral valve	10076976	PT	Broad	A	0	Active	18.1	18.1
Systolic dysfunction	10071436	PT	Broad	A	0	Active	14.1	14.1
Ultrasound Doppler abnormal	10045413	PT	Broad	A	0	Active	11.1	11.1
Vascular resistance pulmonary increased	10067285	PT	Broad	A	0	Active	11.1	11.1
Ventricular arrhythmia	10047281	PT	Broad	A	0	Active	11.1	11.1
Ventricular assist device insertion	10052371	PT	Broad	A	0	Active	11.1	11.1
Ventricular dysfunction	10059056	PT	Broad	A	0	Active	11.1	11.1
Ventricular dyskinesia	10059162	PT	Broad	A	0	Active	11.1	11.1
Ventricular dyssynchrony	10071186	PT	Broad	A	0	Active	14.0	14.0
Ventricular enlargement	10079339	PT	Broad	A	0	Active	20.0	20.0
Ventricular hyperkinesia	10056472	PT	Broad	A	0	Active	11.1	11.1
Ventricular hypertrophy	10047295	PT	Broad	A	0	Active	11.1	11.1
Ventricular hypokinesia	10050510	PT	Broad	A	0	Active	11.1	11.1
Ventricular remodelling	10075291	PT	Broad	A	0	Active	17.1	17.1
Viral myocarditis	10047470	PT	Broad	A	0	Active	11.1	11.1
Wall motion score index abnormal	10079016	PT	Broad	A	0	Active	20.0	20.0

SMQ Export: 23.0 - English		4/21/2021 9:26:46 PM								
	Include Inactive PT: No									
English: Central nervous system vascular disorders (SMQ): Level 1										
	English: Central nervous system haemorrhages and cerebrovascular conditions (SMQ): Level 2									
	English: Conditions associated with central nervous system haemorrhages and cerebrovascular accidents (SMQ): Level 3									
		English	Code	Level	Scope	Category	Weight	Status	Addition Version	Last Modified Version
		Balint's syndrome	10057375	PT	Narrow	A	0	Active	12.0	16.1
		Basilar artery aneurysm	10077607	PT	Narrow	A	0	Active	19.0	19.0
		Carotid artery aneurysm	10007686	PT	Narrow	A	0	Active	12.0	16.1
		Carotid artery dissection	10050403	PT	Narrow	A	0	Active	12.0	16.1
		Cerebral cavernous malformation	10071747	PT	Narrow	A	0	Active	23.0	23.0
		Cerebral endovascular aneurysm repair	10077079	PT	Narrow	A	0	Active	18.1	18.1
		Cerebral reperfusion injury	10075401	PT	Narrow	A	0	Active	17.1	17.1
		Cerebral ventricular rupture	10075249	PT	Narrow	A	0	Active	17.1	17.1
		Cerebrovascular accident prophylaxis	10049165	PT	Narrow	A	0	Active	12.0	16.1
		Cerebrovascular pseudoaneurysm	10084087	PT	Narrow	A	0	Active	23.0	23.0
		Charcot-Bouchard microaneurysms	10054749	PT	Narrow	A	0	Active	12.0	16.1
		Congenital hemiparesis	10071359	PT	Narrow	A	0	Active	14.1	16.1
		CSF bilirubin positive	10071326	PT	Narrow	A	0	Active	14.1	16.1
		Delayed ischaemic neurological deficit	10078388	PT	Narrow	A	0	Active	19.1	19.1
		Hemianesthesia	10077170	PT	Narrow	A	0	Active	18.1	18.1
		Hemiasomatognosia	10077171	PT	Narrow	A	0	Active	18.1	18.1
		Hemiataxia	10081999	PT	Narrow	A	0	Active	22.0	22.0
		Hemidysaesthesia	10083174	PT	Narrow	A	0	Active	22.1	22.1
		Hemihyperaesthesia	10080713	PT	Narrow	A	0	Active	21.0	21.0
		Hemiparaesthesia	10078746	PT	Narrow	A	0	Active	20.0	20.0
		Hemiparesis	10019465	PT	Narrow	A	0	Active	12.0	16.1
		Hemiplegia	10019468	PT	Narrow	A	0	Active	12.0	16.1
		Intra-cerebral aneurysm operation	10022736	PT	Narrow	A	0	Active	12.0	16.1
		Intracranial aneurysm	10022758	PT	Narrow	A	0	Active	12.0	16.1
		Lateropulsion	10081515	PT	Narrow	A	0	Active	21.1	21.1
		Post stroke depression	10070606	PT	Narrow	A	0	Active	13.1	16.1
		Posthaemorrhagic hydrocephalus	10079859	PT	Narrow	A	0	Active	20.1	20.1
		Vein of Galen aneurysmal malformation	10077889	PT	Narrow	A	0	Active	19.0	19.0
		Vertebral artery aneurysm	10077498	PT	Narrow	A	0	Active	19.0	19.0
		Vertebral artery dissection	10071716	PT	Narrow	A	0	Active	14.1	16.1
		Agnosia	10048663	PT	Broad	A	0	Active	12.0	12.0
		Angiogram cerebral abnormal	10052906	PT	Broad	A	0	Active	12.0	12.0
		Aphasia	10002948	PT	Broad	A	0	Active	12.0	12.0
		Brain injury	10067967	PT	Broad	A	0	Active	15.1	15.1
		Central pain syndrome	10064012	PT	Broad	A	0	Active	12.0	12.0
		Cerebral haemosiderin deposition	10070728	PT	Broad	A	0	Active	13.1	14.0
		CSF red blood cell count positive	10075562	PT	Broad	A	0	Active	18.0	18.0
		Diplegia	10013033	PT	Broad	A	0	Active	12.0	12.0
		Dysarthria	10013887	PT	Broad	A	0	Active	12.0	12.0
		Hunt and Hess scale	10083810	PT	Broad	A	0	Active	23.0	23.0
		Internal carotid artery deformity	10082308	PT	Broad	A	0	Active	22.0	22.0
		Intracranial artery dissection	10073565	PT	Broad	A	0	Active	16.1	16.1
		Modified Rankin score decreased	10072882	PT	Broad	A	0	Active	16.0	16.0
		Modified Rankin score increased	10072881	PT	Broad	A	0	Active	16.0	16.0
		Monoparesis	10027925	PT	Broad	A	0	Active	12.0	12.0
		Monoplegia	10027926	PT	Broad	A	0	Active	12.0	12.0
		NIH stroke scale abnormal	10065531	PT	Broad	A	0	Active	16.0	16.0
		NIH stroke scale score decreased	10065529	PT	Broad	A	0	Active	16.0	16.0
		NIH stroke scale score increased	10065528	PT	Broad	A	0	Active	16.0	16.0

		Paralysis	10033799	PT	Broad	A	0	Active	12.0	12.0
		Paraparesis	10033885	PT	Broad	A	0	Active	12.0	12.0
		Paraplegia	10033892	PT	Broad	A	0	Active	12.0	12.0
		Paresis	10033985	PT	Broad	A	0	Active	12.0	12.0
		Quadripareis	10049680	PT	Broad	A	0	Active	12.0	12.0
		Quadriplegia	10037714	PT	Broad	A	0	Active	12.0	12.0
		Right hemisphere deficit syndrome	10075037	PT	Broad	A	0	Active	17.1	17.1
		Superficial siderosis of central nervous system	10070564	PT	Broad	A	0	Active	13.1	13.1
		Visual agnosia	10077168	PT	Broad	A	0	Active	18.1	18.1
		Visual midline shift syndrome	10066856	PT	Broad	A	0	Active	12.0	12.0
		English: Haemorrhagic central nervous system vascular conditions (SMQ): Level 3								
		English	Code	Level	Scope	Category	Weight	Status	Addition Version	Last Modified Version
		Basal ganglia haematoma	10077031	PT	Narrow	A	0	Active	18.1	18.1
		Basal ganglia haemorrhage	10067057	PT	Narrow	A	0	Active	10.0	10.1
		Basal ganglia stroke	10071043	PT	Narrow	A	0	Active	14.0	14.0
		Basilar artery perforation	10075736	PT	Narrow	A	0	Active	18.0	18.0
		Brain stem haematoma	10073230	PT	Narrow	A	0	Active	16.0	16.0
		Brain stem haemorrhage	10006145	PT	Narrow	A	0	Active	9.1	9.1
		Brain stem microhaemorrhage	10071205	PT	Narrow	A	0	Active	14.0	14.0
		Brain stem stroke	10068644	PT	Narrow	A	0	Active	11.1	11.1
		Carotid aneurysm rupture	10051328	PT	Narrow	A	0	Active	9.1	9.1
		Carotid artery perforation	10075728	PT	Narrow	A	0	Active	18.0	18.0
		Central nervous system haemorrhage	10072043	PT	Narrow	A	0	Active	15.0	15.0
		Cerebellar haematoma	10061038	PT	Narrow	A	0	Active	9.1	9.1
		Cerebellar haemorrhage	10008030	PT	Narrow	A	0	Active	9.1	9.1
		Cerebellar microhaemorrhage	10071206	PT	Narrow	A	0	Active	14.0	14.0
		Cerebellar stroke	10079062	PT	Narrow	A	0	Active	20.0	20.0
		Cerebral aneurysm perforation	10075394	PT	Narrow	A	0	Active	17.1	17.1
		Cerebral aneurysm ruptured syphilitic	10008076	PT	Narrow	A	0	Active	16.1	16.1
		Cerebral arteriovenous malformation haemorrhagic	10008086	PT	Narrow	A	0	Active	9.1	9.1
		Cerebral artery perforation	10075734	PT	Narrow	A	0	Active	18.0	18.0
		Cerebral cyst haemorrhage	10082099	PT	Narrow	A	0	Active	22.0	22.0
		Cerebral haematoma	10053942	PT	Narrow	A	0	Active	9.1	9.1
		Cerebral haemorrhage	10008111	PT	Narrow	A	0	Active	9.1	9.1
		Cerebral haemorrhage foetal	10050157	PT	Narrow	A	0	Active	9.1	9.1
		Cerebral haemorrhage neonatal	10008112	PT	Narrow	A	0	Active	9.1	9.1
		Cerebral microhaemorrhage	10067277	PT	Narrow	A	0	Active	10.0	12.1
		Cerebrovascular accident	10008190	PT	Narrow	A	0	Active	9.1	9.1
		Cerebrovascular disorder	10008196	PT	Narrow	A	0	Active	9.1	9.1
		Epidural haemorrhage	10073681	PT	Narrow	A	0	Active	16.1	16.1
		Extra-axial haemorrhage	10078254	PT	Narrow	A	0	Active	19.1	19.1
		Extradural haematoma	10015769	PT	Narrow	A	0	Active	15.1	15.1
		Extradural haematoma evacuation	10082797	PT	Narrow	A	0	Active	22.1	22.1
		Extracerebral cerebral haematoma	10080347	PT	Narrow	A	0	Active	21.0	21.0
		Foville syndrome	10082594	PT	Narrow	A	0	Active	22.1	22.1
		Haemorrhage intracranial	10018985	PT	Narrow	A	0	Active	9.1	9.1
		Haemorrhagic cerebral infarction	10019005	PT	Narrow	A	0	Active	9.1	9.1
		Haemorrhagic stroke	10019016	PT	Narrow	A	0	Active	9.1	9.1
		Haemorrhagic transformation stroke	10055677	PT	Narrow	A	0	Active	9.1	9.1
		Intracerebral haematoma evacuation	10062025	PT	Narrow	A	0	Active	9.1	9.1
		Intracranial haematoma	10059491	PT	Narrow	A	0	Active	9.1	9.1
		Intracranial tumour haemorrhage	10022775	PT	Narrow	A	0	Active	17.0	17.0
		Intraventricular haemorrhage	10022840	PT	Narrow	A	0	Active	9.1	9.1
		Intraventricular haemorrhage neonatal	10022841	PT	Narrow	A	0	Active	9.1	9.1
		Meningorrhagia	10052593	PT	Narrow	A	0	Active	9.1	9.1
		Perinatal stroke	10073945	PT	Narrow	A	0	Active	16.1	16.1
		Periventricular haemorrhage neonatal	10076706	PT	Narrow	A	0	Active	18.1	18.1

		Pituitary apoplexy	10056447	PT	Narrow	A	0	Active	17.0	22.0
		Pituitary haemorrhage	10049760	PT	Narrow	A	0	Active	17.0	17.0
		Putamen haemorrhage	10058940	PT	Narrow	A	0	Active	9.1	9.1
		Ruptured cerebral aneurysm	10039330	PT	Narrow	A	0	Active	9.1	9.1
		Spinal cord haematoma	10076051	PT	Narrow	A	0	Active	18.0	18.0
		Spinal cord haemorrhage	10048992	PT	Narrow	A	0	Active	9.1	9.1
		Spinal epidural haematoma	10050162	PT	Narrow	A	0	Active	15.1	16.1
		Spinal epidural haemorrhage	10049236	PT	Narrow	A	0	Active	9.1	9.1
		Spinal stroke	10082031	PT	Narrow	A	0	Active	22.0	22.0
		Spinal subarachnoid haemorrhage	10073564	PT	Narrow	A	0	Active	16.1	16.1
		Spinal subdural haematoma	10050164	PT	Narrow	A	0	Active	15.1	16.1
		Spinal subdural haemorrhage	10073563	PT	Narrow	A	0	Active	16.1	16.1
		Stroke in evolution	10059613	PT	Narrow	A	0	Active	9.1	9.1
		Subarachnoid haematoma	10076701	PT	Narrow	A	0	Active	18.1	18.1
		Subarachnoid haemorrhage	10042316	PT	Narrow	A	0	Active	9.1	9.1
		Subarachnoid haemorrhage neonatal	10042317	PT	Narrow	A	0	Active	9.1	9.1
		Subdural haematoma	10042361	PT	Narrow	A	0	Active	15.1	15.1
		Subdural haematoma evacuation	10042363	PT	Narrow	A	0	Active	15.1	15.1
		Subdural haemorrhage	10042364	PT	Narrow	A	0	Active	9.1	9.1
		Subdural haemorrhage neonatal	10042365	PT	Narrow	A	0	Active	9.1	9.1
		Thalamus haemorrhage	10058939	PT	Narrow	A	0	Active	9.1	9.1
		Vertebral artery perforation	10075735	PT	Narrow	A	0	Active	18.0	18.0
		Vertebrobasilar stroke	10082484	PT	Narrow	A	0	Active	22.0	22.0
		<b>English: Ischaemic central nervous system vascular conditions (SMQ): Level 3</b>								
		<b>English</b>	<b>Code</b>	<b>Level</b>	<b>Scope</b>	<b>Category</b>	<b>Weight</b>	<b>Status</b>	<b>Addition Version</b>	<b>Last Modified Version</b>
		Amaurosis fugax	10001903	PT	Narrow	A	0	Active	16.1	16.1
		Basal ganglia infarction	10069020	PT	Narrow	A	0	Active	12.0	12.0
		Basal ganglia stroke	10071043	PT	Narrow	A	0	Active	14.0	14.0
		Basilar artery occlusion	10048963	PT	Narrow	A	0	Active	9.1	9.1
		Basilar artery stenosis	10004163	PT	Narrow	A	0	Active	9.1	9.1
		Basilar artery thrombosis	10063093	PT	Narrow	A	0	Active	9.1	9.1
		Brachiocephalic arteriosclerosis	10075449	PT	Narrow	A	0	Active	17.1	17.1
		Brachiocephalic artery occlusion	10069694	PT	Narrow	A	0	Active	13.0	13.0
		Brachiocephalic artery stenosis	10075450	PT	Narrow	A	0	Active	17.1	17.1
		Brain hypoxia	10006127	PT	Narrow	A	0	Active	15.1	15.1
		Brain stem embolism	10074422	PT	Narrow	A	0	Active	17.0	17.0
		Brain stem infarction	10006147	PT	Narrow	A	0	Active	9.1	9.1
		Brain stem ischaemia	10006148	PT	Narrow	A	0	Active	9.1	9.1
		Brain stem stroke	10068644	PT	Narrow	A	0	Active	11.1	11.1
		Brain stem thrombosis	10062573	PT	Narrow	A	0	Active	9.1	9.1
		Brain stent insertion	10080887	PT	Narrow	A	0	Active	21.0	21.0
		CADASIL	10065555	PT	Narrow	A	0	Active	21.1	21.1
		Capsular warning syndrome	10067744	PT	Narrow	A	0	Active	10.1	10.1
		CARASIL syndrome	10081315	PT	Narrow	A	0	Active	21.1	21.1
		Carotid angioplasty	10071260	PT	Narrow	A	0	Active	16.1	16.1
		Carotid arterial embolus	10007684	PT	Narrow	A	0	Active	9.1	9.1
		Carotid arteriosclerosis	10067116	PT	Narrow	A	0	Active	10.0	10.0
		Carotid artery bypass	10053003	PT	Narrow	A	0	Active	10.0	10.0
		Carotid artery disease	10061744	PT	Narrow	A	0	Active	9.1	9.1
		Carotid artery insufficiency	10064949	PT	Narrow	A	0	Active	9.1	9.1
		Carotid artery occlusion	10048964	PT	Narrow	A	0	Active	9.1	9.1
		Carotid artery restenosis	10072558	PT	Narrow	A	0	Active	15.1	15.1
		Carotid artery stenosis	10007687	PT	Narrow	A	0	Active	9.1	9.1
		Carotid artery stent insertion	10066102	PT	Narrow	A	0	Active	10.0	10.0
		Carotid artery stent removal	10069952	PT	Narrow	A	0	Active	13.0	13.0
		Carotid artery thrombosis	10007688	PT	Narrow	A	0	Active	9.1	9.1
		Carotid endarterectomy	10007692	PT	Narrow	A	0	Active	10.0	10.0

			Carotid revascularisation	10072559	PT	Narrow	A	0	Active	15.1	15.1
			Cerebellar artery occlusion	10053633	PT	Narrow	A	0	Active	9.1	9.1
			Cerebellar artery thrombosis	10008023	PT	Narrow	A	0	Active	9.1	9.1
			Cerebellar embolism	10067167	PT	Narrow	A	0	Active	10.0	10.0
			Cerebellar infarction	10008034	PT	Narrow	A	0	Active	9.1	9.1
			Cerebellar ischaemia	10068621	PT	Narrow	A	0	Active	11.1	11.1
			Cerebellar stroke	10079062	PT	Narrow	A	0	Active	20.0	20.0
			Cerebral arteriosclerosis	10065559	PT	Narrow	A	0	Active	9.1	9.1
			Cerebral artery embolism	10008088	PT	Narrow	A	0	Active	9.1	9.1
			Cerebral artery occlusion	10008089	PT	Narrow	A	0	Active	9.1	9.1
			Cerebral artery restenosis	10075423	PT	Narrow	A	0	Active	17.1	17.1
			Cerebral artery stenosis	10063648	PT	Narrow	A	0	Active	9.1	9.1
			Cerebral artery stent insertion	10081893	PT	Narrow	A	0	Active	22.0	22.0
			Cerebral artery thrombosis	10008092	PT	Narrow	A	0	Active	9.1	9.1
			Cerebral gas embolism	10070813	PT	Narrow	A	0	Active	13.1	13.1
			Cerebral infarction	10008118	PT	Narrow	A	0	Active	9.1	9.1
			Cerebral infarction foetal	10008119	PT	Narrow	A	0	Active	9.1	9.1
			Cerebral ischaemia	10008120	PT	Narrow	A	0	Active	9.1	9.1
			Cerebral microembolism	10078311	PT	Narrow	A	0	Active	19.1	19.1
			Cerebral microinfarction	10083668	PT	Narrow	A	0	Active	23.0	23.0
			Cerebral revascularisation	10071508	PT	Narrow	A	0	Active	14.1	14.1
			Cerebral septic infarct	10070671	PT	Narrow	A	0	Active	13.1	13.1
			Cerebral small vessel ischaemic disease	10070878	PT	Narrow	A	0	Active	14.0	14.0
			Cerebral thrombosis	10008132	PT	Narrow	A	0	Active	9.1	9.1
			Cerebral vascular occlusion	10076895	PT	Narrow	A	0	Active	18.1	19.0
			Cerebral vasoconstriction	10059109	PT	Narrow	A	0	Active	9.1	9.1
			Cerebral venous thrombosis	10008138	PT	Narrow	A	0	Active	9.1	9.1
			Cerebrovascular accident	10008190	PT	Narrow	A	0	Active	9.1	9.1
			Cerebrovascular disorder	10008196	PT	Narrow	A	0	Active	9.1	9.1
			Cerebrovascular insufficiency	10058842	PT	Narrow	A	0	Active	9.1	9.1
			Cerebrovascular stenosis	10061751	PT	Narrow	A	0	Active	9.1	9.1
			Delayed ischaemic neurological deficit	10078388	PT	Narrow	A	0	Active	19.1	19.1
			Embolic cerebellar infarction	10084072	PT	Narrow	A	0	Active	23.0	23.0
			Embolic cerebral infarction	10060839	PT	Narrow	A	0	Active	9.1	9.1
			Embolic stroke	10014498	PT	Narrow	A	0	Active	9.1	9.1
			Foville syndrome	10082594	PT	Narrow	A	0	Active	22.1	22.1
			Hypoxic-ischaemic encephalopathy	10070511	PT	Narrow	A	0	Active	15.1	15.1
			Inner ear infarction	10070754	PT	Narrow	A	0	Active	13.1	13.1
			Internal capsule infarction	10083408	PT	Narrow	A	0	Active	23.0	23.0
			Ischaemic cerebral infarction	10060840	PT	Narrow	A	0	Active	9.1	9.1
			Ischaemic stroke	10061256	PT	Narrow	A	0	Active	9.1	9.1
			Jugular vein embolism	10081850	PT	Narrow	A	0	Active	22.0	22.0
			Lacunar infarction	10051078	PT	Narrow	A	0	Active	9.1	9.1
			Lacunar stroke	10076994	PT	Narrow	A	0	Active	18.1	18.1
			Lateral medullary syndrome	10024033	PT	Narrow	A	0	Active	9.1	9.1
			Migrainous infarction	10056237	PT	Narrow	A	0	Active	17.1	17.1
			Millard-Gubler syndrome	10067462	PT	Narrow	A	0	Active	10.1	10.1
			Moyamoya disease	10028047	PT	Narrow	A	0	Active	9.1	9.1
			Perinatal stroke	10073945	PT	Narrow	A	0	Active	16.1	16.1
			Post cardiac arrest syndrome	10078202	PT	Narrow	A	0	Active	19.1	19.1
			Post procedural stroke	10066591	PT	Narrow	A	0	Active	9.1	9.1
			Precerebral arteriosclerosis	10077033	PT	Narrow	A	0	Active	18.1	18.1
			Precerebral artery occlusion	10036511	PT	Narrow	A	0	Active	9.1	9.1
			Reversible cerebral vasoconstriction syndrome	10073240	PT	Narrow	A	0	Active	16.0	18.0
			Reversible ischaemic neurological deficit	10050496	PT	Narrow	A	0	Active	9.1	9.1
			Spinal artery embolism	10049440	PT	Narrow	A	0	Active	9.1	9.1
			Spinal artery thrombosis	10071316	PT	Narrow	A	0	Active	14.1	14.1

		Spinal cord infarction	10058571	PT	Narrow	A	0	Active	21.1	21.1
		Spinal cord ischaemia	10050209	PT	Narrow	A	0	Active	21.1	21.1
		Spinal stroke	10082031	PT	Narrow	A	0	Active	22.0	22.0
		Stroke in evolution	10059613	PT	Narrow	A	0	Active	9.1	9.1
		Subclavian steal syndrome	10042335	PT	Narrow	A	0	Active	15.0	15.0
		Thalamic infarction	10064961	PT	Narrow	A	0	Active	9.1	9.1
		Thrombotic cerebral infarction	10067347	PT	Narrow	A	0	Active	10.1	10.1
		Thrombotic stroke	10043647	PT	Narrow	A	0	Active	9.1	9.1
		Transient ischaemic attack	10044390	PT	Narrow	A	0	Active	9.1	9.1
		Vascular encephalopathy	10063661	PT	Narrow	A	0	Active	9.1	9.1
		Vascular stent occlusion	10077143	PT	Narrow	A	0	Active	18.1	18.1
		Vascular stent stenosis	10077144	PT	Narrow	A	0	Active	18.1	18.1
		Vertebral artery occlusion	10048965	PT	Narrow	A	0	Active	9.1	9.1
		Vertebral artery stenosis	10047330	PT	Narrow	A	0	Active	9.1	9.1
		Vertebral artery thrombosis	10057777	PT	Narrow	A	0	Active	9.1	9.1
		Vertebrobasilar insufficiency	10047334	PT	Narrow	A	0	Active	9.1	9.1
		Vertebrobasilar stroke	10082484	PT	Narrow	A	0	Active	22.0	22.0
English: Central nervous system vascular disorders, not specified as haemorrhagic or ischaemic (SMQ): Level 2										
English	Code	Level	Scope	Category	Weight	Status	Addition Version	Last Modified Version		
Central nervous system vasculitis	10081778	PT	Narrow	A	0	Active	21.1	21.1		
Cerebral arteritis	10008087	PT	Narrow	A	0	Active	12.0	12.0		
Cerebral capillary telangiectasia	10075633	PT	Narrow	A	0	Active	18.0	18.0		
Cerebral circulatory failure	10008097	PT	Narrow	A	0	Active	12.0	12.0		
Cerebral congestion	10076929	PT	Narrow	A	0	Active	18.1	18.1		
Cerebral hypoperfusion	10065384	PT	Narrow	A	0	Active	12.0	12.0		
Cerebral venous sinus thrombosis	10083037	PT	Narrow	A	0	Active	22.1	22.1		
Chronic cerebrospinal venous insufficiency	10082477	PT	Narrow	A	0	Active	22.0	22.0		
Dural arteriovenous fistula	10074462	PT	Narrow	A	0	Active	17.0	17.0		
Superior sagittal sinus thrombosis	10042567	PT	Narrow	A	0	Active	12.0	12.0		
Transverse sinus thrombosis	10044457	PT	Narrow	A	0	Active	12.0	12.0		
Amyloid related imaging abnormalities	10072599	PT	Broad	A	0	Active	15.1	15.1		
Amyloid related imaging abnormality-microhaemorrhage	10072601	PT	Broad	A	0	Active	15.1	21.0		
Amyloid related imaging abnormality-oedema/effusion	10072260	PT	Broad	A	0	Active	15.0	21.0		
Blood brain barrier defect	10057361	PT	Broad	A	0	Active	12.0	12.0		
Carotid artery dolichoectasia	10080308	PT	Broad	A	0	Active	20.1	20.1		
Cerebral amyloid angiopathy	10068044	PT	Broad	A	0	Active	12.0	12.0		
Cerebral microangiopathy	10067466	PT	Broad	A	0	Active	12.0	12.0		
Cerebrovascular arteriovenous malformation	10056371	PT	Broad	A	0	Active	12.0	12.0		
Congenital cerebrovascular anomaly	10062327	PT	Broad	A	0	Active	12.0	12.0		
Foetal cerebrovascular disorder	10053601	PT	Broad	A	0	Active	12.0	12.0		
Hypertensive cerebrovascular disease	10077000	PT	Broad	A	0	Active	18.1	18.1		
Primary familial brain calcification	10078822	PT	Broad	A	0	Active	20.0	20.0		
Sneddon's syndrome	10053841	PT	Broad	A	0	Active	12.0	12.0		
Spinal vascular disorder	10061369	PT	Broad	A	0	Active	12.0	12.0		
Spinal vessel congenital anomaly	10041603	PT	Broad	A	0	Active	12.0	12.0		
Susac's syndrome	10071573	PT	Broad	A	0	Active	14.1	14.1		
Vertebrobasilar dolichoectasia	10071505	PT	Broad	A	0	Active	14.1	14.1		



<b>Central nervous system haemorrhages and cerebrovascular conditions (SMQ): Level 2</b>			
<b>Conditions associated with central nervous system haemorrhages and cerebrovascular accidents (SMQ): Level 3</b>			
<b>English</b>	<b>Code</b>	<b>Level</b>	<b>Scope</b>
Balint's syndrome	10057375	PT	Narrow
Basilar artery aneurysm	10077607	PT	Narrow
Carotid artery aneurysm	10007686	PT	Narrow
Carotid artery dissection	10050403	PT	Narrow
Cerebral cavernous malformation	10071747	PT	Narrow
Cerebral endovascular aneurysm repair	10077079	PT	Narrow
Cerebral reperfusion injury	10075401	PT	Narrow
Cerebral ventricular rupture	10075249	PT	Narrow
Cerebrovascular accident prophylaxis	10049165	PT	Narrow
Cerebrovascular pseudoaneurysm	10084087	PT	Narrow
Charcot-Bouchard microaneurysms	10054749	PT	Narrow
Congenital hemiparesis	10071359	PT	Narrow
CSF bilirubin positive	10071326	PT	Narrow
Delayed ischaemic neurological deficit	10078388	PT	Narrow
Hemianaesthesia	10077170	PT	Narrow
Hemiasomatognosia	10077171	PT	Narrow
Hemiataxia	10081999	PT	Narrow
Hemidysaesthesia	10083174	PT	Narrow
Hemihyperaesthesia	10080713	PT	Narrow
Hemiparaesthesia	10078746	PT	Narrow
Hemiparesis	10019465	PT	Narrow
Hemiplegia	10019468	PT	Narrow
Intra-cerebral aneurysm operation	10022736	PT	Narrow
Intracranial aneurysm	10022758	PT	Narrow
Lateropulsion	10081515	PT	Narrow
Post stroke depression	10070606	PT	Narrow
Posthaemorrhagic hydrocephalus	10079859	PT	Narrow
Vein of Galen aneurysmal malformation	10077889	PT	Narrow
Vertebral artery aneurysm	10077498	PT	Narrow
Vertebral artery dissection	10071716	PT	Narrow
Agnosia	10048663	PT	Broad
Angiogram cerebral abnormal	10052906	PT	Broad
Aphasia	10002948	PT	Broad
Brain injury	10067967	PT	Broad
Central pain syndrome	10064012	PT	Broad
Cerebral haemosiderin deposition	10070728	PT	Broad
CSF red blood cell count positive	10075562	PT	Broad
Diplegia	10013033	PT	Broad
Dysarthria	10013887	PT	Broad
Hunt and Hess scale	10083810	PT	Broad
Internal carotid artery deformity	10082308	PT	Broad
Intracranial artery dissection	10073565	PT	Broad
Modified Rankin score decreased	10072882	PT	Broad
Modified Rankin score increased	10072881	PT	Broad
Monoparesis	10027925	PT	Broad
Monoplegia	10027926	PT	Broad
NIH stroke scale abnormal	10065531	PT	Broad
NIH stroke scale score decreased	10065529	PT	Broad
NIH stroke scale score increased	10065528	PT	Broad
Paralysis	10033799	PT	Broad
Paraparesis	10033885	PT	Broad
Paraplegia	10033892	PT	Broad
Paresis	10033985	PT	Broad
Quadriparesis	10049680	PT	Broad
Quadriplegia	10037714	PT	Broad
Right hemisphere deficit syndrome	10075037	PT	Broad

Superficial siderosis of central nervous system	10070564	PT	Broad
Visual agnosia	10077168	PT	Broad
Visual midline shift syndrome	10066856	PT	Broad

<b>Haemorrhagic central nervous system vascular conditions (SMQ): Level 3</b>			
<b>English</b>	<b>Code</b>	<b>Level</b>	<b>Scope</b>
Basal ganglia haematoma	10077031	PT	Narrow
Basal ganglia haemorrhage	10067057	PT	Narrow
Basal ganglia stroke	10071043	PT	Narrow
Basilar artery perforation	10075736	PT	Narrow
Brain stem haematoma	10073230	PT	Narrow
Brain stem haemorrhage	10006145	PT	Narrow
Brain stem microhaemorrhage	10071205	PT	Narrow
Brain stem stroke	10068644	PT	Narrow
Carotid aneurysm rupture	10051328	PT	Narrow
Carotid artery perforation	10075728	PT	Narrow
Central nervous system haemorrhage	10072043	PT	Narrow
Cerebellar haematoma	10061038	PT	Narrow
Cerebellar haemorrhage	10008030	PT	Narrow
Cerebellar microhaemorrhage	10071206	PT	Narrow
Cerebellar stroke	10079062	PT	Narrow
Cerebral aneurysm perforation	10075394	PT	Narrow
Cerebral aneurysm ruptured syphilitic	10008076	PT	Narrow
Cerebral arteriovenous malformation haemorrhagic	10008086	PT	Narrow
Cerebral artery perforation	10075734	PT	Narrow
Cerebral cyst haemorrhage	10082099	PT	Narrow
Cerebral haematoma	10053942	PT	Narrow
Cerebral haemorrhage	10008111	PT	Narrow
Cerebral haemorrhage foetal	10050157	PT	Narrow
Cerebral haemorrhage neonatal	10008112	PT	Narrow
Cerebral microhaemorrhage	10067277	PT	Narrow
Cerebrovascular accident	10008190	PT	Narrow
Cerebrovascular disorder	10008196	PT	Narrow
Epidural haemorrhage	10073681	PT	Narrow
Extra-axial haemorrhage	10078254	PT	Narrow
Extradural haematoma	10015769	PT	Narrow
Extradural haematoma evacuation	10082797	PT	Narrow
Extracerebral cerebral haematoma	10080347	PT	Narrow
Foville syndrome	10082594	PT	Narrow
Haemorrhage intracranial	10018985	PT	Narrow
Haemorrhagic cerebral infarction	10019005	PT	Narrow
Haemorrhagic stroke	10019016	PT	Narrow
Haemorrhagic transformation stroke	10055677	PT	Narrow
Intracerebral haematoma evacuation	10062025	PT	Narrow
Intracranial haematoma	10059491	PT	Narrow
Intracranial tumour haemorrhage	10022775	PT	Narrow
Intraventricular haemorrhage	10022840	PT	Narrow
Intraventricular haemorrhage neonatal	10022841	PT	Narrow
Meningorrhagia	10052593	PT	Narrow
Perinatal stroke	10073945	PT	Narrow
Periventricular haemorrhage neonatal	10076706	PT	Narrow

Pituitary apoplexy	10056447	PT	Narrow
Pituitary haemorrhage	10049760	PT	Narrow
Putamen haemorrhage	10058940	PT	Narrow
Ruptured cerebral aneurysm	10039330	PT	Narrow
Spinal cord haematoma	10076051	PT	Narrow
Spinal cord haemorrhage	10048992	PT	Narrow
Spinal epidural haematoma	10050162	PT	Narrow
Spinal epidural haemorrhage	10049236	PT	Narrow
Spinal stroke	10082031	PT	Narrow
Spinal subarachnoid haemorrhage	10073564	PT	Narrow
Spinal subdural haematoma	10050164	PT	Narrow
Spinal subdural haemorrhage	10073563	PT	Narrow
Stroke in evolution	10059613	PT	Narrow
Subarachnoid haematoma	10076701	PT	Narrow
Subarachnoid haemorrhage	10042316	PT	Narrow
Subarachnoid haemorrhage neonatal	10042317	PT	Narrow
Subdural haematoma	10042361	PT	Narrow
Subdural haematoma evacuation	10042363	PT	Narrow
Subdural haemorrhage	10042364	PT	Narrow
Subdural haemorrhage neonatal	10042365	PT	Narrow
Thalamus haemorrhage	10058939	PT	Narrow
Vertebral artery perforation	10075735	PT	Narrow
Vertebrobasilar stroke	10082484	PT	Narrow

<b>Ischaemic central nervous system vascular conditions (SMQ): Level 3</b>			
<b>English</b>	<b>Code</b>	<b>Level</b>	<b>Scope</b>
Amaurosis fugax	10001903	PT	Narrow
Basal ganglia infarction	10069020	PT	Narrow
Basal ganglia stroke	10071043	PT	Narrow
Basilar artery occlusion	10048963	PT	Narrow
Basilar artery stenosis	10004163	PT	Narrow
Basilar artery thrombosis	10063093	PT	Narrow
Brachiocephalic arteriosclerosis	10075449	PT	Narrow
Brachiocephalic artery occlusion	10069694	PT	Narrow
Brachiocephalic artery stenosis	10075450	PT	Narrow
Brain hypoxia	10006127	PT	Narrow
Brain stem embolism	10074422	PT	Narrow
Brain stem infarction	10006147	PT	Narrow
Brain stem ischaemia	10006148	PT	Narrow
Brain stem stroke	10068644	PT	Narrow
Brain stem thrombosis	10062573	PT	Narrow
Brain stent insertion	10080887	PT	Narrow
CADASIL	10065555	PT	Narrow
Capsular warning syndrome	10067744	PT	Narrow
CARASIL syndrome	10081315	PT	Narrow
Carotid angioplasty	10071260	PT	Narrow
Carotid arterial embolus	10007684	PT	Narrow
Carotid arteriosclerosis	10067116	PT	Narrow
Carotid artery bypass	10053003	PT	Narrow
Carotid artery disease	10061744	PT	Narrow
Carotid artery insufficiency	10064949	PT	Narrow
Carotid artery occlusion	10048964	PT	Narrow
Carotid artery restenosis	10072558	PT	Narrow
Carotid artery stenosis	10007687	PT	Narrow
Carotid artery stent insertion	10066102	PT	Narrow
Carotid artery stent removal	10069952	PT	Narrow
Carotid artery thrombosis	10007688	PT	Narrow
Carotid endarterectomy	10007692	PT	Narrow
Carotid revascularisation	10072559	PT	Narrow
Cerebellar artery occlusion	10053633	PT	Narrow
Cerebellar artery thrombosis	10008023	PT	Narrow
Cerebellar embolism	10067167	PT	Narrow
Cerebellar infarction	10008034	PT	Narrow
Cerebellar ischaemia	10068621	PT	Narrow
Cerebellar stroke	10079062	PT	Narrow
Cerebral arteriosclerosis	10065559	PT	Narrow
Cerebral artery embolism	10008088	PT	Narrow
Cerebral artery occlusion	10008089	PT	Narrow
Cerebral artery restenosis	10075423	PT	Narrow
Cerebral artery stenosis	10063648	PT	Narrow
Cerebral artery stent insertion	10081893	PT	Narrow

Cerebral artery thrombosis	10008092	PT	Narrow
Cerebral gas embolism	10070813	PT	Narrow
Cerebral infarction	10008118	PT	Narrow
Cerebral infarction foetal	10008119	PT	Narrow
Cerebral ischaemia	10008120	PT	Narrow
Cerebral microembolism	10078311	PT	Narrow
Cerebral microinfarction	10083668	PT	Narrow
Cerebral revascularisation	10071508	PT	Narrow
Cerebral septic infarct	10070671	PT	Narrow
Cerebral small vessel ischaemic disease	10070878	PT	Narrow
Cerebral thrombosis	10008132	PT	Narrow
Cerebral vascular occlusion	10076895	PT	Narrow
Cerebral vasoconstriction	10059109	PT	Narrow
Cerebral venous thrombosis	10008138	PT	Narrow
Cerebrovascular accident	10008190	PT	Narrow
Cerebrovascular disorder	10008196	PT	Narrow
Cerebrovascular insufficiency	10058842	PT	Narrow
Cerebrovascular stenosis	10061751	PT	Narrow
Delayed ischaemic neurological deficit	10078388	PT	Narrow
Embolc cerebellar infarction	10084072	PT	Narrow
Embolc cerebral infarction	10060839	PT	Narrow
Embolc stroke	10014498	PT	Narrow
Foville syndrome	10082594	PT	Narrow
Hypoxic-ischaemic encephalopathy	10070511	PT	Narrow
Inner ear infarction	10070754	PT	Narrow
Internal capsule infarction	10083408	PT	Narrow
Ischaemic cerebral infarction	10060840	PT	Narrow
Ischaemic stroke	10061256	PT	Narrow
Jugular vein embolism	10081850	PT	Narrow
Lacunar infarction	10051078	PT	Narrow
Lacunar stroke	10076994	PT	Narrow
Lateral medullary syndrome	10024033	PT	Narrow
Migrainous infarction	10056237	PT	Narrow
Millard-Gubler syndrome	10067462	PT	Narrow
Moyamoya disease	10028047	PT	Narrow
Perinatal stroke	10073945	PT	Narrow
Post cardiac arrest syndrome	10078202	PT	Narrow
Post procedural stroke	10066591	PT	Narrow
Precerebral arteriosclerosis	10077033	PT	Narrow
Precerebral artery occlusion	10036511	PT	Narrow
Reversible cerebral vasoconstriction syndrome	10073240	PT	Narrow
Reversible ischaemic neurological deficit	10050496	PT	Narrow
Spinal artery embolism	10049440	PT	Narrow
Spinal artery thrombosis	10071316	PT	Narrow
Spinal cord infarction	10058571	PT	Narrow
Spinal cord ischaemia	10050209	PT	Narrow
Spinal stroke	10082031	PT	Narrow

Stroke in evolution	10059613	PT	Narrow
Subclavian steal syndrome	10042335	PT	Narrow
Thalamic infarction	10064961	PT	Narrow
Thrombotic cerebral infarction	10067347	PT	Narrow
Thrombotic stroke	10043647	PT	Narrow
Transient ischaemic attack	10044390	PT	Narrow
Vascular encephalopathy	10063661	PT	Narrow
Vascular stent occlusion	10077143	PT	Narrow
Vascular stent stenosis	10077144	PT	Narrow
Vertebral artery occlusion	10048965	PT	Narrow
Vertebral artery stenosis	10047330	PT	Narrow
Vertebral artery thrombosis	10057777	PT	Narrow
Vertebrobasilar insufficiency	10047334	PT	Narrow
Vertebrobasilar stroke	10082484	PT	Narrow

<b>Central nervous system vascular disorders, not specified as haemorrhagic or ischaemic (SMQ): Level 2</b>			
<b>English</b>	<b>Code</b>	<b>Level</b>	<b>Scope</b>
Central nervous system vasculitis	10081778	PT	Narrow
Cerebral arteritis	10008087	PT	Narrow
Cerebral capillary telangiectasia	10075633	PT	Narrow
Cerebral circulatory failure	10008097	PT	Narrow
Cerebral congestion	10076929	PT	Narrow
Cerebral hypoperfusion	10065384	PT	Narrow
Cerebral venous sinus thrombosis	10083037	PT	Narrow
Chronic cerebrospinal venous insufficiency	10082477	PT	Narrow
Dural arteriovenous fistula	10074462	PT	Narrow
Superior sagittal sinus thrombosis	10042567	PT	Narrow
Transverse sinus thrombosis	10044457	PT	Narrow
Amyloid related imaging abnormalities	10072599	PT	Broad
Amyloid related imaging abnormality-microhaemorrhages and hemosiderin deposits	10072601	PT	Broad
Amyloid related imaging abnormality-oedema/effusion	10072260	PT	Broad
Blood brain barrier defect	10057361	PT	Broad
Carotid artery dolichoectasia	10080308	PT	Broad
Cerebral amyloid angiopathy	10068044	PT	Broad
Cerebral microangiopathy	10067466	PT	Broad
Cerebrovascular arteriovenous malformation	10056371	PT	Broad
Congenital cerebrovascular anomaly	10062327	PT	Broad
Foetal cerebrovascular disorder	10053601	PT	Broad
Hypertensive cerebrovascular disease	10077000	PT	Broad
Primary familial brain calcification	10078822	PT	Broad
Sneddon's syndrome	10053841	PT	Broad
Spinal vascular disorder	10061369	PT	Broad
Spinal vessel congenital anomaly	10041603	PT	Broad
Susac's syndrome	10071573	PT	Broad
Vertebrobasilar dolichoectasia	10071505	PT	Broad



SMQ Export: 23.0 - English		3/23/2021 12:33:06 PM								
	Include Inactive PT: No									
English: Embolic and thrombotic events (SMQ): Level 1										
	English: Embolic and thrombotic events, arterial (SMQ): Level 2									
	English	Code	Level	Scope	Category	Weight	Status	Addition Version	Last Modified Version	
	Acute aortic syndrome	10074337	PT	Narrow	A	0	Active	17.0	17.0	
	Acute myocardial infarction	10000891	PT	Narrow	A	0	Active	10.0	10.0	
	Amaurosis	10001902	PT	Narrow	A	0	Active	10.0	10.0	
	Amaurosis fugax	10001903	PT	Narrow	A	0	Active	10.0	10.0	
	Angioplasty	10002475	PT	Narrow	A	0	Active	16.0	16.0	
	Aortic bypass	10057617	PT	Narrow	A	0	Active	10.0	10.0	
	Aortic embolus	10002897	PT	Narrow	A	0	Active	10.0	10.0	
	Aortic surgery	10061651	PT	Narrow	A	0	Active	10.0	10.0	
	Aortic thrombosis	10002910	PT	Narrow	A	0	Active	10.0	10.0	
	Aortogram abnormal	10057794	PT	Narrow	A	0	Active	10.0	10.0	
	Arterectomy	10071026	PT	Narrow	A	0	Active	14.0	14.0	
	Arterectomy with graft replacement	10003140	PT	Narrow	A	0	Active	10.0	10.0	
	Arterial angioplasty	10081731	PT	Narrow	A	0	Active	21.1	21.1	
	Arterial bypass occlusion	10077766	PT	Narrow	A	0	Active	19.0	19.0	
	Arterial bypass operation	10056418	PT	Narrow	A	0	Active	10.0	10.0	
	Arterial bypass thrombosis	10077765	PT	Narrow	A	0	Active	19.0	19.0	
	Arterial graft	10061655	PT	Narrow	A	0	Active	10.0	10.0	
	Arterial occlusive disease	10062599	PT	Narrow	A	0	Active	10.0	10.0	
	Arterial stent insertion	10061657	PT	Narrow	A	0	Active	10.0	10.0	
	Arterial therapeutic procedure	10052949	PT	Narrow	A	0	Active	10.0	10.0	
	Arterial thrombosis	10003178	PT	Narrow	A	0	Active	10.0	10.0	
	Arteriogram abnormal	10061659	PT	Narrow	A	0	Active	10.0	10.0	
	Arteriogram carotid abnormal	10003195	PT	Narrow	A	0	Active	10.0	10.0	
	Arteriotomy	10078636	PT	Narrow	A	0	Active	19.1	19.1	
	Atherectomy	10063025	PT	Narrow	A	0	Active	10.0	10.0	
	Atherosclerotic plaque rupture	10076604	PT	Narrow	A	0	Active	18.1	18.1	
	Atrial appendage closure	10079735	PT	Narrow	A	0	Active	20.1	20.1	
	Atrial appendage resection	10080843	PT	Narrow	A	0	Active	21.0	21.0	
	Basal ganglia infarction	10069020	PT	Narrow	A	0	Active	12.0	12.0	
	Basilar artery occlusion	10048963	PT	Narrow	A	0	Active	10.0	10.0	
	Basilar artery thrombosis	10063093	PT	Narrow	A	0	Active	10.0	10.0	
	Blindness transient	10005184	PT	Narrow	A	0	Active	10.0	10.0	
	Brachiocephalic artery occlusion	10069694	PT	Narrow	A	0	Active	13.0	13.0	
	Capsular warning syndrome	10067744	PT	Narrow	A	0	Active	10.1	10.1	
	Carotid angioplasty	10071260	PT	Narrow	A	0	Active	14.1	14.1	
	Carotid arterial embolus	10007684	PT	Narrow	A	0	Active	10.0	10.0	
	Carotid artery bypass	10053003	PT	Narrow	A	0	Active	10.0	10.0	
	Carotid artery occlusion	10048964	PT	Narrow	A	0	Active	10.0	10.0	
	Carotid artery stent insertion	10066102	PT	Narrow	A	0	Active	10.0	10.0	

	Carotid artery thrombosis	10007688	PT	Narrow	A	0	Active	10.0	10.0
	Carotid endarterectomy	10007692	PT	Narrow	A	0	Active	10.0	10.0
	Cerebellar artery occlusion	10053633	PT	Narrow	A	0	Active	10.0	10.0
	Cerebellar artery thrombosis	10008023	PT	Narrow	A	0	Active	10.0	10.0
	Cerebral artery embolism	10008088	PT	Narrow	A	0	Active	10.0	10.0
	Cerebral artery occlusion	10008089	PT	Narrow	A	0	Active	10.0	10.0
	Cerebral artery stent insertion	10081893	PT	Narrow	A	0	Active	22.0	22.0
	Cerebral artery thrombosis	10008092	PT	Narrow	A	0	Active	10.0	10.0
	Cerebral hypoperfusion	10065384	PT	Narrow	A	0	Active	10.0	10.0
	Cerebrovascular insufficiency	10058842	PT	Narrow	A	0	Active	10.0	10.0
	Cerebrovascular stenosis	10061751	PT	Narrow	A	0	Active	10.0	10.0
	Coeliac artery occlusion	10069696	PT	Narrow	A	0	Active	13.0	13.0
	Coronary angioplasty	10050329	PT	Narrow	A	0	Active	16.0	16.0
	Coronary arterial stent insertion	10052086	PT	Narrow	A	0	Active	10.0	10.0
	Coronary artery bypass	10011077	PT	Narrow	A	0	Active	10.0	10.0
	Coronary artery embolism	10011084	PT	Narrow	A	0	Active	10.0	10.0
	Coronary artery occlusion	10011086	PT	Narrow	A	0	Active	10.0	10.0
	Coronary artery reocclusion	10053261	PT	Narrow	A	0	Active	10.0	10.0
	Coronary artery surgery	10011090	PT	Narrow	A	0	Active	10.0	20.1
	Coronary artery thrombosis	10011091	PT	Narrow	A	0	Active	16.0	16.0
	Coronary endarterectomy	10011101	PT	Narrow	A	0	Active	10.0	10.0
	Coronary revascularisation	10049887	PT	Narrow	A	0	Active	10.0	10.0
	Coronary vascular graft occlusion	10075162	PT	Narrow	A	0	Active	17.1	17.1
	Embolia cutis medicamentosa	10058729	PT	Narrow	A	0	Active	10.0	10.0
	Embolism arterial	10014513	PT	Narrow	A	0	Active	10.0	13.1
	Endarterectomy	10014648	PT	Narrow	A	0	Active	10.0	10.0
	Femoral artery embolism	10068365	PT	Narrow	A	0	Active	11.1	11.1
	Hepatic artery embolism	10019635	PT	Narrow	A	0	Active	10.0	10.0
	Hepatic artery occlusion	10051991	PT	Narrow	A	0	Active	10.0	10.0
	Hepatic artery thrombosis	10019636	PT	Narrow	A	0	Active	10.0	10.0
	Hypothenar hammer syndrome	10063518	PT	Narrow	A	0	Active	10.0	10.0
	Iliac artery embolism	10021338	PT	Narrow	A	0	Active	10.0	10.0
	Iliac artery occlusion	10064601	PT	Narrow	A	0	Active	10.0	10.0
	Internal capsule infarction	10083408	PT	Narrow	A	0	Active	23.0	23.0
	Intra-aortic balloon placement	10052989	PT	Narrow	A	0	Active	10.0	10.0
	Intraoperative cerebral artery occlusion	10056382	PT	Narrow	A	0	Active	10.0	10.0
	Ischaemic cerebral infarction	10060840	PT	Narrow	A	0	Active	10.0	10.0
	Ischaemic stroke	10061256	PT	Narrow	A	0	Active	10.0	10.0
	Lacunar infarction	10051078	PT	Narrow	A	0	Active	10.0	10.0
	Leriche syndrome	10024242	PT	Narrow	A	0	Active	13.1	13.1
	Mesenteric arterial occlusion	10027394	PT	Narrow	A	0	Active	17.0	17.0
	Mesenteric arteriosclerosis	10065560	PT	Narrow	A	0	Active	10.0	10.0
	Mesenteric artery embolism	10027395	PT	Narrow	A	0	Active	10.0	10.0
	Mesenteric artery stenosis	10027396	PT	Narrow	A	0	Active	10.0	10.0
	Mesenteric artery stent insertion	10071261	PT	Narrow	A	0	Active	14.1	14.1
	Mesenteric artery thrombosis	10027397	PT	Narrow	A	0	Active	10.0	10.0

	Myocardial infarction	10028596	PT	Narrow	A	0	Active	10.0	10.0
	Myocardial necrosis	10028602	PT	Narrow	A	0	Active	10.0	17.0
	Ophthalmic artery thrombosis	10081144	PT	Narrow	A	0	Active	21.1	21.1
	Papillary muscle infarction	10033697	PT	Narrow	A	0	Active	10.0	10.0
	Penile artery occlusion	10068035	PT	Narrow	A	0	Active	11.0	11.0
	Percutaneous coronary intervention	10065608	PT	Narrow	A	0	Active	10.0	10.0
	Peripheral arterial occlusive disease	10062585	PT	Narrow	A	0	Active	10.0	10.0
	Peripheral arterial reocclusion	10069379	PT	Narrow	A	0	Active	12.1	12.1
	Peripheral artery angioplasty	10057518	PT	Narrow	A	0	Active	10.0	10.0
	Peripheral artery bypass	10072561	PT	Narrow	A	0	Active	15.1	15.1
	Peripheral artery occlusion	10057525	PT	Narrow	A	0	Active	10.0	19.0
	Peripheral artery stent insertion	10072562	PT	Narrow	A	0	Active	15.1	15.1
	Peripheral artery surgery	10082470	PT	Narrow	A	0	Active	22.0	22.0
	Peripheral artery thrombosis	10072564	PT	Narrow	A	0	Active	15.1	15.1
	Peripheral embolism	10061340	PT	Narrow	A	0	Active	10.0	10.0
	Peripheral endarterectomy	10072560	PT	Narrow	A	0	Active	15.1	15.1
	Popliteal artery entrapment syndrome	10071642	PT	Narrow	A	0	Active	14.1	14.1
	Post procedural myocardial infarction	10066592	PT	Narrow	A	0	Active	10.0	10.0
	Postinfarction angina	10058144	PT	Narrow	A	0	Active	10.0	10.0
	Precerebral artery occlusion	10036511	PT	Narrow	A	0	Active	10.0	10.0
	Precerebral artery thrombosis	10074717	PT	Narrow	A	0	Active	17.0	17.0
	Profundaplasty	10078867	PT	Narrow	A	0	Active	20.0	20.0
	Pulmonary artery occlusion	10078201	PT	Narrow	A	0	Active	19.1	19.1
	Pulmonary artery therapeutic procedure	10063731	PT	Narrow	A	0	Active	10.0	10.0
	Pulmonary artery thrombosis	10037340	PT	Narrow	A	0	Active	10.0	10.0
	Pulmonary endarterectomy	10072893	PT	Narrow	A	0	Active	16.0	16.0
	Pulmonary tumour thrombotic microangiopathy	10079988	PT	Narrow	A	0	Active	20.1	20.1
	Renal artery angioplasty	10057493	PT	Narrow	A	0	Active	15.1	15.1
	Renal artery occlusion	10048988	PT	Narrow	A	0	Active	10.0	10.0
	Renal artery thrombosis	10038380	PT	Narrow	A	0	Active	10.0	10.0
	Renal embolism	10063544	PT	Narrow	A	0	Active	10.0	10.0
	Retinal artery embolism	10038826	PT	Narrow	A	0	Active	10.0	10.0
	Retinal artery occlusion	10038827	PT	Narrow	A	0	Active	10.0	10.0
	Retinal artery thrombosis	10038831	PT	Narrow	A	0	Active	10.0	10.0
	Silent myocardial infarction	10049768	PT	Narrow	A	0	Active	12.1	12.1
	Spinal artery embolism	10049440	PT	Narrow	A	0	Active	10.0	10.0
	Spinal artery thrombosis	10071316	PT	Narrow	A	0	Active	14.1	14.1
	Splenic artery thrombosis	10074600	PT	Narrow	A	0	Active	17.0	17.0
	Splenic embolism	10068677	PT	Narrow	A	0	Active	11.1	11.1
	Stress cardiomyopathy	10066286	PT	Narrow	A	0	Active	10.0	10.0
	Subclavian artery embolism	10042332	PT	Narrow	A	0	Active	10.0	10.0
	Subclavian artery occlusion	10069695	PT	Narrow	A	0	Active	13.0	13.0
	Subclavian artery thrombosis	10042334	PT	Narrow	A	0	Active	10.0	10.0
	Thromboembolectomy	10064958	PT	Narrow	A	0	Active	10.0	10.0
	Thrombotic microangiopathy	10043645	PT	Narrow	A	0	Active	10.0	10.0
	Thrombotic thrombocytopenic purpura	10043648	PT	Narrow	A	0	Active	10.0	10.0

		Transient ischaemic attack	10044390	PT	Narrow	A	0	Active	10.0	10.0
		Truncus coeliacus thrombosis	10062363	PT	Narrow	A	0	Active	10.0	10.0
		Vascular pseudoaneurysm thrombosis	10078269	PT	Narrow	A	0	Active	19.1	19.1
		Vertebral artery occlusion	10048965	PT	Narrow	A	0	Active	10.0	10.0
		Vertebral artery thrombosis	10057777	PT	Narrow	A	0	Active	10.0	10.0
		Visual acuity reduced transiently	10047532	PT	Narrow	A	0	Active	10.0	10.0
		<b>English: Embolic and thrombotic events, venous (SMQ): Level 2</b>								
		English	Code	Level	Scope	Category	Weight	Status	Addition Version	Last Modified Version
		Axillary vein thrombosis	10003880	PT	Narrow	A	0	Active	10.0	10.0
		Brachiocephalic vein occlusion	10076837	PT	Narrow	A	0	Active	18.1	18.1
		Brachiocephalic vein thrombosis	10063363	PT	Narrow	A	0	Active	10.0	19.1
		Budd-Chiari syndrome	10006537	PT	Narrow	A	0	Active	10.0	10.0
		Catheterisation venous	10052698	PT	Narrow	A	0	Active	10.0	10.0
		Cavernous sinus thrombosis	10007830	PT	Narrow	A	0	Active	10.0	10.0
		Central venous catheterisation	10053377	PT	Narrow	A	0	Active	10.0	10.0
		Cerebral venous sinus thrombosis	10083037	PT	Narrow	A	0	Active	22.1	22.1
		Cerebral venous thrombosis	10008138	PT	Narrow	A	0	Active	10.0	10.0
		Compression garment application	10079209	PT	Narrow	A	0	Active	20.0	20.0
		Deep vein thrombosis	10051055	PT	Narrow	A	0	Active	10.0	10.0
		Deep vein thrombosis postoperative	10066881	PT	Narrow	A	0	Active	10.0	10.0
		Embolism venous	10014522	PT	Narrow	A	0	Active	10.0	10.0
		Hepatic vein embolism	10078810	PT	Narrow	A	0	Active	20.0	20.0
		Hepatic vein occlusion	10058991	PT	Narrow	A	0	Active	10.0	10.0
		Hepatic vein thrombosis	10019713	PT	Narrow	A	0	Active	10.0	10.0
		Homans' sign positive	10051031	PT	Narrow	A	0	Active	14.0	14.0
		Iliac vein occlusion	10058992	PT	Narrow	A	0	Active	10.0	10.0
		Inferior vena cava syndrome	10070911	PT	Narrow	A	0	Active	14.0	14.0
		Inferior vena caval occlusion	10058987	PT	Narrow	A	0	Active	10.0	10.0
		Jugular vein embolism	10081850	PT	Narrow	A	0	Active	22.0	22.0
		Jugular vein occlusion	10076835	PT	Narrow	A	0	Active	18.1	18.1
		Jugular vein thrombosis	10023237	PT	Narrow	A	0	Active	10.0	10.0
		Mahler sign	10075428	PT	Narrow	A	0	Active	17.1	17.1
		May-Thurner syndrome	10069727	PT	Narrow	A	0	Active	13.0	13.0
		Mesenteric vein thrombosis	10027402	PT	Narrow	A	0	Active	10.0	10.0
		Mesenteric venous occlusion	10027403	PT	Narrow	A	0	Active	17.0	17.0
		Obstetrical pulmonary embolism	10029925	PT	Narrow	A	0	Active	10.0	10.0
		Obstructive shock	10073708	PT	Narrow	A	0	Active	16.1	16.1
		Ophthalmic vein thrombosis	10074349	PT	Narrow	A	0	Active	17.0	17.0
		Ovarian vein thrombosis	10072059	PT	Narrow	A	0	Active	15.0	15.0
		Paget-Schroetter syndrome	10050216	PT	Narrow	A	0	Active	10.0	10.0
		Pelvic venous thrombosis	10034272	PT	Narrow	A	0	Active	10.0	10.0
		Penile vein thrombosis	10034324	PT	Narrow	A	0	Active	10.0	10.0
		Peripheral vein occlusion	10083103	PT	Narrow	A	0	Active	22.1	22.1
		Peripheral vein thrombus extension	10082853	PT	Narrow	A	0	Active	22.1	22.1
		Phlebectomy	10048874	PT	Narrow	A	0	Active	10.0	10.0
		Portal vein cavernous transformation	10073979	PT	Narrow	A	0	Active	16.1	16.1

	Portal vein embolism	10082030	PT	Narrow	A	0	Active	22.0	22.0
	Portal vein occlusion	10058989	PT	Narrow	A	0	Active	10.0	10.0
	Portal vein thrombosis	10036206	PT	Narrow	A	0	Active	10.0	10.0
	Portosplenomesenteric venous thrombosis	10077623	PT	Narrow	A	0	Active	19.0	19.0
	Post procedural pulmonary embolism	10063909	PT	Narrow	A	0	Active	10.0	10.0
	Post thrombotic syndrome	10048591	PT	Narrow	A	0	Active	10.0	10.0
	Postoperative thrombosis	10050902	PT	Narrow	A	0	Active	10.0	10.0
	Postpartum venous thrombosis	10036300	PT	Narrow	A	0	Active	10.0	10.0
	Pulmonary embolism	10037377	PT	Narrow	A	0	Active	10.0	10.0
	Pulmonary infarction	10037410	PT	Narrow	A	0	Active	10.0	10.0
	Pulmonary microemboli	10037421	PT	Narrow	A	0	Active	10.0	10.0
	Pulmonary thrombosis	10037437	PT	Narrow	A	0	Active	10.0	10.0
	Pulmonary vein occlusion	10068690	PT	Narrow	A	0	Active	11.1	11.1
	Pulmonary veno-occlusive disease	10037458	PT	Narrow	A	0	Active	10.0	10.0
	Pulmonary venous thrombosis	10037459	PT	Narrow	A	0	Active	10.0	10.0
	Renal vein embolism	10038547	PT	Narrow	A	0	Active	10.0	10.0
	Renal vein occlusion	10056293	PT	Narrow	A	0	Active	10.0	10.0
	Renal vein thrombosis	10038548	PT	Narrow	A	0	Active	10.0	10.0
	Retinal vein occlusion	10038907	PT	Narrow	A	0	Active	10.0	10.0
	Retinal vein thrombosis	10038908	PT	Narrow	A	0	Active	10.0	10.0
	Septic pulmonary embolism	10083093	PT	Narrow	A	0	Active	22.1	22.1
	SI QIII TIII pattern	10068479	PT	Narrow	A	0	Active	11.1	11.1
	Splenic vein occlusion	10068122	PT	Narrow	A	0	Active	11.0	11.0
	Splenic vein thrombosis	10041659	PT	Narrow	A	0	Active	10.0	10.0
	Subclavian vein occlusion	10079164	PT	Narrow	A	0	Active	20.0	20.0
	Subclavian vein thrombosis	10049446	PT	Narrow	A	0	Active	10.0	10.0
	Superior sagittal sinus thrombosis	10042567	PT	Narrow	A	0	Active	10.0	10.0
	Superior vena cava occlusion	10058988	PT	Narrow	A	0	Active	10.0	17.0
	Superior vena cava syndrome	10042569	PT	Narrow	A	0	Active	10.0	14.0
	Thrombophlebitis	10043570	PT	Narrow	A	0	Active	10.0	10.0
	Thrombophlebitis migrans	10043581	PT	Narrow	A	0	Active	10.0	10.0
	Thrombophlebitis neonatal	10043586	PT	Narrow	A	0	Active	10.0	10.0
	Thrombophlebitis superficial	10043595	PT	Narrow	A	0	Active	14.1	14.1
	Thrombosed varicose vein	10043605	PT	Narrow	A	0	Active	10.0	10.0
	Thrombosis corpora cavernosa	10067270	PT	Narrow	A	0	Active	10.0	10.0
	Transverse sinus thrombosis	10044457	PT	Narrow	A	0	Active	10.0	10.0
	Vena cava embolism	10047193	PT	Narrow	A	0	Active	10.0	10.0
	Vena cava filter insertion	10048932	PT	Narrow	A	0	Active	10.0	10.0
	Vena cava filter removal	10074397	PT	Narrow	A	0	Active	17.0	17.0
	Vena cava thrombosis	10047195	PT	Narrow	A	0	Active	10.0	10.0
	Venogram abnormal	10047209	PT	Narrow	A	0	Active	10.0	10.0
	Venoocclusive disease	10062173	PT	Narrow	A	0	Active	10.0	10.0
	Venoocclusive liver disease	10047216	PT	Narrow	A	0	Active	10.0	10.0
	Venous angioplasty	10077826	PT	Narrow	A	0	Active	19.0	19.0
	Venous occlusion	10058990	PT	Narrow	A	0	Active	10.0	10.0
	Venous operation	10062175	PT	Narrow	A	0	Active	10.0	10.0

		Venous recanalisation	10068605	PT	Narrow	A	0	Active	11.1	11.1
		Venous repair	10052964	PT	Narrow	A	0	Active	17.1	17.1
		Venous stent insertion	10063389	PT	Narrow	A	0	Active	10.0	10.0
		Venous thrombosis	10047249	PT	Narrow	A	0	Active	10.0	10.0
		Venous thrombosis in pregnancy	10067030	PT	Narrow	A	0	Active	10.0	10.0
		Venous thrombosis limb	10061408	PT	Narrow	A	0	Active	10.0	10.0
		Venous thrombosis neonatal	10064602	PT	Narrow	A	0	Active	10.0	10.0
		Visceral venous thrombosis	10077829	PT	Narrow	A	0	Active	19.0	19.0
<b>English: Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (SMQ): Level 2</b>										
		English	Code	Level	Scope	Category	Weight	Status	Addition Version	Last Modified Version
		Administration site thrombosis	10075968	PT	Narrow	A	0	Active	18.0	18.0
		Adrenal thrombosis	10075178	PT	Narrow	A	0	Active	17.1	17.1
		Angiogram abnormal	10060956	PT	Narrow	A	0	Active	10.0	14.0
		Angiogram cerebral abnormal	10052906	PT	Narrow	A	0	Active	10.0	14.0
		Angiogram peripheral abnormal	10057517	PT	Narrow	A	0	Active	10.0	14.0
		Antiphospholipid syndrome	10002817	PT	Narrow	A	0	Active	22.0	22.0
		Application site thrombosis	10076026	PT	Narrow	A	0	Active	18.0	18.0
		Arteriovenous fistula occlusion	10058562	PT	Narrow	A	0	Active	10.0	14.0
		Arteriovenous fistula thrombosis	10003192	PT	Narrow	A	0	Active	10.0	14.0
		Arteriovenous graft thrombosis	10053182	PT	Narrow	A	0	Active	10.0	19.0
		Artificial blood vessel occlusion	10078895	PT	Narrow	A	0	Active	20.0	20.0
		Atrial thrombosis	10048632	PT	Narrow	A	0	Active	10.0	14.0
		Basal ganglia stroke	10071043	PT	Narrow	A	0	Active	14.0	14.0
		Bone infarction	10049824	PT	Narrow	A	0	Active	10.0	14.0
		Brain stem embolism	10074422	PT	Narrow	A	0	Active	17.0	17.0
		Brain stem infarction	10006147	PT	Narrow	A	0	Active	10.0	14.0
		Brain stem stroke	10068644	PT	Narrow	A	0	Active	11.1	14.0
		Brain stem thrombosis	10062573	PT	Narrow	A	0	Active	10.0	14.0
		Cardiac ventricular thrombosis	10053994	PT	Narrow	A	0	Active	10.0	17.0
		Catheter site thrombosis	10079523	PT	Narrow	A	0	Active	20.0	20.0
		Cerebellar embolism	10067167	PT	Narrow	A	0	Active	17.0	17.0
		Cerebellar infarction	10008034	PT	Narrow	A	0	Active	10.0	14.0
		Cerebral congestion	10076929	PT	Narrow	A	0	Active	18.1	18.1
		Cerebral infarction	10008118	PT	Narrow	A	0	Active	10.0	14.0
		Cerebral infarction foetal	10008119	PT	Narrow	A	0	Active	10.0	14.0
		Cerebral ischaemia	10008120	PT	Narrow	A	0	Active	10.0	14.0
		Cerebral microembolism	10078311	PT	Narrow	A	0	Active	19.1	19.1
		Cerebral microinfarction	10083668	PT	Narrow	A	0	Active	23.0	23.0
		Cerebral septic infarct	10070671	PT	Narrow	A	0	Active	13.1	14.0
		Cerebral thrombosis	10008132	PT	Narrow	A	0	Active	10.0	14.0
		Cerebral vascular occlusion	10076895	PT	Narrow	A	0	Active	19.0	19.0
		Cerebrospinal thrombotic tamponade	10052173	PT	Narrow	A	0	Active	10.0	14.0
		Cerebrovascular accident	10008190	PT	Narrow	A	0	Active	10.0	14.0
		Cerebrovascular accident prophylaxis	10049165	PT	Narrow	A	0	Active	10.0	14.0
		Cerebrovascular disorder	10008196	PT	Narrow	A	0	Active	10.0	14.0
		Cerebrovascular operation	10051902	PT	Narrow	A	0	Active	10.0	14.0

	Choroidal infarction	10057403	PT	Narrow	A	0	Active	10.0	14.0
	Collateral circulation	10069729	PT	Narrow	A	0	Active	13.0	14.0
	Coronary bypass thrombosis	10059025	PT	Narrow	A	0	Active	10.0	14.0
	Device embolisation	10074896	PT	Narrow	A	0	Active	17.1	17.1
	Device occlusion	10064685	PT	Narrow	A	0	Active	13.0	14.0
	Device related thrombosis	10077455	PT	Narrow	A	0	Active	19.0	19.0
	Diplegia	10013033	PT	Narrow	A	0	Active	10.0	14.0
	Directional Doppler flow tests abnormal	10013048	PT	Narrow	A	0	Active	10.0	14.0
	Disseminated intravascular coagulation	10013442	PT	Narrow	A	0	Active	10.0	14.0
	Disseminated intravascular coagulation in newborn	10013443	PT	Narrow	A	0	Active	10.0	14.0
	Embollic cerebellar infarction	10084072	PT	Narrow	A	0	Active	23.0	23.0
	Embollic cerebral infarction	10060839	PT	Narrow	A	0	Active	10.0	14.0
	Embollic pneumonia	10065680	PT	Narrow	A	0	Active	10.0	14.0
	Embollic stroke	10014498	PT	Narrow	A	0	Active	10.0	14.0
	Embolism	10061169	PT	Narrow	A	0	Active	14.0	14.0
	Eye infarction	10083006	PT	Narrow	A	0	Active	22.1	22.1
	Fluorescence angiogram abnormal	10083087	PT	Narrow	A	0	Active	22.1	22.1
	Foetal cerebrovascular disorder	10053601	PT	Narrow	A	0	Active	10.0	14.0
	Graft thrombosis	10051269	PT	Narrow	A	0	Active	10.0	14.0
	Haemorrhagic adrenal infarction	10079902	PT	Narrow	A	0	Active	20.1	20.1
	Haemorrhagic cerebral infarction	10019005	PT	Narrow	A	0	Active	10.0	14.0
	Haemorrhagic infarction	10019013	PT	Narrow	A	0	Active	10.0	14.0
	Haemorrhagic stroke	10019016	PT	Narrow	A	0	Active	10.0	14.0
	Haemorrhagic transformation stroke	10055677	PT	Narrow	A	0	Active	10.0	14.0
	Haemorrhoids thrombosed	10019023	PT	Narrow	A	0	Active	17.0	17.0
	Hemiparesis	10019465	PT	Narrow	A	0	Active	10.0	14.0
	Hemiplegia	10019468	PT	Narrow	A	0	Active	10.0	14.0
	Heparin-induced thrombocytopenia	10062506	PT	Narrow	A	0	Active	15.1	15.1
	Hepatic infarction	10019680	PT	Narrow	A	0	Active	10.0	14.0
	Hepatic vascular thrombosis	10074494	PT	Narrow	A	0	Active	17.0	17.0
	Implant site thrombosis	10063868	PT	Narrow	A	0	Active	10.0	14.0
	Incision site vessel occlusion	10076839	PT	Narrow	A	0	Active	18.1	18.1
	Infarction	10061216	PT	Narrow	A	0	Active	10.0	14.0
	Infusion site thrombosis	10065489	PT	Narrow	A	0	Active	10.0	14.0
	Injection site thrombosis	10022104	PT	Narrow	A	0	Active	10.0	14.0
	Inner ear infarction	10070754	PT	Narrow	A	0	Active	13.1	14.0
	Instillation site thrombosis	10073625	PT	Narrow	A	0	Active	16.1	16.1
	Intestinal infarction	10022657	PT	Narrow	A	0	Active	10.0	14.0
	Intracardiac mass	10066087	PT	Narrow	A	0	Active	10.0	14.0
	Intracardiac thrombus	10048620	PT	Narrow	A	0	Active	10.0	14.0
	Lambli's excrescences	10083691	PT	Narrow	A	0	Active	23.0	23.0
	Medical device site thrombosis	10076145	PT	Narrow	A	0	Active	18.0	18.0
	Mesenteric vascular insufficiency	10027401	PT	Narrow	A	0	Active	10.0	14.0
	Mesenteric vascular occlusion	10074583	PT	Narrow	A	0	Active	17.0	17.0
	Microembolism	10073734	PT	Narrow	A	0	Active	16.1	16.1
	Monoparesis	10027925	PT	Narrow	A	0	Active	10.0	14.0

	Monoplegia	10027926	PT	Narrow	A	0	Active	10.0	14.0
	Optic nerve infarction	10030936	PT	Narrow	A	0	Active	10.0	14.0
	Pancreatic infarction	10068239	PT	Narrow	A	0	Active	11.0	14.0
	Paradoxical embolism	10066059	PT	Narrow	A	0	Active	10.0	14.0
	Paraneoplastic thrombosis	10079251	PT	Narrow	A	0	Active	20.0	20.0
	Paraparesis	10033885	PT	Narrow	A	0	Active	10.0	14.0
	Paraplegia	10033892	PT	Narrow	A	0	Active	10.0	14.0
	Paresis	10033985	PT	Narrow	A	0	Active	10.0	14.0
	Peripheral revascularisation	10053351	PT	Narrow	A	0	Active	10.0	14.0
	Pituitary infarction	10035092	PT	Narrow	A	0	Active	10.0	14.0
	Placental infarction	10064620	PT	Narrow	A	0	Active	10.0	14.0
	Pneumatic compression therapy	10059829	PT	Narrow	A	0	Active	10.0	14.0
	Portal shunt procedure	10077479	PT	Narrow	A	0	Active	19.0	19.0
	Post procedural stroke	10066591	PT	Narrow	A	0	Active	10.0	14.0
	Postpartum thrombosis	10077022	PT	Narrow	A	0	Active	18.1	18.1
	Prosthetic cardiac valve thrombosis	10063176	PT	Narrow	A	0	Active	21.0	21.0
	Prosthetic vessel implantation	10068628	PT	Narrow	A	0	Active	11.1	14.0
	Quadripareisis	10049680	PT	Narrow	A	0	Active	10.0	14.0
	Quadriplegia	10037714	PT	Narrow	A	0	Active	10.0	14.0
	Renal infarct	10038470	PT	Narrow	A	0	Active	10.0	14.0
	Renal vascular thrombosis	10072226	PT	Narrow	A	0	Active	15.0	15.0
	Retinal infarction	10051742	PT	Narrow	A	0	Active	10.0	14.0
	Retinal vascular thrombosis	10062108	PT	Narrow	A	0	Active	10.0	14.0
	Revascularisation procedure	10084091	PT	Narrow	A	0	Active	23.0	23.0
	Shunt occlusion	10040621	PT	Narrow	A	0	Active	10.0	14.0
	Shunt thrombosis	10059054	PT	Narrow	A	0	Active	10.0	14.0
	Spinal cord infarction	10058571	PT	Narrow	A	0	Active	10.0	14.0
	Spinal stroke	10082031	PT	Narrow	A	0	Active	22.0	22.0
	Splenic infarction	10041648	PT	Narrow	A	0	Active	10.0	14.0
	Splenic thrombosis	10074601	PT	Narrow	A	0	Active	17.0	17.0
	Stoma site thrombosis	10074515	PT	Narrow	A	0	Active	17.0	17.0
	Stroke in evolution	10059613	PT	Narrow	A	0	Active	19.1	19.1
	Surgical vascular shunt	10058408	PT	Narrow	A	0	Active	10.0	14.0
	Testicular infarction	10043337	PT	Narrow	A	0	Active	10.0	14.0
	Thalamic infarction	10064961	PT	Narrow	A	0	Active	10.0	14.0
	Thrombectomy	10043530	PT	Narrow	A	0	Active	10.0	14.0
	Thromboangiitis obliterans	10043540	PT	Narrow	A	0	Active	10.0	14.0
	Thrombolysis	10043568	PT	Narrow	A	0	Active	10.0	14.0
	Thrombosis	10043607	PT	Narrow	A	0	Active	10.0	14.0
	Thrombosis in device	10062546	PT	Narrow	A	0	Active	10.0	14.0
	Thrombosis mesenteric vessel	10043626	PT	Narrow	A	0	Active	10.0	14.0
	Thrombosis prophylaxis	10043634	PT	Narrow	A	0	Active	10.0	14.0
	Thrombotic cerebral infarction	10067347	PT	Narrow	A	0	Active	10.1	14.0
	Thrombotic stroke	10043647	PT	Narrow	A	0	Active	10.0	14.0
	Thyroid infarction	10043742	PT	Narrow	A	0	Active	10.0	14.0
	Tumour embolism	10045168	PT	Narrow	A	0	Active	10.0	14.0



		Tumour thrombectomy	10081994	PT	Narrow	A	0	Active	22.0	22.0
		Tumour thrombosis	10068067	PT	Narrow	A	0	Active	11.0	14.0
		Ultrasonic angiogram abnormal	10061604	PT	Narrow	A	0	Active	10.0	14.0
		Ultrasound Doppler abnormal	10045413	PT	Narrow	A	0	Active	10.0	14.0
		Umbilical cord occlusion	10076714	PT	Narrow	A	0	Active	18.1	18.1
		Umbilical cord thrombosis	10071652	PT	Narrow	A	0	Active	14.1	14.1
		Vaccination site thrombosis	10076190	PT	Narrow	A	0	Active	18.0	18.0
		Vascular access site thrombosis	10078675	PT	Narrow	A	0	Active	19.1	19.1
		Vascular device occlusion	10080803	PT	Narrow	A	0	Active	21.0	21.0
		Vascular graft	10067740	PT	Narrow	A	0	Active	18.1	18.1
		Vascular graft occlusion	10049060	PT	Narrow	A	0	Active	18.1	18.1
		Vascular graft thrombosis	10069922	PT	Narrow	A	0	Active	13.0	14.0
		Vascular operation	10049071	PT	Narrow	A	0	Active	10.0	14.0
		Vascular stent insertion	10063382	PT	Narrow	A	0	Active	10.0	14.0
		Vascular stent occlusion	10077143	PT	Narrow	A	0	Active	18.1	18.1
		Vascular stent thrombosis	10063934	PT	Narrow	A	0	Active	10.0	18.1
		Vasodilation procedure	10058794	PT	Narrow	A	0	Active	10.0	14.0
		Vessel puncture site occlusion	10076838	PT	Narrow	A	0	Active	18.1	18.1
		Vessel puncture site thrombosis	10070649	PT	Narrow	A	0	Active	13.1	14.0
		Visual midline shift syndrome	10066856	PT	Narrow	A	0	Active	10.0	14.0

English: Embolic and thrombotic events, arterial (SMQ): Level 2			
English	Code	Level	Scope
Acute aortic syndrome	10074337	PT	Narrow
Acute myocardial infarction	10000891	PT	Narrow
Amaurosis	10001902	PT	Narrow
Amaurosis fugax	10001903	PT	Narrow
Angioplasty	10002475	PT	Narrow
Aortic bypass	10057617	PT	Narrow
Aortic embolus	10002897	PT	Narrow
Aortic surgery	10061651	PT	Narrow
Aortic thrombosis	10002910	PT	Narrow
Aortogram abnormal	10057794	PT	Narrow
Arterectomy	10071026	PT	Narrow
Arterectomy with graft replacement	10003140	PT	Narrow
Arterial angioplasty	10081731	PT	Narrow
Arterial bypass occlusion	10077766	PT	Narrow
Arterial bypass operation	10056418	PT	Narrow
Arterial bypass thrombosis	10077765	PT	Narrow
Arterial graft	10061655	PT	Narrow
Arterial occlusive disease	10062599	PT	Narrow
Arterial stent insertion	10061657	PT	Narrow
Arterial therapeutic procedure	10052949	PT	Narrow
Arterial thrombosis	10003178	PT	Narrow
Arteriogram abnormal	10061659	PT	Narrow
Arteriogram carotid abnormal	10003195	PT	Narrow
Arteriotomy	10078636	PT	Narrow
Atherectomy	10063025	PT	Narrow
Atherosclerotic plaque rupture	10076604	PT	Narrow
Atrial appendage closure	10079735	PT	Narrow
Atrial appendage resection	10080843	PT	Narrow
Basal ganglia infarction	10069020	PT	Narrow
Basilar artery occlusion	10048963	PT	Narrow
Basilar artery thrombosis	10063093	PT	Narrow
Blindness transient	10005184	PT	Narrow
Brachiocephalic artery occlusion	10069694	PT	Narrow
Capsular warning syndrome	10067744	PT	Narrow
Carotid angioplasty	10071260	PT	Narrow
Carotid arterial embolus	10007684	PT	Narrow
Carotid artery bypass	10053003	PT	Narrow
Carotid artery occlusion	10048964	PT	Narrow
Carotid artery stent insertion	10066102	PT	Narrow
Carotid artery thrombosis	10007688	PT	Narrow
Carotid endarterectomy	10007692	PT	Narrow
Cerebellar artery occlusion	10053633	PT	Narrow
Cerebellar artery thrombosis	10008023	PT	Narrow
Cerebral artery embolism	10008088	PT	Narrow
Cerebral artery occlusion	10008089	PT	Narrow

Cerebral artery stent insertion	10081893	PT	Narrow
Cerebral artery thrombosis	10008092	PT	Narrow
Cerebral hypoperfusion	10065384	PT	Narrow
Cerebrovascular insufficiency	10058842	PT	Narrow
Cerebrovascular stenosis	10061751	PT	Narrow
Coeliac artery occlusion	10069696	PT	Narrow
Coronary angioplasty	10050329	PT	Narrow
Coronary arterial stent insertion	10052086	PT	Narrow
Coronary artery bypass	10011077	PT	Narrow
Coronary artery embolism	10011084	PT	Narrow
Coronary artery occlusion	10011086	PT	Narrow
Coronary artery reocclusion	10053261	PT	Narrow
Coronary artery surgery	10011090	PT	Narrow
Coronary artery thrombosis	10011091	PT	Narrow
Coronary endarterectomy	10011101	PT	Narrow
Coronary revascularisation	10049887	PT	Narrow
Coronary vascular graft occlusion	10075162	PT	Narrow
Embolia cutis medicamentosa	10058729	PT	Narrow
Embolism arterial	10014513	PT	Narrow
Endarterectomy	10014648	PT	Narrow
Femoral artery embolism	10068365	PT	Narrow
Hepatic artery embolism	10019635	PT	Narrow
Hepatic artery occlusion	10051991	PT	Narrow
Hepatic artery thrombosis	10019636	PT	Narrow
Hypothenar hammer syndrome	10063518	PT	Narrow
Iliac artery embolism	10021338	PT	Narrow
Iliac artery occlusion	10064601	PT	Narrow
Internal capsule infarction	10083408	PT	Narrow
Intra-aortic balloon placement	10052989	PT	Narrow
Intraoperative cerebral artery occlusion	10056382	PT	Narrow
Ischaemic cerebral infarction	10060840	PT	Narrow
Ischaemic stroke	10061256	PT	Narrow
Lacunar infarction	10051078	PT	Narrow
Leriche syndrome	10024242	PT	Narrow
Mesenteric arterial occlusion	10027394	PT	Narrow
Mesenteric arteriosclerosis	10065560	PT	Narrow
Mesenteric artery embolism	10027395	PT	Narrow
Mesenteric artery stenosis	10027396	PT	Narrow
Mesenteric artery stent insertion	10071261	PT	Narrow
Mesenteric artery thrombosis	10027397	PT	Narrow
Myocardial infarction	10028596	PT	Narrow
Myocardial necrosis	10028602	PT	Narrow
Ophthalmic artery thrombosis	10081144	PT	Narrow
Papillary muscle infarction	10033697	PT	Narrow
Penile artery occlusion	10068035	PT	Narrow
Percutaneous coronary intervention	10065608	PT	Narrow
Peripheral arterial occlusive disease	10062585	PT	Narrow

Peripheral arterial reocclusion	10069379	PT	Narrow
Peripheral artery angioplasty	10057518	PT	Narrow
Peripheral artery bypass	10072561	PT	Narrow
Peripheral artery occlusion	10057525	PT	Narrow
Peripheral artery stent insertion	10072562	PT	Narrow
Peripheral artery surgery	10082470	PT	Narrow
Peripheral artery thrombosis	10072564	PT	Narrow
Peripheral embolism	10061340	PT	Narrow
Peripheral endarterectomy	10072560	PT	Narrow
Popliteal artery entrapment syndrome	10071642	PT	Narrow
Post procedural myocardial infarction	10066592	PT	Narrow
Postinfarction angina	10058144	PT	Narrow
Precerebral artery occlusion	10036511	PT	Narrow
Precerebral artery thrombosis	10074717	PT	Narrow
Profundaplasty	10078867	PT	Narrow
Pulmonary artery occlusion	10078201	PT	Narrow
Pulmonary artery therapeutic procedure	10063731	PT	Narrow
Pulmonary artery thrombosis	10037340	PT	Narrow
Pulmonary endarterectomy	10072893	PT	Narrow
Pulmonary tumour thrombotic microangiopathy	10079988	PT	Narrow
Renal artery angioplasty	10057493	PT	Narrow
Renal artery occlusion	10048988	PT	Narrow
Renal artery thrombosis	10038380	PT	Narrow
Renal embolism	10063544	PT	Narrow
Retinal artery embolism	10038826	PT	Narrow
Retinal artery occlusion	10038827	PT	Narrow
Retinal artery thrombosis	10038831	PT	Narrow
Silent myocardial infarction	10049768	PT	Narrow
Spinal artery embolism	10049440	PT	Narrow
Spinal artery thrombosis	10071316	PT	Narrow
Splenic artery thrombosis	10074600	PT	Narrow
Splenic embolism	10068677	PT	Narrow
Stress cardiomyopathy	10066286	PT	Narrow
Subclavian artery embolism	10042332	PT	Narrow
Subclavian artery occlusion	10069695	PT	Narrow
Subclavian artery thrombosis	10042334	PT	Narrow
Thromboembolectomy	10064958	PT	Narrow
Thrombotic microangiopathy	10043645	PT	Narrow
Thrombotic thrombocytopenic purpura	10043648	PT	Narrow
Transient ischaemic attack	10044390	PT	Narrow
Truncus coeliacus thrombosis	10062363	PT	Narrow
Vascular pseudoaneurysm thrombosis	10078269	PT	Narrow
Vertebral artery occlusion	10048965	PT	Narrow
Vertebral artery thrombosis	10057777	PT	Narrow
Visual acuity reduced transiently	10047532	PT	Narrow

<b>Embolic and thrombotic events, venous (SMQ): Level 2</b>			
<b>English</b>	<b>Code</b>	<b>Level</b>	<b>Scope</b>
Axillary vein thrombosis	10003880	PT	Narrow
Brachiocephalic vein occlusion	10076837	PT	Narrow
Brachiocephalic vein thrombosis	10063363	PT	Narrow
Budd-Chiari syndrome	10006537	PT	Narrow
Catheterisation venous	10052698	PT	Narrow
Cavernous sinus thrombosis	10007830	PT	Narrow
Central venous catheterisation	10053377	PT	Narrow
Cerebral venous sinus thrombosis	10083037	PT	Narrow
Cerebral venous thrombosis	10008138	PT	Narrow
Compression garment application	10079209	PT	Narrow
Deep vein thrombosis	10051055	PT	Narrow
Deep vein thrombosis postoperative	10066881	PT	Narrow
Embolism venous	10014522	PT	Narrow
Hepatic vein embolism	10078810	PT	Narrow
Hepatic vein occlusion	10058991	PT	Narrow
Hepatic vein thrombosis	10019713	PT	Narrow
Homans' sign positive	10051031	PT	Narrow
Iliac vein occlusion	10058992	PT	Narrow
Inferior vena cava syndrome	10070911	PT	Narrow
Inferior vena caval occlusion	10058987	PT	Narrow
Jugular vein embolism	10081850	PT	Narrow
Jugular vein occlusion	10076835	PT	Narrow
Jugular vein thrombosis	10023237	PT	Narrow
Mahler sign	10075428	PT	Narrow
May-Thurner syndrome	10069727	PT	Narrow
Mesenteric vein thrombosis	10027402	PT	Narrow
Mesenteric venous occlusion	10027403	PT	Narrow
Obstetrical pulmonary embolism	10029925	PT	Narrow
Obstructive shock	10073708	PT	Narrow
Ophthalmic vein thrombosis	10074349	PT	Narrow
Ovarian vein thrombosis	10072059	PT	Narrow
Paget-Schroetter syndrome	10050216	PT	Narrow
Pelvic venous thrombosis	10034272	PT	Narrow
Penile vein thrombosis	10034324	PT	Narrow
Peripheral vein occlusion	10083103	PT	Narrow
Peripheral vein thrombus extension	10082853	PT	Narrow
Phlebectomy	10048874	PT	Narrow
Portal vein cavernous transformation	10073979	PT	Narrow
Portal vein embolism	10082030	PT	Narrow
Portal vein occlusion	10058989	PT	Narrow
Portal vein thrombosis	10036206	PT	Narrow
Portosplenomesenteric venous thrombosis	10077623	PT	Narrow
Post procedural pulmonary embolism	10063909	PT	Narrow
Post thrombotic syndrome	10048591	PT	Narrow
Postoperative thrombosis	10050902	PT	Narrow

Postpartum venous thrombosis	10036300	PT	Narrow
Pulmonary embolism	10037377	PT	Narrow
Pulmonary infarction	10037410	PT	Narrow
Pulmonary microemboli	10037421	PT	Narrow
Pulmonary thrombosis	10037437	PT	Narrow
Pulmonary vein occlusion	10068690	PT	Narrow
Pulmonary veno-occlusive disease	10037458	PT	Narrow
Pulmonary venous thrombosis	10037459	PT	Narrow
Renal vein embolism	10038547	PT	Narrow
Renal vein occlusion	10056293	PT	Narrow
Renal vein thrombosis	10038548	PT	Narrow
Retinal vein occlusion	10038907	PT	Narrow
Retinal vein thrombosis	10038908	PT	Narrow
Septic pulmonary embolism	10083093	PT	Narrow
SI QIII TIII pattern	10068479	PT	Narrow
Splenic vein occlusion	10068122	PT	Narrow
Splenic vein thrombosis	10041659	PT	Narrow
Subclavian vein occlusion	10079164	PT	Narrow
Subclavian vein thrombosis	10049446	PT	Narrow
Superior sagittal sinus thrombosis	10042567	PT	Narrow
Superior vena cava occlusion	10058988	PT	Narrow
Superior vena cava syndrome	10042569	PT	Narrow
Thrombophlebitis	10043570	PT	Narrow
Thrombophlebitis migrans	10043581	PT	Narrow
Thrombophlebitis neonatal	10043586	PT	Narrow
Thrombophlebitis superficial	10043595	PT	Narrow
Thrombosed varicose vein	10043605	PT	Narrow
Thrombosis corpora cavernosa	10067270	PT	Narrow
Transverse sinus thrombosis	10044457	PT	Narrow
Vena cava embolism	10047193	PT	Narrow
Vena cava filter insertion	10048932	PT	Narrow
Vena cava filter removal	10074397	PT	Narrow
Vena cava thrombosis	10047195	PT	Narrow
Venogram abnormal	10047209	PT	Narrow
Venoocclusive disease	10062173	PT	Narrow
Venoocclusive liver disease	10047216	PT	Narrow
Venous angioplasty	10077826	PT	Narrow
Venous occlusion	10058990	PT	Narrow
Venous operation	10062175	PT	Narrow
Venous recanalisation	10068605	PT	Narrow
Venous repair	10052964	PT	Narrow
Venous stent insertion	10063389	PT	Narrow
Venous thrombosis	10047249	PT	Narrow
Venous thrombosis in pregnancy	10067030	PT	Narrow
Venous thrombosis limb	10061408	PT	Narrow
Venous thrombosis neonatal	10064602	PT	Narrow
Visceral venous thrombosis	10077829	PT	Narrow

<b>Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (SMQ): Level 2</b>			
<b>English</b>	<b>Code</b>	<b>Level</b>	<b>Scope</b>
Administration site thrombosis	10075968	PT	Narrow
Adrenal thrombosis	10075178	PT	Narrow
Angiogram abnormal	10060956	PT	Narrow
Angiogram cerebral abnormal	10052906	PT	Narrow
Angiogram peripheral abnormal	10057517	PT	Narrow
Antiphospholipid syndrome	10002817	PT	Narrow
Application site thrombosis	10076026	PT	Narrow
Arteriovenous fistula occlusion	10058562	PT	Narrow
Arteriovenous fistula thrombosis	10003192	PT	Narrow
Arteriovenous graft thrombosis	10053182	PT	Narrow
Artificial blood vessel occlusion	10078895	PT	Narrow
Atrial thrombosis	10048632	PT	Narrow
Basal ganglia stroke	10071043	PT	Narrow
Bone infarction	10049824	PT	Narrow
Brain stem embolism	10074422	PT	Narrow
Brain stem infarction	10006147	PT	Narrow
Brain stem stroke	10068644	PT	Narrow
Brain stem thrombosis	10062573	PT	Narrow
Cardiac ventricular thrombosis	10053994	PT	Narrow
Catheter site thrombosis	10079523	PT	Narrow
Cerebellar embolism	10067167	PT	Narrow
Cerebellar infarction	10008034	PT	Narrow
Cerebral congestion	10076929	PT	Narrow
Cerebral infarction	10008118	PT	Narrow
Cerebral infarction foetal	10008119	PT	Narrow
Cerebral ischaemia	10008120	PT	Narrow
Cerebral microembolism	10078311	PT	Narrow
Cerebral microinfarction	10083668	PT	Narrow
Cerebral septic infarct	10070671	PT	Narrow
Cerebral thrombosis	10008132	PT	Narrow
Cerebral vascular occlusion	10076895	PT	Narrow
Cerebrospinal thrombotic tamponade	10052173	PT	Narrow
Cerebrovascular accident	10008190	PT	Narrow
Cerebrovascular accident prophylaxis	10049165	PT	Narrow
Cerebrovascular disorder	10008196	PT	Narrow
Cerebrovascular operation	10051902	PT	Narrow
Choroidal infarction	10057403	PT	Narrow
Collateral circulation	10069729	PT	Narrow
Coronary bypass thrombosis	10059025	PT	Narrow
Device embolisation	10074896	PT	Narrow
Device occlusion	10064685	PT	Narrow
Device related thrombosis	10077455	PT	Narrow
Diplegia	10013033	PT	Narrow
Directional Doppler flow tests abnormal	10013048	PT	Narrow
Disseminated intravascular coagulation	10013442	PT	Narrow

Disseminated intravascular coagulation in newborn	10013443	PT	Narrow
Embolitic cerebellar infarction	10084072	PT	Narrow
Embolitic cerebral infarction	10060839	PT	Narrow
Embolitic pneumonia	10065680	PT	Narrow
Embolitic stroke	10014498	PT	Narrow
Embolism	10061169	PT	Narrow
Eye infarction	10083006	PT	Narrow
Fluorescence angiogram abnormal	10083087	PT	Narrow
Foetal cerebrovascular disorder	10053601	PT	Narrow
Graft thrombosis	10051269	PT	Narrow
Haemorrhagic adrenal infarction	10079902	PT	Narrow
Haemorrhagic cerebral infarction	10019005	PT	Narrow
Haemorrhagic infarction	10019013	PT	Narrow
Haemorrhagic stroke	10019016	PT	Narrow
Haemorrhagic transformation stroke	10055677	PT	Narrow
Haemorrhoids thrombosed	10019023	PT	Narrow
Hemiparesis	10019465	PT	Narrow
Hemiplegia	10019468	PT	Narrow
Heparin-induced thrombocytopenia	10062506	PT	Narrow
Hepatic infarction	10019680	PT	Narrow
Hepatic vascular thrombosis	10074494	PT	Narrow
Implant site thrombosis	10063868	PT	Narrow
Incision site vessel occlusion	10076839	PT	Narrow
Infarction	10061216	PT	Narrow
Infusion site thrombosis	10065489	PT	Narrow
Injection site thrombosis	10022104	PT	Narrow
Inner ear infarction	10070754	PT	Narrow
Instillation site thrombosis	10073625	PT	Narrow
Intestinal infarction	10022657	PT	Narrow
Intracardiac mass	10066087	PT	Narrow
Intracardiac thrombus	10048620	PT	Narrow
Lambli's excrescences	10083691	PT	Narrow
Medical device site thrombosis	10076145	PT	Narrow
Mesenteric vascular insufficiency	10027401	PT	Narrow
Mesenteric vascular occlusion	10074583	PT	Narrow
Microembolism	10073734	PT	Narrow
Monoparesis	10027925	PT	Narrow
Monoplegia	10027926	PT	Narrow
Optic nerve infarction	10030936	PT	Narrow
Pancreatic infarction	10068239	PT	Narrow
Paradoxical embolism	10066059	PT	Narrow
Paraneoplastic thrombosis	10079251	PT	Narrow
Paraparesis	10033885	PT	Narrow
Paraplegia	10033892	PT	Narrow
Paresis	10033985	PT	Narrow
Peripheral revascularisation	10053351	PT	Narrow
Pituitary infarction	10035092	PT	Narrow



Placental infarction	10064620	PT	Narrow
Pneumatic compression therapy	10059829	PT	Narrow
Portal shunt procedure	10077479	PT	Narrow
Post procedural stroke	10066591	PT	Narrow
Postpartum thrombosis	10077022	PT	Narrow
Prosthetic cardiac valve thrombosis	10063176	PT	Narrow
Prosthetic vessel implantation	10068628	PT	Narrow
Quadriparesis	10049680	PT	Narrow
Quadriplegia	10037714	PT	Narrow
Renal infarct	10038470	PT	Narrow
Renal vascular thrombosis	10072226	PT	Narrow
Retinal infarction	10051742	PT	Narrow
Retinal vascular thrombosis	10062108	PT	Narrow
Revascularisation procedure	10084091	PT	Narrow
Shunt occlusion	10040621	PT	Narrow
Shunt thrombosis	10059054	PT	Narrow
Spinal cord infarction	10058571	PT	Narrow
Spinal stroke	10082031	PT	Narrow
Splenic infarction	10041648	PT	Narrow
Splenic thrombosis	10074601	PT	Narrow
Stoma site thrombosis	10074515	PT	Narrow
Stroke in evolution	10059613	PT	Narrow
Surgical vascular shunt	10058408	PT	Narrow
Testicular infarction	10043337	PT	Narrow
Thalamic infarction	10064961	PT	Narrow
Thrombectomy	10043530	PT	Narrow
Thromboangiitis obliterans	10043540	PT	Narrow
Thrombolysis	10043568	PT	Narrow
Thrombosis	10043607	PT	Narrow
Thrombosis in device	10062546	PT	Narrow
Thrombosis mesenteric vessel	10043626	PT	Narrow
Thrombosis prophylaxis	10043634	PT	Narrow
Thrombotic cerebral infarction	10067347	PT	Narrow
Thrombotic stroke	10043647	PT	Narrow
Thyroid infarction	10043742	PT	Narrow
Tumour embolism	10045168	PT	Narrow
Tumour thrombectomy	10081994	PT	Narrow
Tumour thrombosis	10068067	PT	Narrow
Ultrasonic angiogram abnormal	10061604	PT	Narrow
Ultrasound Doppler abnormal	10045413	PT	Narrow
Umbilical cord occlusion	10076714	PT	Narrow
Umbilical cord thrombosis	10071652	PT	Narrow
Vaccination site thrombosis	10076190	PT	Narrow
Vascular access site thrombosis	10078675	PT	Narrow
Vascular device occlusion	10080803	PT	Narrow
Vascular graft	10067740	PT	Narrow
Vascular graft occlusion	10049060	PT	Narrow

Vascular graft thrombosis	10069922	PT	Narrow
Vascular operation	10049071	PT	Narrow
Vascular stent insertion	10063382	PT	Narrow
Vascular stent occlusion	10077143	PT	Narrow
Vascular stent thrombosis	10063934	PT	Narrow
Vasodilation procedure	10058794	PT	Narrow
Vessel puncture site occlusion	10076838	PT	Narrow
Vessel puncture site thrombosis	10070649	PT	Narrow
Visual midline shift syndrome	10066856	PT	Narrow

SMQ Export: 23.0 - English				4/21/2021 9:31:13 PM						
	Include Inactive PT: No									
English: Haematopoietic cytopenias (SMQ)										
	English: Haematopoietic cytopenias affecting more than one type of blood cell (SMQ): Level 2									
	English	Code	Level	Scope	Category	Weight	Status	Addition Version	Last Modified Version	
	Aplastic anaemia	10002967	PT	Narrow	A	0	Active	8.1	8.1	
	Autoimmune aplastic anaemia	10071576	PT	Narrow	A	0	Active	14.1	14.1	
	Bicytopenia	10058956	PT	Narrow	A	0	Active	8.1	8.1	
	Bone marrow failure	10065553	PT	Narrow	A	0	Active	9.0	9.0	
	Cytopenia	10066274	PT	Narrow	A	0	Active	9.1	18.0	
	Febrile bone marrow aplasia	10053213	PT	Narrow	A	0	Active	8.1	8.1	
	Full blood count decreased	10017413	PT	Narrow	A	0	Active	8.1	8.1	
	Gelatinous transformation of the bone marrow	10078097	PT	Narrow	A	0	Active	19.1	19.1	
	Immune-mediated pancytopenia	10083004	PT	Narrow	A	0	Active	22.1	22.1	
	Pancytopenia	10033661	PT	Narrow	A	0	Active	8.1	8.1	
	Panmyelopathy	10050026	PT	Narrow	A	0	Active	8.1	8.1	
	Aspiration bone marrow abnormal	10003506	PT	Broad	A	0	Active	8.1	8.1	
	Biopsy bone marrow abnormal	10004738	PT	Broad	A	0	Active	8.1	8.1	
	Blood count abnormal	10064198	PT	Broad	A	0	Active	8.1	8.1	
	Blood disorder	10061590	PT	Broad	A	0	Active	8.1	8.1	
	Bone marrow disorder	10061729	PT	Broad	A	0	Active	8.1	8.1	
	Bone marrow infiltration	10075173	PT	Broad	A	0	Active	17.1	17.1	
	Bone marrow myelogram abnormal	10057528	PT	Broad	A	0	Active	8.1	8.1	
	Bone marrow necrosis	10058822	PT	Broad	A	0	Active	8.1	8.1	
	Bone marrow toxicity	10051779	PT	Broad	A	0	Active	8.1	8.1	
	Congenital aplastic anaemia	10053138	PT	Broad	A	0	Active	8.1	8.1	
	Haematotoxicity	10061188	PT	Broad	A	0	Active	8.1	8.1	
	Myelodysplastic syndrome	10028533	PT	Broad	A	0	Active	8.1	8.1	
	Myelodysplastic syndrome transformation	10067387	PT	Broad	A	0	Active	10.1	11.1	
	Myelofibrosis	10028537	PT	Broad	A	0	Active	18.1	18.1	
	Myeloid metaplasia	10028561	PT	Broad	A	0	Active	17.1	18.0	
	Plasmablast count decreased	10058774	PT	Broad	A	0	Active	8.1	8.1	
	Primary myelofibrosis	10077161	PT	Broad	A	0	Active	18.1	18.1	
	Scan bone marrow abnormal	10053504	PT	Broad	A	0	Active	8.1	8.1	
	English: Haematopoietic erythropenia (SMQ): Level 2									
	English	Code	Level	Scope	Category	Weight	Status	Addition Version	Last Modified Version	
	Anaemia macrocytic	10002064	PT	Narrow	A	0	Active	8.1	8.1	
	Aplasia pure red cell	10002965	PT	Narrow	A	0	Active	8.1	8.1	
	Aplastic anaemia	10002967	PT	Narrow	A	0	Active	8.1	8.1	
	Erythroblast count decreased	10058505	PT	Narrow	A	0	Active	8.1	8.1	
	Erythroid maturation arrest	10015279	PT	Narrow	A	0	Active	8.1	8.1	
	Erythropenia	10015287	PT	Narrow	A	0	Active	8.1	8.1	

		Hypoplastic anaemia	10021074	PT	Narrow	A	0	Active	8.1	8.1
		Microcytic anaemia	10027538	PT	Narrow	A	0	Active	8.1	8.1
		Proerythroblast count decreased	10060229	PT	Narrow	A	0	Active	8.1	8.1
		Red blood cell count decreased	10038153	PT	Narrow	A	0	Active	8.1	8.1
		Reticulocyte count decreased	10038790	PT	Narrow	A	0	Active	8.1	8.1
		Reticulocytopenia	10038795	PT	Narrow	A	0	Active	8.1	8.1
		Anaemia	10002034	PT	Broad	A	0	Active	8.1	8.1
		Anaemia neonatal	10002068	PT	Broad	A	0	Active	8.1	8.1
		Erythroblast count abnormal	10058508	PT	Broad	A	0	Active	8.1	8.1
		Erythropoiesis abnormal	10049467	PT	Broad	A	0	Active	8.1	8.1
		Foetal anaemia	10077577	PT	Broad	A	0	Active	19.0	19.0
		Haematocrit abnormal	10049221	PT	Broad	A	0	Active	8.1	8.1
		Haematocrit decreased	10018838	PT	Broad	A	0	Active	8.1	8.1
		Haemoglobin abnormal	10018879	PT	Broad	A	0	Active	15.1	15.1
		Haemoglobin decreased	10018884	PT	Broad	A	0	Active	15.1	15.1
		Leukoerythroblastic anaemia	10053199	PT	Broad	A	0	Active	8.1	8.1
		Normochromic anaemia	10029782	PT	Broad	A	0	Active	8.1	20.1
		Normochromic normocytic anaemia	10029783	PT	Broad	A	0	Active	8.1	8.1
		Normocytic anaemia	10029784	PT	Broad	A	0	Active	8.1	20.1
		Proerythroblast count abnormal	10060227	PT	Broad	A	0	Active	8.1	8.1
		Red blood cell count abnormal	10038151	PT	Broad	A	0	Active	8.1	8.1
		Reticulocyte count abnormal	10038788	PT	Broad	A	0	Active	8.1	8.1
		Reticulocyte percentage decreased	10059921	PT	Broad	A	0	Active	8.1	8.1
		<b>English: Haematopoietic leukopenia (SMQ): Level 2</b>								
		<b>English</b>	<b>Code</b>	<b>Level</b>	<b>Scope</b>	<b>Category</b>	<b>Weight</b>	<b>Status</b>	<b>Addition Version</b>	<b>Last Modified Version</b>
		Agranulocytosis	10001507	PT	Narrow	A	0	Active	8.1	8.1
		Band neutrophil count decreased	10057950	PT	Narrow	A	0	Active	8.1	8.1
		Band neutrophil percentage decreased	10059130	PT	Narrow	A	0	Active	8.1	8.1
		Basophil count decreased	10004167	PT	Narrow	A	0	Active	8.1	8.1
		Basophilopenia	10075813	PT	Narrow	A	0	Active	18.0	18.0
		B-lymphocyte count decreased	10051313	PT	Narrow	A	0	Active	8.1	8.1
		Cyclic neutropenia	10053176	PT	Narrow	A	0	Active	8.1	8.1
		Eosinopenia	10014940	PT	Narrow	A	0	Active	8.1	8.1
		Eosinophil count decreased	10014943	PT	Narrow	A	0	Active	8.1	8.1
		Febrile neutropenia	10016288	PT	Narrow	A	0	Active	8.1	8.1
		Granulocyte count decreased	10018681	PT	Narrow	A	0	Active	8.1	8.1
		Granulocytes maturation arrest	10050443	PT	Narrow	A	0	Active	8.1	8.1
		Granulocytopenia	10018687	PT	Narrow	A	0	Active	8.1	8.1
		Idiopathic neutropenia	10051645	PT	Narrow	A	0	Active	8.1	8.1
		Leukopenia	10024384	PT	Narrow	A	0	Active	8.1	8.1
		Lymphocyte count decreased	10025256	PT	Narrow	A	0	Active	8.1	8.1
		Lymphopenia	10025327	PT	Narrow	A	0	Active	8.1	8.1
		Metamyelocyte count decreased	10050984	PT	Narrow	A	0	Active	8.1	8.1
		Monoblast count decreased	10058772	PT	Narrow	A	0	Active	8.1	8.1

		Monocyte count decreased	10027878	PT	Narrow	A	0	Active	8.1	8.1
		Monocytopenia	10027905	PT	Narrow	A	0	Active	8.1	8.1
		Myeloblast count decreased	10050961	PT	Narrow	A	0	Active	8.1	8.1
		Myelocyte count decreased	10050986	PT	Narrow	A	0	Active	8.1	8.1
		Neutropenia	10029354	PT	Narrow	A	0	Active	8.1	8.1
		Neutropenic infection	10059482	PT	Narrow	A	0	Active	8.1	8.1
		Neutropenic sepsis	10049151	PT	Narrow	A	0	Active	8.1	8.1
		Neutrophil count decreased	10029366	PT	Narrow	A	0	Active	8.1	8.1
		Promyelocyte count decreased	10050987	PT	Narrow	A	0	Active	8.1	8.1
		Pure white cell aplasia	10068043	PT	Narrow	A	0	Active	11.0	11.0
		Radiation leukopenia	10067354	PT	Narrow	A	0	Active	10.1	10.1
		T-lymphocyte count decreased	10051318	PT	Narrow	A	0	Active	8.1	8.1
		White blood cell count decreased	10047942	PT	Narrow	A	0	Active	8.1	8.1
		Basophil count abnormal	10060978	PT	Broad	A	0	Active	8.1	8.1
		Basophil percentage decreased	10052219	PT	Broad	A	0	Active	8.1	8.1
		B-lymphocyte abnormalities	10053775	PT	Broad	A	0	Active	8.1	8.1
		B-lymphocyte count abnormal	10078589	PT	Broad	A	0	Active	19.1	19.1
		Differential white blood cell count abnormal	10012785	PT	Broad	A	0	Active	8.1	8.1
		Eosinophil count abnormal	10061125	PT	Broad	A	0	Active	8.1	8.1
		Eosinophil percentage decreased	10052221	PT	Broad	A	0	Active	8.1	8.1
		Full blood count abnormal	10017412	PT	Broad	A	0	Active	8.1	8.1
		Granulocytes abnormal	10018685	PT	Broad	A	0	Active	8.1	8.1
		Granulocytopenia neonatal	10018688	PT	Broad	A	0	Active	8.1	8.1
		Leukopenia neonatal	10050504	PT	Broad	A	0	Active	8.1	8.1
		Lymphocyte count abnormal	10025252	PT	Broad	A	0	Active	8.1	8.1
		Lymphocyte percentage abnormal	10063337	PT	Broad	A	0	Active	8.1	8.1
		Lymphocyte percentage decreased	10052231	PT	Broad	A	0	Active	8.1	8.1
		Lymphocytopenia neonatal	10025279	PT	Broad	A	0	Active	8.1	8.1
		Monocyte count abnormal	10061293	PT	Broad	A	0	Active	8.1	8.1
		Monocyte percentage decreased	10052229	PT	Broad	A	0	Active	8.1	8.1
		Mononuclear cell count decreased	10082036	PT	Broad	A	0	Active	22.0	22.0
		Myeloblast percentage decreased	10052225	PT	Broad	A	0	Active	8.1	8.1
		Myelocyte percentage decreased	10052227	PT	Broad	A	0	Active	8.1	8.1
		Myeloid maturation arrest	10028560	PT	Broad	A	0	Active	8.1	8.1
		Neutropenia neonatal	10029358	PT	Broad	A	0	Active	8.1	8.1
		Neutrophil count abnormal	10061313	PT	Broad	A	0	Active	8.1	8.1
		Neutrophil percentage decreased	10052223	PT	Broad	A	0	Active	8.1	8.1
		Plasma cell disorder	10062081	PT	Broad	A	0	Active	8.1	8.1
		Plasma cells absent	10035230	PT	Broad	A	0	Active	8.1	8.1
		T-lymphocyte count abnormal	10057284	PT	Broad	A	0	Active	8.1	8.1
		White blood cell analysis abnormal	10073323	PT	Broad	A	0	Active	16.0	16.0
		White blood cell count abnormal	10047940	PT	Broad	A	0	Active	8.1	8.1
		White blood cell disorder	10061414	PT	Broad	A	0	Active	8.1	8.1
English: Haematopoietic thrombocytopenia (SMQ): Level 2										

		English	Code	Level	Scope	Category	Weight	Status	Addition Version	Last Modified Version
		Acquired amegakaryocytic thrombocytopenia	10076747	PT	Narrow	A	0	Active	18.1	18.1
		Megakaryocytes decreased	10027119	PT	Narrow	A	0	Active	8.1	8.1
		Platelet count decreased	10035528	PT	Narrow	A	0	Active	8.1	8.1
		Platelet maturation arrest	10035537	PT	Narrow	A	0	Active	8.1	8.1
		Platelet production decreased	10035540	PT	Narrow	A	0	Active	8.1	8.1
		Platelet toxicity	10059440	PT	Narrow	A	0	Active	8.1	8.1
		Thrombocytopenia	10043554	PT	Narrow	A	0	Active	8.1	8.1
		Megakaryocytes abnormal	10027118	PT	Broad	A	0	Active	8.1	8.1
		Platelet count abnormal	10035526	PT	Broad	A	0	Active	8.1	8.1
		Platelet disorder	10035532	PT	Broad	A	0	Active	8.1	8.1
		Plateletcrit abnormal	10064785	PT	Broad	A	0	Active	8.1	8.1
		Plateletcrit decreased	10064784	PT	Broad	A	0	Active	8.1	8.1
		Thrombocytopenia neonatal	10043557	PT	Broad	A	0	Active	8.1	8.1

Haematopoietic cytopenias affecting more than one type of blood cell (SMQ): Level 2			
English	Code	Level	Scope
Aplastic anaemia	10002967	PT	Narrow
Autoimmune aplastic anaemia	10071576	PT	Narrow
Bicytopenia	10058956	PT	Narrow
Bone marrow failure	10065553	PT	Narrow
Cytopenia	10066274	PT	Narrow
Febrile bone marrow aplasia	10053213	PT	Narrow
Full blood count decreased	10017413	PT	Narrow
Gelatinous transformation of the bone marrow	10078097	PT	Narrow
Immune-mediated pancytopenia	10083004	PT	Narrow
Pancytopenia	10033661	PT	Narrow
Panmyelopathy	10050026	PT	Narrow
Aspiration bone marrow abnormal	10003506	PT	Broad
Biopsy bone marrow abnormal	10004738	PT	Broad
Blood count abnormal	10064198	PT	Broad
Blood disorder	10061590	PT	Broad
Bone marrow disorder	10061729	PT	Broad
Bone marrow infiltration	10075173	PT	Broad
Bone marrow myelogram abnormal	10057528	PT	Broad
Bone marrow necrosis	10058822	PT	Broad
Bone marrow toxicity	10051779	PT	Broad
Congenital aplastic anaemia	10053138	PT	Broad
Haematotoxicity	10061188	PT	Broad
Myelodysplastic syndrome	10028533	PT	Broad
Myelodysplastic syndrome transformation	10067387	PT	Broad
Myelofibrosis	10028537	PT	Broad
Myeloid metaplasia	10028561	PT	Broad
Plasmablast count decreased	10058774	PT	Broad
Primary myelofibrosis	10077161	PT	Broad
Scan bone marrow abnormal	10053504	PT	Broad

<b>Haematopoietic erythropenia (SMQ): Level 2</b>			
<b>English</b>	<b>Code</b>	<b>Level</b>	<b>Scope</b>
Anaemia macrocytic	10002064	PT	Narrow
Aplasia pure red cell	10002965	PT	Narrow
Aplastic anaemia	10002967	PT	Narrow
Erythroblast count decreased	10058505	PT	Narrow
Erythroid maturation arrest	10015279	PT	Narrow
Erythropenia	10015287	PT	Narrow
Hypoplastic anaemia	10021074	PT	Narrow
Microcytic anaemia	10027538	PT	Narrow
Proerythroblast count decreased	10060229	PT	Narrow
Red blood cell count decreased	10038153	PT	Narrow
Reticulocyte count decreased	10038790	PT	Narrow
Reticulocytopenia	10038795	PT	Narrow
Anaemia	10002034	PT	Broad
Anaemia neonatal	10002068	PT	Broad
Erythroblast count abnormal	10058508	PT	Broad
Erythropoiesis abnormal	10049467	PT	Broad
Foetal anaemia	10077577	PT	Broad
Haematocrit abnormal	10049221	PT	Broad
Haematocrit decreased	10018838	PT	Broad
Haemoglobin abnormal	10018879	PT	Broad
Haemoglobin decreased	10018884	PT	Broad
Leukoerythroblastic anaemia	10053199	PT	Broad
Normochromic anaemia	10029782	PT	Broad
Normochromic normocytic anaemia	10029783	PT	Broad
Normocytic anaemia	10029784	PT	Broad
Proerythroblast count abnormal	10060227	PT	Broad
Red blood cell count abnormal	10038151	PT	Broad
Reticulocyte count abnormal	10038788	PT	Broad
Reticulocyte percentage decreased	10059921	PT	Broad



<b>Haematopoietic leukopenia (SMQ): Level 2</b>			
<b>English</b>	<b>Code</b>	<b>Level</b>	<b>Scope</b>
Agranulocytosis	10001507	PT	Narrow
Band neutrophil count decreased	10057950	PT	Narrow
Band neutrophil percentage decreased	10059130	PT	Narrow
Basophil count decreased	10004167	PT	Narrow
Basophilopenia	10075813	PT	Narrow
B-lymphocyte count decreased	10051313	PT	Narrow
Cyclic neutropenia	10053176	PT	Narrow
Eosinopenia	10014940	PT	Narrow
Eosinophil count decreased	10014943	PT	Narrow
Febrile neutropenia	10016288	PT	Narrow
Granulocyte count decreased	10018681	PT	Narrow
Granulocytes maturation arrest	10050443	PT	Narrow
Granulocytopenia	10018687	PT	Narrow
Idiopathic neutropenia	10051645	PT	Narrow
Leukopenia	10024384	PT	Narrow
Lymphocyte count decreased	10025256	PT	Narrow
Lymphopenia	10025327	PT	Narrow
Metamyelocyte count decreased	10050984	PT	Narrow
Monoblast count decreased	10058772	PT	Narrow
Monocyte count decreased	10027878	PT	Narrow
Monocytopenia	10027905	PT	Narrow
Myeloblast count decreased	10050961	PT	Narrow
Myelocyte count decreased	10050986	PT	Narrow
Neutropenia	10029354	PT	Narrow
Neutropenic infection	10059482	PT	Narrow
Neutropenic sepsis	10049151	PT	Narrow
Neutrophil count decreased	10029366	PT	Narrow
Promyelocyte count decreased	10050987	PT	Narrow
Pure white cell aplasia	10068043	PT	Narrow
Radiation leukopenia	10067354	PT	Narrow
T-lymphocyte count decreased	10051318	PT	Narrow
White blood cell count decreased	10047942	PT	Narrow
Basophil count abnormal	10060978	PT	Broad
Basophil percentage decreased	10052219	PT	Broad
B-lymphocyte abnormalities	10053775	PT	Broad
B-lymphocyte count abnormal	10078589	PT	Broad
Differential white blood cell count abnormal	10012785	PT	Broad
Eosinophil count abnormal	10061125	PT	Broad
Eosinophil percentage decreased	10052221	PT	Broad
Full blood count abnormal	10017412	PT	Broad
Granulocytes abnormal	10018685	PT	Broad
Granulocytopenia neonatal	10018688	PT	Broad
Leukopenia neonatal	10050504	PT	Broad
Lymphocyte count abnormal	10025252	PT	Broad
Lymphocyte percentage abnormal	10063337	PT	Broad

Lymphocyte percentage decreased	10052231	PT	Broad
Lymphocytopenia neonatal	10025279	PT	Broad
Monocyte count abnormal	10061293	PT	Broad
Monocyte percentage decreased	10052229	PT	Broad
Mononuclear cell count decreased	10082036	PT	Broad
Myeloblast percentage decreased	10052225	PT	Broad
Myelocyte percentage decreased	10052227	PT	Broad
Myeloid maturation arrest	10028560	PT	Broad
Neutropenia neonatal	10029358	PT	Broad
Neutrophil count abnormal	10061313	PT	Broad
Neutrophil percentage decreased	10052223	PT	Broad
Plasma cell disorder	10062081	PT	Broad
Plasma cells absent	10035230	PT	Broad
T-lymphocyte count abnormal	10057284	PT	Broad
White blood cell analysis abnormal	10073323	PT	Broad
White blood cell count abnormal	10047940	PT	Broad
White blood cell disorder	10061414	PT	Broad

Haematopoietic thrombocytopenia (SMQ): Level 2			
<b>English</b>	<b>Code</b>	<b>Level</b>	<b>Scope</b>
Acquired amegakaryocytic thrombocytopenia	10076747	PT	Narrow
Megakaryocytes decreased	10027119	PT	Narrow
Platelet count decreased	10035528	PT	Narrow
Platelet maturation arrest	10035537	PT	Narrow
Platelet production decreased	10035540	PT	Narrow
Platelet toxicity	10059440	PT	Narrow
Thrombocytopenia	10043554	PT	Narrow
Megakaryocytes abnormal	10027118	PT	Broad
Platelet count abnormal	10035526	PT	Broad
Platelet disorder	10035532	PT	Broad
Plateletcrit abnormal	10064785	PT	Broad
Plateletcrit decreased	10064784	PT	Broad
Thrombocytopenia neonatal	10043557	PT	Broad

SMQ Export: 23.0 - English			4/21/2021 9:24:38 PM							
	Include Inactive PT: No									
English: Hearing and vestibular disorders (SMQ)										
	English: Hearing impairment (SMQ)									
	English	Code	Level	Scope	Category	Weight	Status	Addition Version	Last Modified Version	
	Acoustic neuritis	10063162	PT	Narrow	A	0	Active	12.0	12.0	
	Acoustic stimulation tests abnormal	10000526	PT	Narrow	A	0	Active	12.0	12.0	
	Altered pitch perception	10075083	PT	Narrow	A	0	Active	17.1	17.1	
	Audiogram abnormal	10003761	PT	Narrow	A	0	Active	12.0	12.0	
	Auditory disorder	10003778	PT	Narrow	A	0	Active	12.0	19.0	
	Auditory recruitment	10003789	PT	Narrow	A	0	Active	12.0	12.0	
	Autophony	10048827	PT	Narrow	A	0	Active	12.0	12.0	
	Barotitis media	10004129	PT	Narrow	A	0	Active	12.0	12.0	
	Bone anchored hearing aid implantation	10070723	PT	Narrow	A	0	Active	13.1	17.1	
	Cochlea implant	10009830	PT	Narrow	A	0	Active	12.0	12.0	
	Conductive deafness	10010280	PT	Narrow	A	0	Active	12.0	12.0	
	Deafness	10011878	PT	Narrow	A	0	Active	12.0	12.0	
	Deafness bilateral	10052556	PT	Narrow	A	0	Active	12.0	12.0	
	Deafness neurosensory	10011891	PT	Narrow	A	0	Active	12.0	12.0	
	Deafness occupational	10011893	PT	Narrow	A	0	Active	12.0	12.0	
	Deafness permanent	10011894	PT	Narrow	A	0	Active	12.0	12.0	
	Deafness transitory	10011900	PT	Narrow	A	0	Active	12.0	12.0	
	Deafness unilateral	10048812	PT	Narrow	A	0	Active	12.0	12.0	
	Diplacusis	10013032	PT	Narrow	A	0	Active	12.0	12.0	
	Dysacusis	10049712	PT	Narrow	A	0	Active	12.0	12.0	
	Electrocochleogram abnormal	10014399	PT	Narrow	A	0	Active	12.0	12.0	
	Eustachian tube disorder	10061462	PT	Narrow	A	0	Active	12.0	12.0	
	Eustachian tube dysfunction	10015543	PT	Narrow	A	0	Active	12.0	12.0	
	Eustachian tube obstruction	10015544	PT	Narrow	A	0	Active	12.0	12.0	
	Haematotympanum	10063013	PT	Narrow	A	0	Active	12.0	12.0	
	Hearing aid therapy	10075385	PT	Narrow	A	0	Active	17.1	17.1	
	Hyperacusis	10020559	PT	Narrow	A	0	Active	12.0	12.0	
	Hypoacusis	10048865	PT	Narrow	A	0	Active	12.0	12.0	
	Middle ear adhesions	10027582	PT	Narrow	A	0	Active	12.0	12.0	
	Middle ear effusion	10062545	PT	Narrow	A	0	Active	12.0	12.0	
	Middle ear inflammation	10065838	PT	Narrow	A	0	Active	12.0	12.0	
	Misophonia	10079388	PT	Narrow	A	0	Active	20.0	20.0	
	Mixed deafness	10027757	PT	Narrow	A	0	Active	12.0	12.0	
	Myringitis	10061302	PT	Narrow	A	0	Active	12.0	12.0	

	Neonatal deafness	10080897	PT	Narrow	A	0	Active	21.0	21.0
	Neonatal hypoacusis	10080902	PT	Narrow	A	0	Active	21.0	21.0
	Neurosensory hypoacusis	10067587	PT	Narrow	A	0	Active	12.0	12.0
	Noninfective myringitis	10078830	PT	Narrow	A	0	Active	20.0	20.0
	Ossicle disorder	10061327	PT	Narrow	A	0	Active	12.0	12.0
	Otoacoustic emissions test abnormal	10063643	PT	Narrow	A	0	Active	12.0	12.0
	Otosalpingitis	10033102	PT	Narrow	A	0	Active	12.0	12.0
	Otosclerosis	10033103	PT	Narrow	A	0	Active	12.0	12.0
	Ototoxicity	10033109	PT	Narrow	A	0	Active	20.1	20.1
	Presbycusis	10036626	PT	Narrow	A	0	Active	12.0	12.0
	Rinne tuning fork test abnormal	10039191	PT	Narrow	A	0	Active	12.0	12.0
	Sudden hearing loss	10061373	PT	Narrow	A	0	Active	12.0	12.0
	Tinnitus	10043882	PT	Narrow	A	0	Active	12.0	12.0
	Tympanic membrane atrophic	10045208	PT	Narrow	A	0	Active	12.0	12.0
	Tympanic membrane disorder	10062218	PT	Narrow	A	0	Active	12.0	12.0
	Tympanic membrane perforation	10045210	PT	Narrow	A	0	Active	12.0	12.0
	Tympanic membrane scarring	10063604	PT	Narrow	A	0	Active	12.0	12.0
	Tympanometry abnormal	10045215	PT	Narrow	A	0	Active	12.0	12.0
	Tympanosclerosis	10045218	PT	Narrow	A	0	Active	12.0	12.0
	Weber tuning fork test abnormal	10047878	PT	Narrow	A	0	Active	12.0	12.0
	Auditory nerve disorder	10078794	PT	Broad	A	0	Active	20.0	20.0
	Auriclectomy	10079865	PT	Broad	A	0	Active	20.1	20.1
	Cholesterin granuloma of middle ear	10008649	PT	Broad	A	0	Active	12.0	12.0
	Deaf mutism	10011875	PT	Broad	A	0	Active	12.0	12.0
	Ear operation	10061831	PT	Broad	A	0	Active	12.0	12.0
	Ear procedural complication	10081321	PT	Broad	A	0	Active	21.1	21.1
	Ear tube insertion	10057900	PT	Broad	A	0	Active	12.0	12.0
	Ear tube removal	10057927	PT	Broad	A	0	Active	12.0	12.0
	Eosinophilic otitis media	10081430	PT	Broad	A	0	Active	21.1	21.1
	Eustachian tube operation	10015545	PT	Broad	A	0	Active	12.0	12.0
	Eustachian tube patulous	10015546	PT	Broad	A	0	Active	12.0	12.0
	Facial paralysis	10016062	PT	Broad	A	0	Active	19.0	19.0
	Gradenigo's syndrome	10063095	PT	Broad	A	0	Active	12.0	12.0
	Inner ear operation	10062990	PT	Broad	A	0	Active	12.0	12.0
	Middle ear disorder	10061290	PT	Broad	A	0	Active	12.0	12.0
	Middle ear irrigation	10081220	PT	Broad	A	0	Active	21.1	21.1
	Middle ear lesion excision	10027587	PT	Broad	A	0	Active	12.0	12.0
	Middle ear operation	10068893	PT	Broad	A	0	Active	12.0	12.0
	Middle ear prosthesis insertion	10027589	PT	Broad	A	0	Active	12.0	12.0
	Middle ear prosthesis removal	10053296	PT	Broad	A	0	Active	12.0	12.0
	Myringotomy	10028662	PT	Broad	A	0	Active	12.0	12.0

	Ossicular operation	10061892	PT	Broad	A	0	Active	12.0	12.0
	Ossiculoplasty	10031147	PT	Broad	A	0	Active	12.0	12.0
	Paracentesis ear	10033755	PT	Broad	A	0	Active	12.0	12.0
	Paracentesis ear abnormal	10033756	PT	Broad	A	0	Active	12.0	12.0
	Petrositis	10034762	PT	Broad	A	0	Active	12.0	12.0
	Politzerisation	10053290	PT	Broad	A	0	Active	12.0	12.0
	Stapedectomy	10041915	PT	Broad	A	0	Active	12.0	12.0
	Stapedotomy	10069123	PT	Broad	A	0	Active	12.0	12.0
	Stapes fracture	10081442	PT	Broad	A	0	Active	21.1	21.1
	Stapes mobilisation	10056212	PT	Broad	A	0	Active	12.0	12.0
	Superior semicircular canal dehiscence	10079888	PT	Broad	A	0	Active	20.1	20.1
	Tympanoplasty	10045217	PT	Broad	A	0	Active	12.0	12.0
	Tympanoscopy	10081281	PT	Broad	A	0	Active	21.1	21.1
	VIIIth nerve injury	10047409	PT	Broad	A	0	Active	12.0	12.0
	VIIIth nerve lesion	10062177	PT	Broad	A	0	Active	12.0	12.0
	<b>English: Vestibular disorders (SMQ)</b>								
	English	Code	Level	Scope	Category	Weight	Status	Addition Version	Last Modified Version
	Acute vestibular syndrome	10063559	PT	Narrow	A	0	Active	12.0	12.0
	Meniere's disease	10027183	PT	Narrow	A	0	Active	12.0	12.0
	Vertigo	10047340	PT	Narrow	A	0	Active	12.0	12.0
	Vertigo labyrinthine	10047344	PT	Narrow	A	0	Active	12.0	12.0
	Vertigo positional	10047348	PT	Narrow	A	0	Active	12.0	12.0
	Vestibular ataxia	10047385	PT	Narrow	A	0	Active	12.0	12.0
	Vestibular disorder	10047386	PT	Narrow	A	0	Active	12.0	12.0
	Vestibular function test abnormal	10047390	PT	Narrow	A	0	Active	12.0	12.0
	Vestibular migraine	10077920	PT	Narrow	A	0	Active	19.0	19.0
	Vestibular neuronitis	10047393	PT	Narrow	A	0	Active	12.0	12.0
	Balance disorder	10049848	PT	Broad	A	0	Active	12.0	12.0
	Canalith repositioning procedure	10053470	PT	Broad	A	0	Active	12.0	12.0
	Dizziness	10013573	PT	Broad	A	0	Active	12.0	12.0
	Ear operation	10061831	PT	Broad	A	0	Active	12.0	12.0
	Endolymphatic hydrops	10049934	PT	Broad	A	0	Active	12.0	12.0
	Endolymphatic shunt placement	10076623	PT	Broad	A	0	Active	18.1	18.1
	Inner ear disorder	10061524	PT	Broad	A	0	Active	12.0	12.0
	Inner ear operation	10062990	PT	Broad	A	0	Active	12.0	12.0
	Labyrinthectomy	10079362	PT	Broad	A	0	Active	20.0	20.0
	Labyrinthine fistula	10023563	PT	Broad	A	0	Active	12.0	12.0
	Labyrinthitis	10023567	PT	Broad	A	0	Active	12.0	12.0
	Middle ear irrigation	10081220	PT	Broad	A	0	Active	21.1	21.1
	Motion sickness	10027990	PT	Broad	A	0	Active	12.0	12.0
	Nystagmus	10029864	PT	Broad	A	0	Active	12.0	12.0

		Otolithiasis	10081585	PT	Broad	A	0	Active	21.1	21.1
		Saccotomy	10066849	PT	Broad	A	0	Active	12.0	12.0
		Superior semicircular canal dehiscence	10079888	PT	Broad	A	0	Active	20.1	20.1
		Tympanoscopy	10081281	PT	Broad	A	0	Active	21.1	21.1
		Vestibular apparatus operation	10047384	PT	Broad	A	0	Active	12.0	12.0
		VIIIth nerve injury	10047409	PT	Broad	A	0	Active	12.0	12.0
		VIIIth nerve lesion	10062177	PT	Broad	A	0	Active	12.0	12.0

<b>Hearing impairment (SMQ): Level 2</b>			
<b>English</b>	<b>Code</b>	<b>Level</b>	<b>Scope</b>
Acoustic neuritis	10063162	PT	Narrow
Acoustic stimulation tests abnormal	10000526	PT	Narrow
Altered pitch perception	10075083	PT	Narrow
Audiogram abnormal	10003761	PT	Narrow
Auditory disorder	10003778	PT	Narrow
Auditory recruitment	10003789	PT	Narrow
Autophony	10048827	PT	Narrow
Barotitis media	10004129	PT	Narrow
Bone anchored hearing aid implantation	10070723	PT	Narrow
Cochlea implant	10009830	PT	Narrow
Conductive deafness	10010280	PT	Narrow
Deafness	10011878	PT	Narrow
Deafness bilateral	10052556	PT	Narrow
Deafness neurosensory	10011891	PT	Narrow
Deafness occupational	10011893	PT	Narrow
Deafness permanent	10011894	PT	Narrow
Deafness transitory	10011900	PT	Narrow
Deafness unilateral	10048812	PT	Narrow
Diplacusis	10013032	PT	Narrow
Dysacusis	10049712	PT	Narrow
Electrocochleogram abnormal	10014399	PT	Narrow
Eustachian tube disorder	10061462	PT	Narrow
Eustachian tube dysfunction	10015543	PT	Narrow
Eustachian tube obstruction	10015544	PT	Narrow
Haematotympanum	10063013	PT	Narrow
Hearing aid therapy	10075385	PT	Narrow
Hyperacusis	10020559	PT	Narrow
Hypoacusis	10048865	PT	Narrow
Middle ear adhesions	10027582	PT	Narrow
Middle ear effusion	10062545	PT	Narrow
Middle ear inflammation	10065838	PT	Narrow
Misophonia	10079388	PT	Narrow
Mixed deafness	10027757	PT	Narrow
Myringitis	10061302	PT	Narrow
Neonatal deafness	10080897	PT	Narrow
Neonatal hypoacusis	10080902	PT	Narrow
Neurosensory hypoacusis	10067587	PT	Narrow
Noninfective myringitis	10078830	PT	Narrow
Ossicle disorder	10061327	PT	Narrow
Otoacoustic emissions test abnormal	10063643	PT	Narrow
Otosalpingitis	10033102	PT	Narrow
Otosclerosis	10033103	PT	Narrow
Ototoxicity	10033109	PT	Narrow
Presbycusis	10036626	PT	Narrow
Rinne tuning fork test abnormal	10039191	PT	Narrow



Sudden hearing loss	10061373	PT	Narrow
Tinnitus	10043882	PT	Narrow
Tympanic membrane atrophic	10045208	PT	Narrow
Tympanic membrane disorder	10062218	PT	Narrow
Tympanic membrane perforation	10045210	PT	Narrow
Tympanic membrane scarring	10063604	PT	Narrow
Tympanometry abnormal	10045215	PT	Narrow
Tympanosclerosis	10045218	PT	Narrow
Weber tuning fork test abnormal	10047878	PT	Narrow
Auditory nerve disorder	10078794	PT	Broad
Auriculectomy	10079865	PT	Broad
Cholesterin granuloma of middle ear	10008649	PT	Broad
Deaf mutism	10011875	PT	Broad
Ear operation	10061831	PT	Broad
Ear procedural complication	10081321	PT	Broad
Ear tube insertion	10057900	PT	Broad
Ear tube removal	10057927	PT	Broad
Eosinophilic otitis media	10081430	PT	Broad
Eustachian tube operation	10015545	PT	Broad
Eustachian tube patulous	10015546	PT	Broad
Facial paralysis	10016062	PT	Broad
Gradenigo's syndrome	10063095	PT	Broad
Inner ear operation	10062990	PT	Broad
Middle ear disorder	10061290	PT	Broad
Middle ear irrigation	10081220	PT	Broad
Middle ear lesion excision	10027587	PT	Broad
Middle ear operation	10068893	PT	Broad
Middle ear prosthesis insertion	10027589	PT	Broad
Middle ear prosthesis removal	10053296	PT	Broad
Myringotomy	10028662	PT	Broad
Ossicular operation	10061892	PT	Broad
Ossiculoplasty	10031147	PT	Broad
Paracentesis ear	10033755	PT	Broad
Paracentesis ear abnormal	10033756	PT	Broad
Petrositis	10034762	PT	Broad
Poltzerisation	10053290	PT	Broad
Stapedectomy	10041915	PT	Broad
Stapedotomy	10069123	PT	Broad
Stapes fracture	10081442	PT	Broad
Stapes mobilisation	10056212	PT	Broad
Superior semicircular canal dehiscence	10079888	PT	Broad
Tympanoplasty	10045217	PT	Broad
Tympanoscopy	10081281	PT	Broad
VIIIth nerve injury	10047409	PT	Broad
VIIIth nerve lesion	10062177	PT	Broad

<b>Vestibular disorders (SMQ): Level 2</b>			
<b>English</b>	<b>Code</b>	<b>Level</b>	<b>Scope</b>
Acute vestibular syndrome	10063559	PT	Narrow
Meniere's disease	10027183	PT	Narrow
Vertigo	10047340	PT	Narrow
Vertigo labyrinthine	10047344	PT	Narrow
Vertigo positional	10047348	PT	Narrow
Vestibular ataxia	10047385	PT	Narrow
Vestibular disorder	10047386	PT	Narrow
Vestibular function test abnormal	10047390	PT	Narrow
Vestibular migraine	10077920	PT	Narrow
Vestibular neuronitis	10047393	PT	Narrow
Balance disorder	10049848	PT	Broad
Canalith repositioning procedure	10053470	PT	Broad
Dizziness	10013573	PT	Broad
Ear operation	10061831	PT	Broad
Endolymphatic hydrops	10049934	PT	Broad
Endolymphatic shunt placement	10076623	PT	Broad
Inner ear disorder	10061524	PT	Broad
Inner ear operation	10062990	PT	Broad
Labyrinthectomy	10079362	PT	Broad
Labyrinthine fistula	10023563	PT	Broad
Labyrinthitis	10023567	PT	Broad
Middle ear irrigation	10081220	PT	Broad
Motion sickness	10027990	PT	Broad
Nystagmus	10029864	PT	Broad
Otolithiasis	10081585	PT	Broad
Sacotomy	10066849	PT	Broad
Superior semicircular canal dehiscence	10079888	PT	Broad
Tympanoscopy	10081281	PT	Broad
Vestibular apparatus operation	10047384	PT	Broad
VIIIth nerve injury	10047409	PT	Broad
VIIIth nerve lesion	10062177	PT	Broad

PT	PT Code
Acute cutaneous lupus erythematosus	10057928
Acute disseminated encephalomyelitis	10000709
Acute febrile neutrophilic dermatosis	10000748
Acute haemorrhagic oedema of infancy	10070599
Acute haemorrhagic ulcerative colitis	10075634
Acute motor axonal neuropathy	10076658
Acute motor-sensory axonal neuropathy	10076657
Acute painful neuropathy of rapid glycaemic control	10072909
Acute polyneuropathy	10066699
Addison's disease	10001130
Administration site vasculitis	10075969
Allergic granulomatous angiitis	10048594
Alopecia	10001760
Alopecia areata	10001761
Alopecia scarring	10001764
Alopecia syphilitic	10001765
Alopecia totalis	10001766
Alopecia universalis	10001767
Amyotrophic lateral sclerosis	10002026
Amyotrophy	10002027
Androgenic alopecia	10068168
Angiopathic neuropathy	10079036
Ankylosing spondylitis	10002556
Antibody test abnormal	10061425
Antibody test positive	10061427
Anti-glomerular basement membrane disease	10081981
Anti-myelin-associated glycoprotein associated polyneuropathy	10078324
Antineutrophil cytoplasmic antibody increased	10060138
Antineutrophil cytoplasmic antibody positive	10060136
Anti-neutrophil cytoplasmic antibody positive vasculitis	10050894
Antiphospholipid syndrome	10002817
Antisynthetase syndrome	10068801
Aortitis	10002921
Application site alopecia	10059046
Application site vasculitis	10076027
Arteritis	10003230
Arteritis coronary	10003232
Arthritis reactive	10003267
Autoimmune aplastic anaemia	10071576
Autoimmune cholangitis	10083636
Autoimmune crescentic glomerulonephritis	10018378
Autoimmune haemolytic anaemia	10073785
Autoimmune hepatitis	10003827
Autoimmune hypothyroidism	10076644
Autoimmune inner ear disease	10065996
Autoimmune myocarditis	10064539
Autoimmune neuropathy	10070439
Autoimmune thrombocytopenia	10050245
Autoimmune thyroiditis	10049046
Autoimmune uveitis	10075690
Axial spondyloarthritis	10071400

Axonal neuropathy	10003882
Basedow's disease	10004161
Behcet's syndrome	10004213
Benign familial pemphigus	10004265
Bickerstaff's encephalitis	10076985
Biopsy peripheral nerve abnormal	10004846
Blood viscosity increased	10051293
CANDLE syndrome	10073960
Capillaritis	10068406
Cardiac sarcoidosis	10007604
Cardiomyopathy	10007636
Central nervous system lupus	10076328
Central nervous system vasculitis	10081778
Cerebral arteritis	10008087
Cholangitis sclerosing	10008609
Chronic autoimmune glomerulonephritis	10073016
Chronic cutaneous lupus erythematosus	10057929
Chronic inflammatory demyelinating polyradiculoneuropathy	10057645
Chronic pigmented purpura	10072726
Coeliac disease	10009839
Cogan's syndrome	10056667
Cold type haemolytic anaemia	10009868
Colitis ulcerative	10009900
CREST Syndrome	10011380
Cranial nerve paralysis	10061908
Crohn's disease	10011401
Cryoglobulinaemia	10011474
Cryoglobulins present	10011478
Cutaneous lupus erythematosus	10056509
Cutaneous sarcoidosis	10011674
Cutaneous vasculitis	10011686
Decreased vibratory sense	10067502
Demyelinating polyneuropathy	10061811
Dermatitis herpetiformis	10012468
Dermatomyositis	10012503
Diabetic arteritis	10077357
Diffuse alopecia	10073736
Diffuse vasculitis	10012978
Drug eruption	10013687
Encephalomyelitis	10014619
Encephalomyelitis rubella	10014622
Eosinophilic granulomatosis with polyangiitis	10078117
Erythema induratum	10015213
Erythema nodosum	10015226
Evans syndrome	10053873
Facial paralysis	10016062
Glomerulonephritis	10018364
Glomerulonephritis chronic	10018367
Glomerulonephritis membranous	10018372
Goodpasture's syndrome	10018620
Granulomatosis with polyangiitis	10072579
Guillain-Barre syndrome	10018767

Haemorrhagic vasculitis	10071252
Hashimoto's encephalopathy	10069432
Henoch-Schonlein purpura	10019617
Henoch-Schonlein purpura nephritis	10069440
Hypergammaglobulinaemia benign monoclonal	10020631
Hypersensitivity vasculitis	10020764
Idiopathic pulmonary fibrosis	10021240
Immune recovery uveitis	10077392
Immune thrombocytopenia	10083842
Immune-mediated neuropathy	10078963
Immune-mediated uveitis	10083069
Infective uveitis	10074700
Inflammatory bowel disease	10021972
Infusion site vasculitis	10074851
Injection site alopecia	10081519
Injection site vasculitis	10067995
Ischaemic neuropathy	10051307
Joint position sense decreased	10081223
Juvenile idiopathic arthritis	10059176
Kawasaki's disease	10023320
Keratouveitis	10078693
Langerhans' cell histiocytosis	10069698
Leukocytoclastic vasculitis	10024377
Leukoencephalomyelitis	10048999
Lewis-Sumner syndrome	10065580
Lichen planus	10024429
Liver sarcoidosis	10068664
Loss of proprioception	10057332
Lupus cystitis	10074714
Lupus encephalitis	10025130
Lupus endocarditis	10058225
Lupus enteritis	10067738
Lupus hepatitis	10067737
Lupus miliaris disseminatus faciei	10056301
Lupus myocarditis	10066391
Lupus myositis	10079642
Lupus nephritis	10025140
Lupus pancreatitis	10067750
Lupus pleurisy	10073694
Lupus pneumonitis	10057481
Lupus vasculitis	10058143
Lupus vulgaris	10025143
Lupus-like syndrome	10050551
MAGIC syndrome	10078132
Marburg's variant multiple sclerosis	10067067
Marine Lenhart syndrome	10068828
Medical device site vasculitis	10076146
Membranoproliferative glomerulonephritis	10027168
Mesangioproliferative glomerulonephritis	10066453
Microscopic polyangiitis	10063344
Miller Fisher syndrome	10049567
Mixed connective tissue disease	10027754

Monoclonal gammopathy	10060880
Morphoea	10027982
Morvan syndrome	10075006
Multifocal motor neuropathy	10065579
Multiple sclerosis	10028245
Multiple sclerosis relapse	10048393
Multiple sclerosis relapse prophylaxis	10070495
Muscular sarcoidosis	10028365
Myasthenia gravis	10028417
Myasthenia gravis crisis	10062758
Myasthenic syndrome	10028424
Myelitis transverse	10028527
Myelopathy	10028570
Myocarditis	10028606
Narcolepsy	10028713
Neonatal lupus erythematosus	10057887
Nephrotic syndrome	10029164
Nerve conduction studies abnormal	10029175
Neuralgia	10029223
Neuralgic amyotrophy	10029229
Neuritis	10029240
Neuromyelitis optica spectrum disorder	10077875
Neuronal neuropathy	10071579
Neuropathic muscular atrophy	10075469
Neuropathy peripheral	10029331
Neuropsychiatric lupus	10063663
Neurosarcoidosis	10078011
Nodular vasculitis	10029491
Noninfective encephalomyelitis	10074713
Non-scarring alopecia	10082395
Notalgia paraesthetica	10072643
Ocular sarcoidosis	10065700
Ocular vasculitis	10066926
Optic neuritis	10030942
Optic neuritis meningococcal	10030943
Oral lichen planus	10030983
Overlap syndrome	10068786
Palpable purpura	10056872
Paralysis	10033799
Paraneoplastic dermatomyositis	10066267
Paraneoplastic encephalomyelitis	10069587
Paraproteinaemia	10061333
Parapsoriasis	10033898
Paresis	10033985
Paresis cranial nerve	10061911
Paroxysmal extreme pain disorder	10081856
Pemphigoid	10034277
Pemphigus	10034280
Pemphigus disease area index	10083520
Pericarditis lupus	10058149
Peripheral motor neuropathy	10034580
Peripheral nervous system function test abnormal	10034591

Peripheral sensorimotor neuropathy	10056673
Peripheral sensory neuropathy	10034620
Peritonitis lupus	10062898
Pernicious anaemia	10034695
Plasma viscosity abnormal	10035468
POEMS syndrome	10053869
Polyarteritis nodosa	10036024
Polychondritis	10065159
Polyglandular autoimmune syndrome type I	10036072
Polyglandular autoimmune syndrome type II	10036073
Polyglandular autoimmune syndrome type III	10064115
Polymyalgia rheumatica	10036099
Polymyositis	10036102
Polyneuropathy	10036105
Polyneuropathy chronic	10064135
Polyneuropathy idiopathic progressive	10036111
Primary biliary cholangitis	10080429
Primary progressive multiple sclerosis	10063401
Proctitis ulcerative	10036783
Progressive multiple sclerosis	10053395
Progressive relapsing multiple sclerosis	10067063
Pseudovasculitis	10065255
Psoriasis	10037153
Psoriatic arthropathy	10037162
Pulmonary sarcoidosis	10037430
Pulmonary vasculitis	10037457
Raynaud's phenomenon	10037912
Relapsing multiple sclerosis	10080700
Relapsing-remitting multiple sclerosis	10063399
Renal arteritis	10038373
Renal vasculitis	10038546
Retinal vasculitis	10038905
Rheumatoid arthritis	10039073
Rheumatoid vasculitis	10048628
Sarcoidosis	10039486
Secondary progressive multiple sclerosis	10063400
Segmented hyalinising vasculitis	10067527
Sensorimotor disorder	10062162
Sensory disturbance	10040026
Sensory loss	10040030
Sjögren's syndrome	10040767
Small fibre neuropathy	10073928
Stevens-Johnson syndrome	10042033
Still's disease	10042061
Subacute cutaneous lupus erythematosus	10057903
Subacute inflammatory demyelinating polyneuropathy	10081726
Susac's syndrome	10071573
Systemic lupus erythematosus	10042945
Systemic lupus erythematosus disease activity index abnormal	10067659
Systemic lupus erythematosus disease activity index decreased	10067658
Systemic lupus erythematosus disease activity index increased	10067657
Systemic lupus erythematosus rash	10042946

Systemic scleroderma	10078638
Takayasu's arteritis	10043097
Temporal arteritis	10043207
Thromboangiitis obliterans	10043540
Toxic neuropathy	10067722
Tubulointerstitial nephritis and uveitis syndrome	10069034
Tumefactive multiple sclerosis	10078556
Type 1 diabetes mellitus	10067584
Type 2 lepra reaction	10070517
Urticarial vasculitis	10048820
Uveitis	10046851
Uveitis-glaucoma-hyphaema syndrome	10068148
Vaccination site vasculitis	10076191
Vascular purpura	10047097
Vasculitic rash	10047111
Vasculitis	10047115
Vasculitis gastrointestinal	10048319
Vasculitis necrotising	10047124
Viral keratouveitis	10078694
Viral uveitis	10071005
Viral vasculitis	10056281
Vitiligo	10047642
Vogt-Koyanagi-Harada disease	10082001
Warm type haemolytic anaemia	10047822
Wegener's granulomatosis	10072579
Zika virus associated Guillain Barre syndrome	10081046



CMQ	Potential Dermal Filler Reaction post Vaccination	
	Preferred Name	Code
	Allergic oedema	10060934
	Allergy to vaccine	10055048
	Blepharitis allergic	10005149
	Cheilitis	10008417
	Circumoral oedema	10052250
	Eye oedema	10052139
	Eye swelling	10015967
	Eyelid oedema	10015993
	Eyelid rash	10074620
	Face oedema	10016029
	Lip oedema	10024558
	Lip swelling	10024570
	Periorbital oedema	10034545
	Periorbital swelling	10056647
	Swelling face	10042682
	Swelling of eyelid	10042690

# **Charter for the COVID-19 Vaccine Data and Safety Monitoring Board**

**June 24, 2020**

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## LIST OF ABBREVIATIONS

COI	Conflict of interest
COVID-19	Coronavirus disease 2019
DSMB	Data and Safety Monitoring Board
IND	Investigational new drug (application)
NIAID	National Institute of Allergy and Infectious Diseases
QC	Quality control
SAP	Statistical analysis plan
SSG	Statistical Support Group
USG	United States Government

## 1 INTRODUCTION

The Coronavirus Disease 2019 (COVID-19) Vaccine Data and Safety Monitoring Board (DSMB) will monitor all randomized COVID-19 vaccine studies supported by the United States Government (USG). Additional COVID-19 vaccine studies could be included in the portfolio of this DSMB at the discretion of the DSMB Chairperson and Executive Secretary.

The primary role of the DSMB is to make certain that appropriate safeguards are in place to ensure the safety of all study participants and that the studies are conducted with scientific rigor. To accomplish these goals, the DSMB will review enrollment, data completeness, and accumulating safety and outcome data on a regular basis while studies are ongoing. The DSMB will review each study as a stand-alone entity. This Charter describes the organization and procedures of the standing DSMB that will oversee the randomized vaccine studies.

It is anticipated that each protocol will be managed by its own Governance Committee consisting of pharmaceutical company and USG representatives. The Governance Committee will be responsible for the overall conduct of the study.

It is anticipated that the individual investigational new drug applications (INDs) for these studies will be held by the pharmaceutical companies responsible for the study vaccines.

The Director of the National Institute of Allergy and Infectious Diseases (NIAID) will serve as the designated senior representative of the USG.

This document details the roles and responsibilities of the different entities involved in the DSMB review process for each study. The process described in this document will be the same for each study but will occur separately for each study. The defined entities in this document will have the same responsibilities for each study but will be specific for each study. It also outlines what data will be provided to the DSMB, the process for disseminating study data, and the communication plan.

## 2 OVERVIEW OF THE DSMB PROCESS

The DSMB will review unblinded analyses of accumulating outcome and safety data for studies in order to assess the risk-benefit ratio of the vaccines under investigation. The DSMB will make recommendations concerning the conduct of the studies, including changes to the informed consent form.

At the conclusion of each study, the responsibilities of the DSMB for the study ceases.

## 3 DSMB MEMBERSHIP

The DSMB is a multidisciplinary group independent of a study's academic partners, Governance Committee, Sponsor, and USG. DSMB Members are listed in the Charter ([Appendix 1](#)). Members have expertise in biostatistics, clinical trials, infectious diseases, vaccine development, and ethics.

The DSMB may consult additional experts on an *ad hoc* basis as needed. All DSMB Members will agree to maintain confidentiality about the proceedings of the DSMB meetings and related activities.

DSMB Members will have no involvement in the study outside their role on the DSMB.

### **3.1 Conflicts of Interest**

DSMB Members must be free of conflicts of interest (COIs) with study investigators, academic partners, funders, and protocol steering committees. Consideration of and decisions regarding potential COIs will follow the NIAID policy on COI for data and safety monitoring (see [Appendix 2](#)). A COI is a situation when an individual has or is perceived to have competing professional obligations, proprietary conflicts, and/or financial or other personal interests that would make it difficult to fulfill his/her duties fairly.

The DSMB Members are responsible for disclosing any new COI before each DSMB review and advising the Sponsor and USG in writing of any potential COIs throughout the duration of the study. The Sponsor and USG are responsible for (i) deciding whether any situation of a DSMB Member has the potential to create an actual or perceived COI, and (ii) providing disclosure to all other DSMB Members of any potential COIs that the Sponsor and USG determine do not impede objectivity. Members of the DSMB who develop significant potential or perceived COIs will be asked to resign from the DSMB.

### **3.2 Confidentiality of DSMB Deliberations**

DSMB Members must agree to maintain the confidentiality of interim data, their deliberations, and their recommendations. Outside of DSMB meetings, written and verbal communications with the Governance Committees or others are not permitted without prior approval of the Sponsors and USG.

## **4 ROLES AND RESPONSIBILITIES**

### **4.1 Responsibilities of DSMB Members**

The fundamental responsibility of the DSMB is to assure the ongoing safety of study participants and to monitor the study for crossing of boundaries related to efficacy. As part of this important role, the DSMB will:

- Review the vaccine protocols and any amendments during the course of the study.
- Review and endorse the proposed statistical analysis plan (SAP) as written by the Governance committee and endorsed by the Sponsor.
- Provide an independent review and assessment of the accumulating safety and efficacy data.
- Provide an independent review and assessment of the overall study conduct.
- Make recommendations to the study Sponsors and USG on study continuation.
- Review and approve summaries of the DSMB meetings.

## 4.2 Responsibilities of the DSMB Chairperson

The DSMB Chairperson will have the following additional responsibilities:

- Set an agenda for the closed session of the meeting.
- Communicate DSMB recommendations to the Governance Committees, study Sponsors, and USG.
- Facilitate discussion by DSMB Members on the closed data and the formulation of recommendations.
- Provide initial review and approval of summaries of the DSMB meetings prepared by the Executive Secretary.
- In circumstances when there is a major recommendation (eg, to stop a study or study arm, or substantially modify the study for safety reasons), inform the Sponsors and USG.

## 4.3 Responsibilities of the DSMB Executive Secretary

The DSMB Executive Secretary is a biostatistician in the Biostatistics Research Branch of the Division of Clinical Research, NIAID. The Executive Secretary will be the point of contact between the DSMB and the Sponsor and USG.

The Executive Secretary will have the following responsibilities:

- Work with the Governance Committee to set an agenda for the open session of the meeting.
- Attend all meetings or provide designated back up.
- Coordinate timelines for production and distribution of the open and closed reports with the unblinded biostatisticians.
- Supervise technical support for the DSMB meetings, including scheduling.
- Draft preliminary DSMB recommendations and provide them for approval to the DSMB Chairperson, followed by DSMB Members, within 1 week of the DSMB review.
- Draft and revise meeting summaries.
- Distribute the final open meeting summary to the DSMB and the protocol leadership and Sponsor within 1 week of the meeting.
- Distribute closed meeting summary documents, if any, to the DSMB and unblinded statisticians within 1 week of the meeting.
- In circumstances where a major recommendation is accepted by the Sponsor (eg, to stop a study arm or substantially modify the study for safety reasons), provide written summary recommendations to the Governance Committee within 72 hours of the DSMB review, after approval by the DSMB Chairperson and DSMB Members.
- Archive meeting summaries as well as closed session data reports and documents for 7 years after study completion.

## 4.4 Responsibilities of Pharmaceutical Company Sponsors

The Sponsors will ensure that the data are provided to the Statistical Support Group (SSG, section 4.6).

The Sponsors (in coordination with the Governance Committees) will forward the required reports and documents to the appropriate regulatory bodies.

The Sponsors (in coordination with the USG and Governance Committees) will be responsible for acting on the recommendations of the DSMB.

The Sponsor is responsible for selecting a group independent of the study that will support the DSMB and perform all analyses for the DSMB reports (referred to as the Statistical Support Group).

#### **4.5 Responsibilities of the US Government**

The USG (in coordination with the Sponsors and Governance Committees) will be responsible for acting on the recommendations of the DSMB.

#### **4.6 Responsibilities of the Statistical Support Group**

The SSG includes an unblinded statistician (SSG Statistician) and may additionally include a project manager and a programmer. One person may serve more than one role.

The SSG Statistician has the following major responsibilities:

- Ensure the SAP is agreed to by the DSMB Members and the Governance Committee.
- Oversee the SSG programming staff to ensure that tables, listings, and figures for the open and closed report follow the SAP, conducting a quality control (QC) review of all reports prior to sending to the DSMB Members.
- Obtain the treatment assignment data from the appropriate party.
- Work with the SSG programming staff to maintain an archive of electronic copies of the datasets and the SAS or R programs used to generate DSMB reports.
- Inform the DSMB Chairperson and Executive Secretary when the potential harm boundary has been crossed.
- Serve as a liaison between the DSMB and the Governance Committee when the need arises for additional information.

SSG responsibilities include the following:

- Immediately inform DSMB Members of the death of study participants.
- Send the data package to DSMB Members.
- Send reports to FDA if detailed in the SAP or as directed by the DSMB.
- Request transfers of the clinical datasets from the Sponsor and randomization code from the appropriate party.
- Request additional data relevant to the reports from the Protocol Governance Committee.



## 4.7 DSMB Responsibilities of the Protocol Governance Committee

The Governance Committee will determine who from the protocol team will attend the open sessions of the DSMB. The primary responsibilities of the Governance Committee with respect to the DSMB are:

- In conjunction with SSG, prepare open reports for the DSMB.
- Review and approve the open session DSMB meeting summary.
- Notify the DSMB of protocol amendments.
- Update the DSMB on information from other studies relevant to the conduct of the study under review.
- Notify the DSMB of any significant new safety information.
- Implement DSMB recommendations endorsed by the USG and the sponsor.
- Notify the institutional review boards of DSMB recommendations within the timeframes of national/local requirements.
- Provide data to the SSG relevant to the closed report.

## 5 DSMB MEETINGS

Most meetings of the DSMB will be by teleconference. All DSMB Members are expected to participate in each meeting of the DSMB. Every effort will be made to schedule meetings to ensure that all Members can participate. However, given that there will be meetings when not all Members can attend, an official DSMB meeting may be held with a quorum consisting of at least 3 voting members present, including at least 1 clinician and 1 biostatistician.

Data review meetings will be scheduled according to the interim monitoring schedule outlined in the protocol and SAP. At a minimum, it is anticipated that meetings will occur monthly. The DSMB may alter the review schedule if they determine a change in the review schedule is indicated to fulfill its responsibilities. To promptly address emerging and unanticipated issues that require urgent DSMB attention, the Chairperson may convene additional *ad hoc* meetings as needed.

### 5.1 Meeting Format

Each scheduled DSMB meeting will consist of open, closed, and executive sessions.

### 5.2 Open Session

The open session is open to members of the Governance Committee, Sponsor representatives of any study being reviewed, and USG representatives including those from the Food and Drug Administration. This session will deal with issues relating to the general conduct and progress of the study, such as accrual, patient demographics and other baseline characteristics, data QC, adherence to the protocol, retention, and follow-up.

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### 5.3 Closed Session

At the closed session, safety and efficacy data by treatment group will be reviewed. Comparative results are presented to the DSMB in closed reports, and closed sessions are attended only by DSMB Members, the Executive Secretary, the SSG, and *ad-hoc* members if required.

### 5.4 Closed Executive Session

This session involves only the DSMB Members (including *ad-hoc* members if applicable) and the Executive Secretary in order to ensure complete objectivity as they discuss outcome results, make decisions, and formulate recommendations regarding a study. This session does not include the SSG.

The DSMB will have the option to invite other participants to attend any part of the meeting to assist in fulfilling its responsibilities.

## 6 DATA REPORTS

Study data reports will be prepared by the SSG. The Governance Committee and the sponsor will determine the report contents and format initially; the DSMB may request additions and other modifications for subsequent reports. Reports for the meetings consist of separate open and closed session reports.

Data will be provided in both electronic and/or paper form as requested by the DSMB. For each report, a data cutoff will be established to allow a reasonable amount of time to process the data required for DSMB meetings. Open and closed reports will be considered confidential and will be appropriately secured. Copies of reports for closed sessions, except for archival copies retained by the SSG and Executive Secretary, will be destroyed following the meeting. All closed reports will be discarded in a confidential manner 7 years after study completion.

### 6.1 Open Data Report

This report is distributed to the DSMB Members, the Executive Secretary, Governance Committee, Sponsor, and USG and is reviewed in the open session. Information in the open report includes overall data on study conduct, protocol compliance, site performance, QC, follow-up, and participant baseline characteristics exclusive of data by treatment group. Note: Pooled safety data may also be reported with limited distribution, and discussion of this data may require a session with restricted attendance. This process would be described in the SAP or could occur at the discretion of the DSMB.

### 6.2 Closed Data Report

This report is distributed to DSMB Members and the Executive Secretary only and is reviewed in the closed session. In addition to information included in the open report, the closed report includes safety and efficacy outcome data by vaccine/placebo arm. Ordinarily, the by-arm reports are coded as a safeguard against disclosure through lost documents, and code keys are provided separately to DSMB Members and the Executive Secretary.

All material presented at any session, including closed session documents, will be considered confidential. Copies of reports for closed sessions, except for archival copies retained by the SSG and Executive Secretary, will be destroyed or discarded following the meeting. The SSG will be responsible for ensuring the reports are appropriately discarded.

## **7 DSMB RECOMMENDATIONS**

### **7.1 Routine Recommendations**

Within 1 week after the meeting, the DSMB Executive Secretary works closely with the DSMB Chairperson to prepare and distribute a report summarizing the DSMB recommendations, omitting any confidential information presented at the meeting. After approval of the summary recommendations by the full DSMB, the DSMB Executive Secretary forwards the final version to the Governance Committee Chair. The Sponsor and Governance Committee Chair are then responsible for disseminating the DSMB summary report to other bodies as necessary.

It is acceptable and encouraged for the DSMB to verbally share any recommendations of a routine nature with the Governance Committee, Sponsor, and USG representatives at the meeting.

### **7.2 Major Recommendations**

In circumstances when there is a major recommendation (eg, to stop a study arm), the DSMB instead first communicates its formal recommendations only to the Sponsor and USG. After consulting with the DSMB, the Sponsor and USG make the final decision to accept the recommendations or not. The Sponsor and USG may consult with the Governance Committee leadership prior to making a final decision to accept recommendations or not. If approved, the Executive Secretary circulates the DSMB recommendations as described above (section [7.1](#)).

## **8 DOCUMENTATION**

Original documents needed by the Sponsor (eg, meeting agendas, meeting minutes, safety reports/tables/line listings, DSMB Members' meeting reports, QC checklists, document checklists, DSMB Members' faxed signature pages, correspondence) will be managed by the SSG Statistician.

Reports needed by the USG (eg, copies of the reports, open and closed meeting summaries, and COIs) will be maintained by the Executive Secretary.

## APPENDIX 1: COVID-19 VACCINE DSMB ROSTER

Name	Affiliation
Richard J. Whitley, M.D.	Division Director, Department of Pediatrics Infectious Diseases University of Alabama School of Medicine
Abdel Babiker, Ph.D.	Professor of Epidemiology and Medical Statistics MRC Clinical Trials Unit at University College London
Lisa Angeline Cooper, M.D., M.P.H., FACP	James F. Fries Professor of Medicine Welch Center for Prevention, Epidemiology, & Clinical Research Johns Hopkins University School of Medicine and Bloomberg School of Public Health
Susan Smith Ellenberg, Ph.D.	Professor of Biostatistics University of Pennsylvania/USA
Alan Fix, M.D., M.S.	Senior Medical Officer Vaccine Development Global Program Center for Vaccine Innovation and Access PATH
Marie Griffin, M.D.	Professor, Health Policy and Medicine Department of Health Policy Vanderbilt University Medical Center
Steven Joffe, M.D., M.P.H.	Interim Chair, Department of Medical Ethics and Health Policy Perelman School of Medicine University of Pennsylvania
Jorge Kalil, M.D.	Professor and Head of the Clinical Immunology and Allergy Department Heart Institute, Clinics Hospital (HC-FMUSP) Universidade de São Paulo/Brazil
Myron Levine, M.D.	Associate Dean for Global Health, Vaccinology and Infectious Diseases University of Maryland School of Medicine
Malegapuru William Makgoba, MBChB	Vice Chancellors Office Ombud, Complaints Centre and Assessments University of KwaZulu-Natal
Anastasios A. Tsiatis, Ph.D.	Professor Emeritus Department of Statistics North Carolina State University
Sally Hunsberger, Ph.D.	Executive Secretary Mathematical Statistician Biostatistics Research Branch National Institute of Allergy and Infectious Diseases, NIH

Martha Nason, Ph.D.	Executive Secretary (Back-Up) Biostatistics Research Branch National Institutes of Health National Institute of Allergy and Infectious Diseases, NIH
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## APPENDIX 2: DEFINITIONS

*From the NIAID Policy for Identifying Potential Conflict of Interest for Individuals Serving on Advisory Committees or as Independent Safety Monitors Responsible for Data and Safety Monitoring of Clinical Trials.*

Conflict of Interest (COI) – A situation when someone has or is perceived to have competing professional obligations, proprietary conflicts and/or financial or other personal interests that would make it difficult to fulfill his/her duties fairly. The three types addressed in this policy are as follows :

1. Professional: where the individual, their spouse, dependent children, other relatives with whom the individual has a close relationship, or household members acts as an officer, member, director, expert advisor, etc., of any organization whose study is under review.
2. Financial: where the individual, their spouse, dependent children, other relatives with whom the individual has a close relationship, or household members have significant financial or equity interests in excess of \$5,000 in any entity whose study is under review.
3. Proprietary: where the individual, their spouse, dependent children, other relatives with whom the individual has a close relationship, or household members own or otherwise control rights, including but not necessarily limited to intellectual property rights, relevant to the development and commercialization of any product being reviewed.

# **Charter for the COVID-19 Vaccine Data and Safety Monitoring Board**

**July 22, 2020**

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## LIST OF ABBREVIATIONS

COI	Conflict of interest
COVID-19	Coronavirus disease 2019
DSMB	Data and Safety Monitoring Board
IND	Investigational new drug (application)
NIAID	National Institute of Allergy and Infectious Diseases
QC	Quality control
SAP	Statistical analysis plan
SSG	Statistical Support Group
USG	United States Government



## 1 INTRODUCTION

The Coronavirus Disease 2019 (COVID-19) Vaccine Data and Safety Monitoring Board (DSMB) will monitor all randomized COVID-19 vaccine studies supported by the United States Government (USG). Additional COVID-19 vaccine studies could be included in the portfolio of this DSMB at the discretion of the DSMB Chairperson and Executive Secretary.

The primary role of the DSMB is to make certain that appropriate safeguards are in place to ensure the safety of all study participants and that the studies are conducted with scientific rigor. To accomplish these goals, the DSMB will review enrollment, data completeness, and accumulating safety and outcome data on a regular basis while studies are ongoing. The DSMB will review each study as a stand-alone entity. This Charter describes the organization and procedures of the standing DSMB that will oversee the randomized vaccine studies.

It is anticipated that each protocol will be managed by its own Governance Committee consisting of pharmaceutical company and USG representatives. The Governance Committee will be responsible for the overall conduct of the study.

It is anticipated that the individual investigational new drug applications (INDs) for these studies will be held by the pharmaceutical companies responsible for the study vaccines.

The Director of the National Institute of Allergy and Infectious Diseases (NIAID) will serve as the designated senior representative of the USG.

This document details the roles and responsibilities of the different entities involved in the DSMB review process for each study. The process described in this document will be the same for each study but will occur separately for each study. The defined entities in this document will have the same responsibilities for each study but will be specific for each study. It also outlines what data will be provided to the DSMB, the process for disseminating study data, and the communication plan.

## 2 OVERVIEW OF THE DSMB PROCESS

The DSMB will review unblinded analyses of accumulating efficacy and safety data for studies in order to assess the risk-benefit ratio of the vaccines under investigation. The reviews will be performed according to a specified monitoring plan. The DSMB will make recommendations concerning the conduct of the studies, including changes to the informed consent form.

At the conclusion of each study, the responsibilities of the DSMB for the study ceases.

## 3 DSMB MEMBERSHIP

The DSMB is a multidisciplinary group independent of a study's academic partners, Governance Committee, Sponsor, and USG. DSMB Members are listed in the Charter ([Appendix 1](#)). Members have expertise in biostatistics, clinical trials, infectious diseases, vaccine development, vaccine safety and ethics.

The DSMB may consult additional experts on an *ad hoc* basis as needed. All DSMB Members will agree to maintain confidentiality about the proceedings of the DSMB meetings and related activities.

DSMB Members will have no involvement in the study outside their role on the DSMB.

### **3.1 Conflicts of Interest**

DSMB Members must be free of conflicts of interest (COIs) with study investigators, academic partners, funders, and protocol steering committees. Consideration of and decisions regarding potential COIs will follow the NIAID policy on COI for data and safety monitoring (see [Appendix 2](#)). A COI is a situation when an individual has or is perceived to have competing professional obligations, proprietary conflicts, and/or financial or other personal interests that would make it difficult to fulfill his/her duties fairly.

The DSMB Members are responsible for disclosing any new COI before each DSMB review and advising the Sponsor and USG in writing of any potential COIs throughout the duration of the study. The Sponsor and USG are responsible for (i) deciding whether any situation of a DSMB Member has the potential to create an actual or perceived COI, and (ii) providing disclosure to all other DSMB Members of any potential COIs that the Sponsor and USG determine do not impede objectivity. Members of the DSMB who develop significant potential or perceived COIs will be asked to resign from the DSMB.

### **3.2 Confidentiality of DSMB Deliberations**

DSMB Members must agree to maintain the confidentiality of interim data, their deliberations, and their recommendations. Outside of DSMB meetings, written and verbal communications with the Governance Committees or others are not permitted without prior approval of the Sponsors and USG.

## **4 ROLES AND RESPONSIBILITIES**

### **4.1 Responsibilities of DSMB Members**

The fundamental responsibility of the DSMB is to assure the ongoing safety of study participants and to monitor the study for crossing of boundaries related to efficacy. As part of this important role, the DSMB will:

- Review the vaccine protocols and any amendments during the course of the study.
- Review and endorse the proposed statistical analysis plan (SAP) as written by the Governance committee and endorsed by the Sponsor.
- Provide an independent review and assessment of the accumulating safety and efficacy data.
- Provide an independent review and assessment of the overall study conduct.
- Make recommendations to the study Sponsors and USG on study continuation.
- Review and approve summaries of the DSMB meetings.

## 4.2 Responsibilities of the DSMB Chairperson

The DSMB Chairperson will have the following additional responsibilities:

- Set an agenda for the closed session of the meeting.
- Communicate DSMB recommendations to the Governance Committees, study Sponsors, and USG.
- Facilitate discussion by DSMB Members on the closed data and the formulation of recommendations.
- Provide initial review and approval of summaries of the DSMB meetings prepared by the Executive Secretary.
- In circumstances when there is a major recommendation (eg, to stop a study or study arm, or substantially modify the study for safety reasons), inform the Sponsors and USG.

## 4.3 Responsibilities of the DSMB Executive Secretary

The DSMB Executive Secretary is a biostatistician in the Biostatistics Research Branch of the Division of Clinical Research, NIAID. The Executive Secretary will be the point of contact between the DSMB and the Sponsor and USG.

The Executive Secretary will have the following responsibilities:

- Work with the Governance Committee to set an agenda for the open session of the meeting.
- Attend all meetings or provide designated back up.
- Coordinate timelines for production and distribution of the open and closed reports with the unblinded biostatisticians.
- Supervise technical support for the DSMB meetings, including scheduling.
- Draft preliminary DSMB recommendations and provide them for approval to the DSMB Chairperson, followed by DSMB Members, within 1 week of the DSMB review.
- Draft and revise meeting summaries.
- Distribute the final open meeting summary to the DSMB and the protocol leadership and Sponsor within 1 week of the meeting.
- Distribute closed meeting summary documents, if any, to the DSMB and unblinded statisticians within 1 week of the meeting.
- In circumstances where a major recommendation is accepted by the Sponsor (eg, to stop a study arm or substantially modify the study for safety reasons), provide written summary recommendations to the Governance Committee within 72 hours of the DSMB review, after approval by the DSMB Chairperson and DSMB Members.
- Archive meeting summaries as well as closed session data reports and documents for 7 years after study completion.

## 4.4 Responsibilities of Pharmaceutical Company Sponsors

The Sponsors will ensure that the data are provided to the Statistical Support Group (SSG, section 4.6).

The Sponsors (in coordination with the Governance Committees) will forward the required reports and documents to the appropriate regulatory bodies.

The Sponsors (in coordination with the USG and Governance Committees) will be responsible for acting on the recommendations of the DSMB.

The Sponsor is responsible for selecting a group independent of the study that will support the DSMB and perform all analyses for the DSMB reports (referred to as the Statistical Support Group).

#### **4.5 Responsibilities of the US Government**

The USG (in coordination with the Sponsors and Governance Committees) will be responsible for acting on the recommendations of the DSMB.

#### **4.6 Responsibilities of the Statistical Support Group**

The SSG includes an unblinded statistician (SSG Statistician) and may additionally include a project manager and a programmer. One person may serve more than one role.

The SSG Statistician has the following major responsibilities:

- Ensure the SAP is agreed to by the DSMB Members and the Governance Committee.
- Oversee the SSG programming staff to ensure that tables, listings, and figures for the open and closed report follow the SAP, conducting a quality control (QC) review of all reports prior to sending to the DSMB Members.
- Obtain the treatment assignment data from the appropriate party.
- Work with the SSG programming staff to maintain an archive of electronic copies of the datasets and the SAS or R programs used to generate DSMB reports.
- Inform the DSMB Chairperson and Executive Secretary when the potential harm boundary has been crossed.
- Serve as a liaison between the DSMB and the Governance Committee when the need arises for additional information.

SSG responsibilities include the following:

- Immediately inform DSMB Members of the death of study participants.
- Send the data package to DSMB Members.
- Send reports to FDA if detailed in the SAP or as directed by the DSMB.
- Request transfers of the clinical datasets from the Sponsor and randomization code from the appropriate party.
- Request additional data relevant to the reports from the Protocol Governance Committee.

## 4.7 DSMB Responsibilities of the Protocol Governance Committee

The Governance Committee will determine who from the protocol team will attend the open sessions of the DSMB. The primary responsibilities of the Governance Committee with respect to the DSMB are:

- In conjunction with SSG, prepare open reports for the DSMB.
- Review and approve the open session DSMB meeting summary.
- Notify the DSMB of protocol amendments.
- Update the DSMB on information from other studies relevant to the conduct of the study under review.
- Notify the DSMB of any significant new safety information.
- Implement DSMB recommendations endorsed by the USG and the sponsor.
- Notify the institutional review boards of DSMB recommendations within the timeframes of national/local requirements.
- Provide data to the SSG relevant to the closed report.

## 5 DSMB MEETINGS

Most meetings of the DSMB will be by teleconference. All DSMB Members are expected to participate in each meeting of the DSMB. Every effort will be made to schedule meetings to ensure that all Members can participate. However, given that there will be meetings when not all Members can attend, an official DSMB meeting may be held with a quorum consisting of at least 7 voting members present, including at least 1 clinician and 1 biostatistician. With approval from the full DSMB, a smaller group of members could be empowered to address a specific issue.

Data review meetings will be scheduled according to the interim monitoring schedule outlined in the protocol and SAP. At a minimum, it is anticipated that meetings will occur monthly. The DSMB may alter the review schedule if they determine a change in the review schedule is indicated to fulfill its responsibilities. To promptly address emerging and unanticipated issues that require urgent DSMB attention, the Chairperson may convene additional *ad hoc* meetings as needed.

### 5.1 Meeting Format

Each scheduled DSMB meeting will consist of open, closed, and executive sessions.

### 5.2 Open Session

The open session is open to members of the Governance Committee, Sponsor representatives of any study being reviewed, and USG representatives including those from the Food and Drug Administration. This session will deal with issues relating to the general conduct and progress of the study, such as accrual, patient demographics and other baseline characteristics, data QC, adherence to the protocol, retention, and follow-up.

### 5.3 Closed Session

At the closed session, safety and efficacy data by treatment group will be reviewed. Comparative results are presented to the DSMB in closed reports, and closed sessions are attended only by DSMB Members, the Executive Secretary, the SSG, and *ad-hoc* members if required.

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This session involves only the DSMB Members (including *ad-hoc* members if applicable) and the Executive Secretary in order to ensure complete objectivity as they discuss outcome results, make decisions, and formulate recommendations regarding a study. This session does not include the SSG.

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### 6.1 Open Data Report

This report is distributed to the DSMB Members, the Executive Secretary, Governance Committee, Sponsor, and USG and is reviewed in the open session. Information in the open report includes overall data on study conduct, protocol compliance, site performance, QC, follow-up, and participant baseline characteristics exclusive of data by treatment group. Note: Pooled safety data may also be reported with limited distribution, and discussion of this data may require a session with restricted attendance. This process would be described in the SAP or could occur at the discretion of the DSMB.

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All material presented at any session, including closed session documents, will be considered confidential. Copies of reports for closed sessions, except for archival copies retained by the SSG and Executive Secretary, will be destroyed or discarded following the meeting. The SSG will be responsible for ensuring the reports are appropriately discarded.

## **7 DSMB RECOMMENDATIONS**

### **7.1 Routine Recommendations**

Within 1 week after the meeting, the DSMB Executive Secretary works closely with the DSMB Chairperson to prepare and distribute a report summarizing the DSMB recommendations, omitting any confidential information presented at the meeting. After approval of the summary recommendations by the full DSMB, the DSMB Executive Secretary forwards the final version to the Governance Committee Chair. The Sponsor and Governance Committee Chair are then responsible for disseminating the DSMB summary report to other bodies as necessary.

It is acceptable and encouraged for the DSMB to verbally share any recommendations of a routine nature with the Governance Committee, Sponsor, and USG representatives at the meeting.

### **7.2 Major Recommendations**

In circumstances when there is a major recommendation (eg, to stop a study arm), the DSMB instead first communicates its formal recommendations only to the Sponsor and USG. After consulting with the DSMB, the Sponsor and USG make the final decision to accept the recommendations or not. The Sponsor and USG may consult with the Governance Committee leadership prior to making a final decision to accept recommendations or not. If approved, the Executive Secretary circulates the DSMB recommendations as described above (section 7.1).

## **8 DOCUMENTATION**

Original documents needed by the Sponsor (eg, meeting agendas, meeting minutes, safety reports/tables/line listings, DSMB Members' meeting reports, QC checklists, document checklists, DSMB Members' faxed signature pages, correspondence) will be managed by the SSG Statistician.

Reports needed by the USG (eg, copies of the reports, open and closed meeting summaries, and COIs) will be maintained by the Executive Secretary.

## APPENDIX 1: COVID-19 VACCINE DSMB ROSTER

Name	Affiliation	Signature	Date
Richard J. Whitley, M.D.	Division Director, Department of Pediatrics Infectious Diseases University of Alabama School of Medicine		
Abdel Babiker, Ph.D.	Professor of Epidemiology and Medical Statistics MRC Clinical Trials Unit at University College London		
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## APPENDIX 1: COVID-19 VACCINE DSMB ROSTER

Name	Affiliation	Signature	Date
Richard J. Whitley, M.D.	Division Director, Department of Pediatrics Infectious Diseases University of Alabama School of Medicine	Richard J. Whitley <small>Digitally signed by Richard J. Whitley DN: cn=Richard J. Whitley, o=University of Alabama at Birmingham, ou=Department of Pediatrics-Infectious Diseases (b) (6) Date: 2020.07.14 13:23:45 -0500</small>	7/14/2020
Abdel Babiker, Ph.D.	Professor of Epidemiology and Medical Statistics MRC Clinical Trials Unit at University College London		
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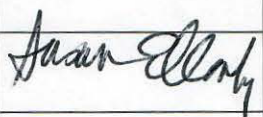
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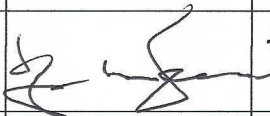
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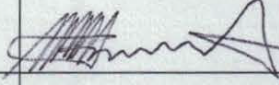


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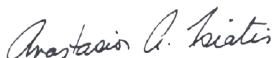
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## APPENDIX 2: DEFINITIONS

*From the NIAID Policy for Identifying Potential Conflict of Interest for Individuals Serving on Advisory Committees or as Independent Safety Monitors Responsible for Data and Safety Monitoring of Clinical Trials.*

Conflict of Interest (COI) – A situation when someone has or is perceived to have competing professional obligations, proprietary conflicts and/or financial or other personal interests that would make it difficult to fulfill his/her duties fairly. The three types addressed in this policy are as follows :

1. Professional: where the individual, their spouse, dependent children, other relatives with whom the individual has a close relationship, or household members acts as an officer, member, director, expert advisor, etc., of any organization whose study is under review.
2. Financial: where the individual, their spouse, dependent children, other relatives with whom the individual has a close relationship, or household members have significant financial or equity interests in excess of \$5,000 in any entity whose study is under review.
3. Proprietary: where the individual, their spouse, dependent children, other relatives with whom the individual has a close relationship, or household members own or otherwise control rights, including but not necessarily limited to intellectual property rights, relevant to the development and commercialization of any product being reviewed.

## **Charter for the COVID-19 Vaccine Data and Safety Monitoring Board**

**August 3, 2020**



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## LIST OF ABBREVIATIONS

COI	Conflict of interest
COVID-19	Coronavirus disease 2019
DSMB	Data and Safety Monitoring Board
IND	Investigational new drug (application)
NIAID	National Institute of Allergy and Infectious Diseases
QC	Quality control
SAP	Statistical analysis plan
SSG	Statistical Support Group
USG	United States Government

## 1 INTRODUCTION

The Coronavirus Disease 2019 (COVID-19) Vaccine Data and Safety Monitoring Board (DSMB) will monitor all randomized COVID-19 vaccine studies supported by the United States Government (USG). Additional COVID-19 vaccine studies could be included in the portfolio of this DSMB at the discretion of the DSMB Chairperson and Executive Secretary.

The primary role of the DSMB is to make certain that appropriate safeguards are in place to ensure the safety of all study participants and that the studies are conducted with scientific rigor. To accomplish these goals, the DSMB will review enrollment, data completeness, and accumulating safety and outcome data on a regular basis while studies are ongoing. The DSMB will review each study as a stand-alone entity. This Charter describes the organization and procedures of the standing DSMB that will oversee the randomized vaccine studies.

It is anticipated that each protocol will be managed by its own Oversight Group consisting of pharmaceutical company and USG representatives. The Oversight Group will be responsible for the overall conduct of the study.

It is anticipated that the individual investigational new drug applications (INDs) for these studies will be held by the pharmaceutical companies responsible for the study vaccines.

The Director of the National Institute of Allergy and Infectious Diseases (NIAID) will serve as the designated senior representative of the USG.

This document details the roles and responsibilities of the different entities involved in the DSMB review process for each study. The process described in this document will be the same for each study but will occur separately for each study. The defined entities in this document will have the same responsibilities for each study but will be specific for each study. It also outlines what data will be provided to the DSMB, the process for disseminating study data, and the communication plan.

## 2 OVERVIEW OF THE DSMB PROCESS

The DSMB will review unblinded analyses of accumulating efficacy and safety data for studies in order to assess the risk-benefit ratio of the vaccines under investigation. The reviews will be performed according to a specified monitoring plan. The DSMB will make recommendations concerning the conduct of the studies, including changes to the informed consent form.

At the conclusion of each study, the responsibilities of the DSMB for the study ceases.

## 3 DSMB MEMBERSHIP

The DSMB is a multidisciplinary group independent of a study's academic partners, Oversight Group, Sponsor, and USG. DSMB Members are listed in the Charter ([Appendix 1](#)). Members



have expertise in biostatistics, clinical trials, infectious diseases, vaccine development, vaccine safety and ethics.

The DSMB may consult additional experts on an *ad hoc* basis as needed. All DSMB Members will agree to maintain confidentiality about the proceedings of the DSMB meetings and related activities.

DSMB Members will have no involvement in the study outside their role on the DSMB.

### **3.1 Conflicts of Interest**

DSMB Members must be free of conflicts of interest (COIs) with study investigators, academic partners, funders, and protocol steering committees. Consideration of and decisions regarding potential COIs will follow the NIAID policy on COI for data and safety monitoring (see [Appendix 2](#)). A COI is a situation when an individual has or is perceived to have competing professional obligations, proprietary conflicts, and/or financial or other personal interests that would make it difficult to fulfill his/her duties fairly.

The DSMB Members are responsible for disclosing any new COI before each DSMB review and advising the Sponsor and USG in writing of any potential COIs throughout the duration of the study. The Sponsor and USG are responsible for (i) deciding whether any situation of a DSMB Member has the potential to create an actual or perceived COI, and (ii) providing disclosure to all other DSMB Members of any potential COIs that the Sponsor and USG determine do not impede objectivity. Members of the DSMB who develop significant potential or perceived COIs will be asked to resign from the DSMB.

### **3.2 Confidentiality of DSMB Deliberations**

DSMB Members must agree to maintain the confidentiality of interim data, their deliberations, and their recommendations. Outside of DSMB meetings, written and verbal communications with the Oversight Group or others are not permitted without prior approval of the Sponsors and USG.

## **4 ROLES AND RESPONSIBILITIES**

### **4.1 Responsibilities of DSMB Members**

The fundamental responsibility of the DSMB is to assure the ongoing safety of study participants and to monitor the study for crossing of boundaries related to efficacy. As part of this important role, the DSMB will:

- Review the vaccine protocols and any amendments during the course of the study.
- Review and endorse the proposed statistical analysis plan (SAP) as written by the Oversight Group and endorsed by the Sponsor.
- Provide an independent review and assessment of the accumulating safety and efficacy data.

- Provide an independent review and assessment of the overall study conduct.
- Make recommendations to the study Sponsors and USG on study continuation.
- Review and approve summaries of the DSMB meetings.

## **4.2 Responsibilities of the DSMB Chairperson**

The DSMB Chairperson will have the following additional responsibilities:

- Set an agenda for the closed session of the meeting.
- Communicate DSMB recommendations to the Oversight Group, study Sponsors, and USG.
- Facilitate discussion by DSMB Members on the closed data and the formulation of recommendations.
- Provide initial review and approval of summaries of the DSMB meetings prepared by the Executive Secretary.
- In circumstances when there is a major recommendation (eg, to stop a study or study arm, or substantially modify the study for safety reasons), inform the Sponsors and USG.

## **4.3 Responsibilities of the DSMB Executive Secretary**

The DSMB Executive Secretary is a biostatistician in the Biostatistics Research Branch of the Division of Clinical Research, NIAID. The Executive Secretary will be the point of contact between the DSMB and the Sponsor and USG.

The Executive Secretary will have the following responsibilities:

- Work with the Oversight Group to set an agenda for the open session of the meeting.
- Attend all meetings or provide designated back up.
- Coordinate timelines for production and distribution of the open and closed reports with the unblinded biostatisticians.
- Supervise technical support for the DSMB meetings, including scheduling.
- Draft preliminary DSMB recommendations and provide them for approval to the DSMB Chairperson, followed by DSMB Members, within 1 week of the DSMB review.
- Draft and revise meeting summaries.
- Distribute the final open meeting summary to the DSMB and the protocol leadership and Sponsor within 1 week of the meeting.
- Distribute closed meeting summary documents, if any, to the DSMB and unblinded statisticians within 1 week of the meeting.
- In circumstances where a major recommendation is accepted by the Sponsor (eg, to stop a study arm or substantially modify the study for safety reasons), provide written summary recommendations to the Oversight Group within 72 hours of the DSMB review, after approval by the DSMB Chairperson and DSMB Members.
- Archive meeting summaries as well as closed session data reports and documents for 7 years after study completion.

#### **4.4 Responsibilities of Pharmaceutical Company Sponsors**

The Sponsors will ensure that the data are provided to the Statistical Support Group (SSG, section 4.6).

The Sponsors (in coordination with the Oversight Group) will forward the required reports and documents to the appropriate regulatory bodies.

The Sponsors (in coordination with the USG and Oversight Group) will be responsible for acting on the recommendations of the DSMB.

The Sponsor is responsible for selecting a group independent of the study that will support the DSMB and perform all analyses for the DSMB reports (referred to as the Statistical Support Group).

#### **4.5 Responsibilities of the US Government**

The USG (in coordination with the Sponsors and Oversight Group) will be responsible for acting on the recommendations of the DSMB.

#### **4.6 Responsibilities of the Statistical Support Group**

The SSG includes an unblinded statistician (SSG Statistician) and may additionally include a project manager and a programmer. One person may serve more than one role.

The SSG Statistician has the following major responsibilities:

- Ensure the SAP is agreed to by the DSMB Members and the Oversight Group.
- Oversee the SSG programming staff to ensure that tables, listings, and figures for the open and closed report follow the SAP, conducting a quality control (QC) review of all reports prior to sending to the DSMB Members.
- Obtain the treatment assignment data from the appropriate party.
- Work with the SSG programming staff to maintain an archive of electronic copies of the datasets and the SAS or R programs used to generate DSMB reports.
- Inform the DSMB Chairperson and Executive Secretary when the potential harm boundary has been crossed.
- Serve as a liaison between the DSMB and the Oversight Group when the need arises for additional information.

SSG responsibilities include the following:

- Immediately inform DSMB Members of the death of study participants.
- Send the data package to DSMB Members.
- Send reports to FDA if detailed in the SAP or as directed by the DSMB.
- Request transfers of the clinical datasets from the Sponsor and randomization code from the appropriate party.
- Request additional data relevant to the reports from the Protocol Oversight Group.

#### **4.7 DSMB Responsibilities of the Protocol Oversight Group**

The Oversight Group will determine who from the protocol team will attend the open sessions of the DSMB. The primary responsibilities of the Oversight Group with respect to the DSMB are:

- In conjunction with SSG, prepare open reports for the DSMB.
- Review and approve the open session DSMB meeting summary.
- Notify the DSMB of protocol amendments.
- Update the DSMB on information from other studies relevant to the conduct of the study under review.
- Notify the DSMB of any significant new safety information.
- Implement DSMB recommendations endorsed by the USG and the sponsor.
- Notify the institutional review boards of DSMB recommendations within the timeframes of national/local requirements.
- Provide data to the SSG relevant to the closed report.

### **5 DSMB MEETINGS**

Most meetings of the DSMB will be by teleconference. All DSMB Members are expected to participate in each meeting of the DSMB. Every effort will be made to schedule meetings to ensure that all Members can participate. However, given that there will be meetings when not all Members can attend, an official DSMB meeting may be held with a quorum consisting of at least 7 voting members present, including at least 1 clinician and 1 biostatistician. With approval from the full DSMB, a smaller group of members could be empowered to address a specific issue.

Data review meetings will be scheduled according to the interim monitoring schedule outlined in the protocol and SAP. At a minimum, it is anticipated that meetings will occur monthly. The DSMB may alter the review schedule if they determine a change in the review schedule is indicated to fulfill its responsibilities. To promptly address emerging and unanticipated issues that require urgent DSMB attention, the Chairperson may convene additional *ad hoc* meetings as needed.

#### **5.1 Meeting Format**

Each scheduled DSMB meeting will consist of open, closed, and executive sessions.

#### **5.2 Open Session**

The open session is open to members of the Oversight Group, Sponsor representatives of any study being reviewed, and USG representatives including those from the Food and Drug Administration. This session will deal with issues relating to the general conduct and progress of the study, such as accrual, patient demographics and other baseline characteristics, data QC, adherence to the protocol, retention, and follow-up.

### 5.3 Closed Session

At the closed session, safety and efficacy data by treatment group will be reviewed. Comparative results are presented to the DSMB in closed reports, and closed sessions are attended only by DSMB Members, the Executive Secretary, the SSG, and *ad-hoc* members if required.

### 5.4 Closed Executive Session

This session involves only the DSMB Members (including *ad-hoc* members if applicable) and the Executive Secretary in order to ensure complete objectivity as they discuss outcome results, make decisions, and formulate recommendations regarding a study. This session does not include the SSG.

The DSMB will have the option to invite other participants to attend any part of the meeting to assist in fulfilling its responsibilities.

## 6 DATA REPORTS

Study data reports will be prepared by the SSG. The Oversight Group and the sponsor will determine the report contents and format initially; the DSMB may request additions and other modifications for subsequent reports. Reports for the meetings consist of separate open and closed session reports.

Data will be provided in both electronic and/or paper form as requested by the DSMB. For each report, a data cutoff will be established to allow a reasonable amount of time to process the data required for DSMB meetings. Open and closed reports will be considered confidential and will be appropriately secured. Copies of reports for closed sessions, except for archival copies retained by the SSG and Executive Secretary, will be destroyed following the meeting. All closed reports will be discarded in a confidential manner 7 years after study completion.

### 6.1 Open Data Report

This report is distributed to the DSMB Members, the Executive Secretary, Oversight Group, Sponsor, and USG and is reviewed in the open session. Information in the open report includes overall data on study conduct, protocol compliance, site performance, QC, follow-up, and participant baseline characteristics exclusive of data by treatment group. Note: Pooled safety data may also be reported with limited distribution, and discussion of this data may require a session with restricted attendance. This process would be described in the SAP or could occur at the discretion of the DSMB.

### 6.2 Closed Data Report

This report is distributed to DSMB Members and the Executive Secretary only and is reviewed in the closed session. In addition to information included in the open report, the closed report includes safety and efficacy outcome data by vaccine/placebo arm. Ordinarily, the by-arm

reports are coded as a safeguard against disclosure through lost documents, and code keys are provided separately to DSMB Members and the Executive Secretary.

All material presented at any session, including closed session documents, will be considered confidential. Copies of reports for closed sessions, except for archival copies retained by the SSG and Executive Secretary, will be destroyed or discarded following the meeting. The SSG will be responsible for ensuring the reports are appropriately discarded.

## **7 DSMB RECOMMENDATIONS**

### **7.1 Routine Recommendations**

Within 1 week after the meeting, the DSMB Executive Secretary works closely with the DSMB Chairperson to prepare and distribute a report summarizing the DSMB recommendations, omitting any confidential information presented at the meeting. After approval of the summary recommendations by the full DSMB, the DSMB Executive Secretary forwards the final version to the Oversight Group Chair. The Sponsor and Oversight Group Chair are then responsible for disseminating the DSMB summary report to other bodies as necessary.

It is acceptable and encouraged for the DSMB to verbally share any recommendations of a routine nature with the Oversight Group, Sponsor, and USG representatives at the meeting.

### **7.2 Major Recommendations**

In circumstances where there is a major recommendation (eg, to stop a study arm), the DSMB first communicates its formal recommendations to the Oversight Group leadership as described in any signed clinical trials agreement or, in the absence of specific language in the clinical trial agreement, to the Sponsor and USG. After consulting with the DSMB, the Sponsor and USG make the final decision to accept the recommendations or not. If the DSMB communicates directly with the Sponsor and USG they may consult with the Oversight Group leadership prior to making a final decision to accept recommendations or not. If approved, the Executive Secretary circulates the DSMB recommendations as described above (section [7.1](#)).

## **8 DOCUMENTATION**

Original documents needed by the Sponsor (eg, meeting agendas, meeting minutes, safety reports/tables/line listings, DSMB Members' meeting reports, QC checklists, document checklists, DSMB Members' faxed signature pages, correspondence) will be managed by the SSG Statistician.

Reports needed by the USG (eg, copies of the reports, open and closed meeting summaries, and COIs) will be maintained by the Executive Secretary.

## APPENDIX 1: COVID-19 VACCINE DSMB ROSTER

Name	Affiliation	Signature	Date
Richard J. Whitley, M.D.	Division Director, Department of Pediatrics Infectious Diseases University of Alabama School of Medicine		
Abdel Babiker, Ph.D.	Professor of Epidemiology and Medical Statistics MRC Clinical Trials Unit at University College London		
Lisa Angeline Cooper, M.D., M.P.H., FACP	James F. Fries Professor of Medicine Welch Center for Prevention, Epidemiology, & Clinical Research Johns Hopkins University School of Medicine and Bloomberg School of Public Health		
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Anastasios A. Tsiatis, Ph.D.	Professor Emeritus Department of Statistics North Carolina State University		

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**APPENDIX 1: COVID-19 VACCINE DSMB ROSTER (cont.)**

<b>Executive Secretaries</b>	
<b>Name</b>	<b>Affiliation</b>
Sally Hunsberger, Ph.D.	Executive Secretary Mathematical Statistician Biostatistics Research Branch National Institute of Allergy and Infectious Diseases, NIH
Martha Nason, Ph.D.	Executive Secretary (Back-Up) Biostatistics Research Branch National Institutes of Health National Institute of Allergy and Infectious Diseases, NIH



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Richard J. Whitley, M.D.	Division Director, Department of Pediatrics Infectious Diseases University of Alabama School of Medicine	Richard J. Whitley <small>Digitally signed by Richard J. Whitley DN: cn=Richard J. Whitley, ou=University of Alabama at Birmingham, ou=Department of Pediatrics Infectious Diseases, c=US</small>	6 Aug 20
Abdel Babiker, Ph.D.	Professor of Epidemiology and Medical Statistics MRC Clinical Trials Unit at University College London		
Lisa Angeline Cooper, M.D., M.P.H., FACP	James F. Fries Professor of Medicine Welch Center for Prevention, Epidemiology, & Clinical Research Johns Hopkins University School of Medicine and Bloomberg School of Public Health		
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Lisa Angeline Cooper, M.D., M.P.H., FACP	James F. Fries Professor of Medicine Welch Center for Prevention, Epidemiology, & Clinical Research Johns Hopkins University School of Medicine and Bloomberg School of Public Health		
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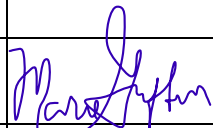
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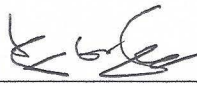
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Steven Joffe, M.D., M.P.H.	Interim Chair, Department of Medical Ethics and Health Policy Perelman School of Medicine University of Pennsylvania	Steve Joffe	Digitally signed by Steve Joffe Date: 2020.08.05 15:58:16 -04'00'
Jorge Kalil, M.D.	Professor and Head of the Clinical Immunology and Allergy Department Heart Institute, Clinics Hospital (HC-FMUSP) Universidade de São Paulo/Brazil		
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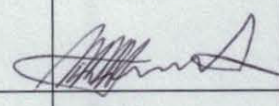


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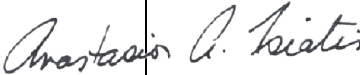
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Anastasios A. Tsiatis, Ph.D.	Professor Emeritus Department of Statistics North Carolina State University		

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Anastasios A. Tsiatis, Ph.D.	Professor Emeritus Department of Statistics North Carolina State University		08/12/2020

## APPENDIX 2: DEFINITIONS

*From the NIAID Policy for Identifying Potential Conflict of Interest for Individuals Serving on Advisory Committees or as Independent Safety Monitors Responsible for Data and Safety Monitoring of Clinical Trials.*

Conflict of Interest (COI) – A situation when someone has or is perceived to have competing professional obligations, proprietary conflicts and/or financial or other personal interests that would make it difficult to fulfill his/her duties fairly. The three types addressed in this policy are as follows :

1. Professional: where the individual, their spouse, dependent children, other relatives with whom the individual has a close relationship, or household members acts as an officer, member, director, expert advisor, etc., of any organization whose study is under review.
2. Financial: where the individual, their spouse, dependent children, other relatives with whom the individual has a close relationship, or household members have significant financial or equity interests in excess of \$5,000 in any entity whose study is under review.
3. Proprietary: where the individual, their spouse, dependent children, other relatives with whom the individual has a close relationship, or household members own or otherwise control rights, including but not necessarily limited to intellectual property rights, relevant to the development and commercialization of any product being reviewed.

# **Charter for the COVID-19 Vaccine Data and Safety Monitoring Board**

**October 30, 2020**

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## LIST OF ABBREVIATIONS

COI	Conflict of interest
COVID-19	Coronavirus disease 2019
DSMB	Data and Safety Monitoring Board
IND	Investigational new drug (application)
NIAID	National Institute of Allergy and Infectious Diseases
NRA	National Regulatory Agency of a country that is accruing participants into the study
QC	Quality control
SAP	Statistical analysis plan
SSG	Statistical Support Group
USG	United States Government

## 1 INTRODUCTION

The Coronavirus Disease 2019 (COVID-19) Vaccine Data and Safety Monitoring Board (DSMB) will monitor all randomized COVID-19 vaccine studies supported by the United States Government (USG). Additional COVID-19 vaccine studies could be included in the portfolio of this DSMB at the discretion of the DSMB Chairperson and Executive Secretary.

The primary role of the DSMB is to make certain that appropriate safeguards are in place to ensure the safety of all study participants and that the studies are conducted with scientific rigor. To accomplish these goals, the DSMB will review enrollment, data completeness, and accumulating safety and outcome data on a regular basis while studies are ongoing. The DSMB will review each study as a stand-alone entity. This Charter describes the organization and procedures of the standing DSMB that will oversee the randomized vaccine studies.

It is anticipated that each protocol will be managed by its own Oversight Group consisting of pharmaceutical company and USG representatives. The Oversight Group will be responsible for the overall conduct of the study.

It is anticipated that the individual investigational new drug applications (INDs) for these studies will be held by the pharmaceutical companies responsible for the study vaccines.

The Director of the National Institute of Allergy and Infectious Diseases (NIAID) will serve as the designated senior representative of the USG.

This document details the roles and responsibilities of the different entities involved in the DSMB review process for each study. The process described in this document will be the same for each study but will occur separately for each study. The defined entities in this document will have the same responsibilities for each study but will be specific for each study. It also outlines what data will be provided to the DSMB, the process for disseminating study data, and the communication plan.

## 2 OVERVIEW OF THE DSMB PROCESS

The DSMB will review unblinded analyses of accumulating efficacy and safety data for studies in order to assess the risk-benefit ratio of the vaccines under investigation. The reviews will be performed according to a specified monitoring plan. The DSMB will make recommendations to the Oversight Group for the particular study concerning the conduct of the studies, including changes to the informed consent form.

At the conclusion of each study, the responsibilities of the DSMB for the study ceases.



### 3 DSMB MEMBERSHIP

The DSMB is a multidisciplinary group independent of a study's academic partners, Oversight Group, Sponsor, and USG. Members have expertise in biostatistics, clinical trials, infectious diseases, vaccine development, vaccine safety and ethics.

The DSMB may consult additional experts on an *ad hoc* basis as needed. All DSMB Members will agree to maintain confidentiality about the proceedings of the DSMB meetings and related activities.

DSMB Members will have no involvement in the study outside their role on the DSMB.

#### 3.1 Conflicts of Interest

DSMB Members must be free of conflicts of interest (COIs) with study investigators, academic partners, funders, and protocol steering committees. Consideration of and decisions regarding potential COIs will follow the NIAID policy on COI for data and safety monitoring (see [Appendix 1](#)). A COI is a situation when an individual has or is perceived to have competing professional obligations, proprietary conflicts, and/or financial or other personal interests that would make it difficult to fulfill his/her duties fairly.

The DSMB Members are responsible for disclosing any new COI before each DSMB review and advising the Sponsor and USG in writing of any potential COIs throughout the duration of the study. The Sponsor and USG are responsible for (i) deciding whether any situation of a DSMB Member has the potential to create an actual or perceived COI, and (ii) providing disclosure to all other DSMB Members of any potential COIs that the Sponsor and USG determine do not impede objectivity. Members of the DSMB who develop significant potential or perceived COIs will be asked to resign from the DSMB.

#### 3.2 Confidentiality of DSMB Deliberations

DSMB Members must agree to maintain the confidentiality of interim data, their deliberations, and their recommendations. Outside of DSMB meetings, written and verbal communications of this information are not permitted without prior approval of the Sponsors and USG other than except for the following circumstance.

At the request of a NRA, a NRA and DSMB may discuss matters related to participant safety in relation to clinical hold. If a discussion occurs, adequate language translation services will be negotiated between the two parties for non-English speaking NRAs. The DSMB and/or DSMB chair may engage in such discussions outside of a formal approval from the Sponsors and USG. Such discussions should not include data on efficacy. In such instances, the Sponsors and USG will be notified that a discussion is planned and/or has taken place. Any written documentation from these meetings will be maintained by the DSMB executive secretary and turned over to the sponsor at the end of the study with all other study materials.

## **4 ROLES AND RESPONSIBILITIES**

### **4.1 Responsibilities of DSMB Members**

The fundamental responsibility of the DSMB is to assure the ongoing safety of study participants and to monitor the study for crossing of boundaries related to efficacy, futility and safety. As part of this important role, the DSMB will:

- Review the vaccine protocols and any amendments during the course of the study.
- Review and endorse the proposed statistical analysis plan (SAP) as written by the Oversight Group and endorsed by the Sponsor.
- Provide an independent review and assessment of the accumulating safety and efficacy data.
- Provide an independent review and assessment of the overall study conduct.
- Make recommendations to the study Sponsors and USG on study continuation, modification or discontinuation.
- Review and approve summaries of the DSMB meetings.

### **4.2 Responsibilities of the DSMB Chairperson**

The DSMB Chairperson will have the following additional responsibilities:

- Set an agenda for the closed session of the meeting.
- Communicate DSMB recommendations to the Oversight Group, study Sponsors, and USG.
- Facilitate discussion by DSMB Members on the closed data and the formulation of recommendations.
- Provide initial review and approval of summaries of the DSMB meetings prepared by the Executive Secretary.
- Discuss confidential safety issues with the NRA as the boards representative.
- In circumstances when there is a major recommendation (eg, to stop a study or study arm, or substantially modify the study for safety reasons), inform the Sponsors and USG.

### **4.3 Responsibilities of the DSMB Executive Secretary**

The DSMB Executive Secretary is a biostatistician in the Biostatistics Research Branch of the Division of Clinical Research, NIAID. The Executive Secretary will be the point of contact between the DSMB and the Sponsor and USG.

The Executive Secretary will have the following responsibilities:

- Work with the Oversight Group to set an agenda for the open session of the meeting.
- Attend all meetings or provide designated back up.
- Coordinate timelines for production and distribution of the open and closed reports with the unblinded biostatisticians.
- Supervise technical support for the DSMB meetings, including scheduling.

- Draft preliminary DSMB recommendations and provide them for approval to the DSMB Chairperson, followed by DSMB Members, within 1 week of the DSMB review.
- Draft and revise meeting summaries.
- Distribute the final open meeting summary to the DSMB and the protocol leadership and Sponsor within 1 week of the meeting.
- Distribute closed meeting summary documents, if any, to the DSMB and unblinded statisticians within 1 week of the meeting.
- In circumstances where a major recommendation is accepted by the Sponsor (eg, to stop a study arm or substantially modify the study for safety reasons), provide written summary recommendations to the Oversight Group within 72 hours of the DSMB review, after approval by the DSMB Chairperson and DSMB Members.
- Archive meeting summaries as well as closed session data reports and documents for 7 years after study completion.

#### **4.4 Responsibilities of Pharmaceutical Company Sponsors**

The Sponsors will ensure that the data are provided to the Statistical Support Group (SSG, section [4.6](#)).

The Sponsors (in coordination with the Oversight Group) will forward the required reports and documents to the appropriate regulatory bodies.

The Sponsors (in coordination with the USG and Oversight Group) will be responsible for acting on the recommendations of the DSMB.

The Sponsor is responsible for selecting a group independent of the study that will support the DSMB and perform all analyses for the DSMB reports (referred to as the Statistical Support Group).

#### **4.5 Responsibilities of the US Government**

The USG (in coordination with the Sponsors and Oversight Group) will be responsible for acting on the recommendations of the DSMB.

#### **4.6 Responsibilities of the Statistical Support Group**

The SSG includes an unblinded statistician (SSG Statistician) and may additionally include a project manager and a programmer. One person may serve more than one role.

The SSG Statistician has the following major responsibilities:

- Ensure the SAP is agreed to by the DSMB Members and the Oversight Group.
- Oversee the SSG programming staff to ensure that tables, listings, and figures for the open and closed report follow the SAP, conducting a quality control (QC) review of all reports prior to sending to the DSMB Members.

- Obtain the treatment assignment data from the appropriate party.
- Work with the SSG programming staff to maintain an archive of electronic copies of the datasets and the SAS or R programs used to generate DSMB reports.
- Inform the DSMB Chairperson and Executive Secretary when the potential harm boundary has been crossed.
- Serve as a liaison between the DSMB and the Oversight Group when the need arises for additional information.

SSG responsibilities include the following:

- Immediately inform DSMB Members of the death of study participants.
- Send the data package to DSMB Members.
- Send reports to NRA if detailed in the SAP or as directed by the DSMB.
- Request transfers of the clinical datasets from the Sponsor and randomization code from the appropriate party.
- Request additional data relevant to the reports from the Protocol Oversight Group.

#### **4.7 DSMB Responsibilities of the Protocol Oversight Group**

The Oversight Group will determine who from the protocol team will attend the open sessions of the DSMB. The primary responsibilities of the Oversight Group with respect to the DSMB are:

- In conjunction with SSG, prepare open reports for the DSMB.
- Review and approve the open session DSMB meeting summary.
- Notify the DSMB of protocol amendments.
- Update the DSMB on information from other studies relevant to the conduct of the study under review.
- Notify the DSMB of any significant new safety information.
- Implement DSMB recommendations endorsed by the USG and the sponsor.
- Notify the institutional review boards of DSMB recommendations within the timeframes of national/local requirements.
- Provide data to the SSG relevant to the closed report.

## **5 DSMB MEETINGS**

Most meetings of the DSMB will be by teleconference. All DSMB Members are expected to participate in each meeting of the DSMB. Every effort will be made to schedule meetings to ensure that all Members can participate. However, given that there will be meetings when not all Members can attend, an official DSMB meeting may be held with a quorum consisting of at least 7 voting members present, including at least 1 clinician and 1 biostatistician. With approval from the full DSMB, a smaller group of members could be empowered to address a specific issue.

Data review meetings will be scheduled according to the interim monitoring schedule outlined in the protocol and SAP. At a minimum, it is anticipated that meetings to review each open study will occur monthly. The DSMB may alter the review schedule if they determine a change in the

review schedule is indicated to fulfill its responsibilities. To promptly address emerging and unanticipated issues that require urgent DSMB attention, the Chairperson may convene additional *ad hoc* meetings as needed.

## **5.1 Meeting Format**

Each scheduled DSMB meeting will consist of open, closed, and executive sessions.

## **5.2 Open Session**

The open session is open to members of the Oversight Group, Sponsor representatives of any study being reviewed, and USG representatives including those from the NRAs. This session will deal with issues relating to the general conduct and progress of the study, such as accrual, patient demographics and other baseline characteristics, data QC, adherence to the protocol, retention, and follow-up.

## **5.3 Closed Session**

At the closed session, safety and efficacy data by treatment group will be reviewed. Comparative results are presented to the DSMB in closed reports, and closed sessions are attended only by DSMB Members, the Executive Secretary, the SSG, and *ad-hoc* members if required.

## **5.4 Closed Executive Session**

This session involves only the DSMB Members (including *ad-hoc* members if applicable) and the Executive Secretary in order to ensure complete objectivity as they discuss outcome results, make decisions, and formulate recommendations regarding a study. This session does not include the SSG.

The DSMB will have the option to invite other participants to attend any part of the meeting to assist in fulfilling its responsibilities.

# **6 DATA REPORTS**

Study data reports will be prepared by the SSG. The Oversight Group and the sponsor will determine the report contents and format initially; the DSMB may request additions and other modifications for subsequent reports. Reports for the meetings consist of separate open and closed session reports.

Data will be provided in both electronic and/or paper form as requested by the DSMB. For each report, a data cutoff will be established to allow a reasonable amount of time to process the data required for DSMB meetings. Open and closed reports will be considered confidential and will be appropriately secured. Copies of reports for closed sessions, except for archival copies retained by the SSG and Executive Secretary, will be destroyed following the meeting. All closed reports will be discarded in a confidential manner 7 years after study completion.

## **6.1 Open Data Report**

This report is distributed to the DSMB Members, the Executive Secretary, Oversight Group, Sponsor, and USG and is reviewed in the open session. Information in the open report includes overall data on study conduct, protocol compliance, site performance, QC, follow-up, and participant baseline characteristics exclusive of data by treatment group. Note: Pooled safety data may also be reported with limited distribution, and discussion of this data may require a session with restricted attendance. This process would be described in the SAP or could occur at the discretion of the DSMB.

## **6.2 Closed Data Report**

This report is distributed to DSMB Members and the Executive Secretary only and is reviewed in the closed session. In addition to information included in the open report, the closed report includes safety and efficacy outcome data by vaccine/placebo arm. Ordinarily, the by-arm reports are coded as a safeguard against disclosure through lost documents, and code keys are provided separately to DSMB Members and the Executive Secretary.

All material presented at any session, including closed session documents, will be considered confidential. Copies of reports for closed sessions, except for archival copies retained by the SSG and Executive Secretary, will be destroyed or discarded following the meeting. The SSG will be responsible for ensuring the reports are appropriately discarded.

# **7 DSMB RECOMMENDATIONS**

## **7.1 Routine Recommendations**

Within 1 week after the meeting, the DSMB Executive Secretary works closely with the DSMB Chairperson to prepare and distribute a report summarizing the DSMB recommendations, omitting any confidential information presented at the meeting. After approval of the summary recommendations by the full DSMB, the DSMB Executive Secretary forwards the final version to the Oversight Group Chair. The Sponsor and Oversight Group Chair are then responsible for disseminating the DSMB summary report to other bodies as necessary.

It is acceptable and encouraged for the DSMB to verbally share any recommendations of a routine nature with the Oversight Group, Sponsor, and USG representatives at the meeting.

## **7.2 Major Recommendations**

In circumstances where there is a major recommendation (eg, to stop a study arm), the DSMB first communicates its formal recommendations to the Oversight Group leadership as described in any signed clinical trials agreement or, in the absence of specific language in the clinical trial agreement, to the Sponsor and USG. After consulting with the DSMB, the Sponsor and USG make the final decision to accept the recommendations or not. If the DSMB communicates directly with the Sponsor and USG they may consult with the Oversight Group leadership prior

to making a final decision to accept recommendations or not. If approved, the Executive Secretary circulates the DSMB recommendations as described above (section [7.1](#)).

## **8 DOCUMENTATION**

Original documents needed by the Sponsor (eg, meeting agendas, meeting minutes, safety reports/tables/line listings, DSMB Members' meeting reports, QC checklists, document checklists, DSMB Members' faxed signature pages, correspondence) will be managed by the SSG Statistician.

Reports needed by the USG (eg, copies of the reports, open and closed meeting summaries, and COIs) will be maintained by the Executive Secretary.

## APPENDIX 1: DEFINITIONS

*From the NIAID Policy for Identifying Potential Conflict of Interest for Individuals Serving on Advisory Committees or as Independent Safety Monitors Responsible for Data and Safety Monitoring of Clinical Trials.*

Conflict of Interest (COI) – A situation when someone has or is perceived to have competing professional obligations, proprietary conflicts and/or financial or other personal interests that would make it difficult to fulfill his/her duties fairly. The three types addressed in this policy are as follows :

1. Professional: where the individual, their spouse, dependent children, other relatives with whom the individual has a close relationship, or household members acts as an officer, member, director, expert advisor, etc., of any organization whose study is under review.
2. Financial: where the individual, their spouse, dependent children, other relatives with whom the individual has a close relationship, or household members have significant financial or equity interests in excess of \$5,000 in any entity whose study is under review.
3. Proprietary: where the individual, their spouse, dependent children, other relatives with whom the individual has a close relationship, or household members own or otherwise control rights, including but not necessarily limited to intellectual property rights, relevant to the development and commercialization of any product being reviewed.





**Analysis Plan for DATA SAFETY MONITORING BOARD  
(DSMB)**

**A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled  
Study to Evaluate the Safety, Efficacy, and Immunogenicity of mRNA-  
1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older**

**Moderna Therapeutics, Inc.**

**Protocol mRNA-1273-P301**

**Investigational Medicinal Product: mRNA-1273**

**Date: 07 August 2020**

**Version: 2.0**

**STATEMENT OF CONFIDENTIALITY**

The confidential information in the following document is provided to you as an investigator, potential investigator, or consultant, for review by you, your staff, and applicable institutional review board(s). It is understood that the information will not be used, divulged, or published without the written consent of Moderna Therapeutics, Inc., except to the extent necessary to obtain informed consent from those persons to whom study medication may be administered.

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## PURPOSE

The Coronavirus Disease 2019 (COVID-19) Vaccine Data and Safety Monitoring Board (DSMB) will monitor all randomized COVID-19 vaccine studies supported by the United States Government (USG). This document describes the statistical considerations for Moderna mRNA-1273-P301 study.

### 1. STUDY OVERVIEW

Study P301 is a Phase 3, randomized, stratified, observer-blind, placebo-controlled study to evaluate the efficacy, safety, and immunogenicity of mRNA-1273 vaccine compared to placebo in adults 18 years of age and older who have no known history of SARS-CoV-2 infection but whose locations or circumstances put them at appreciable risk of acquiring COVID-19 and/or SARS-CoV-2 infection. Figure 1 shows the study flow.

#### Randomization

Up to approximately 30,000 participants will be randomized in 1:1 ratio to receive either mRNA-1273 100 µg or placebo.

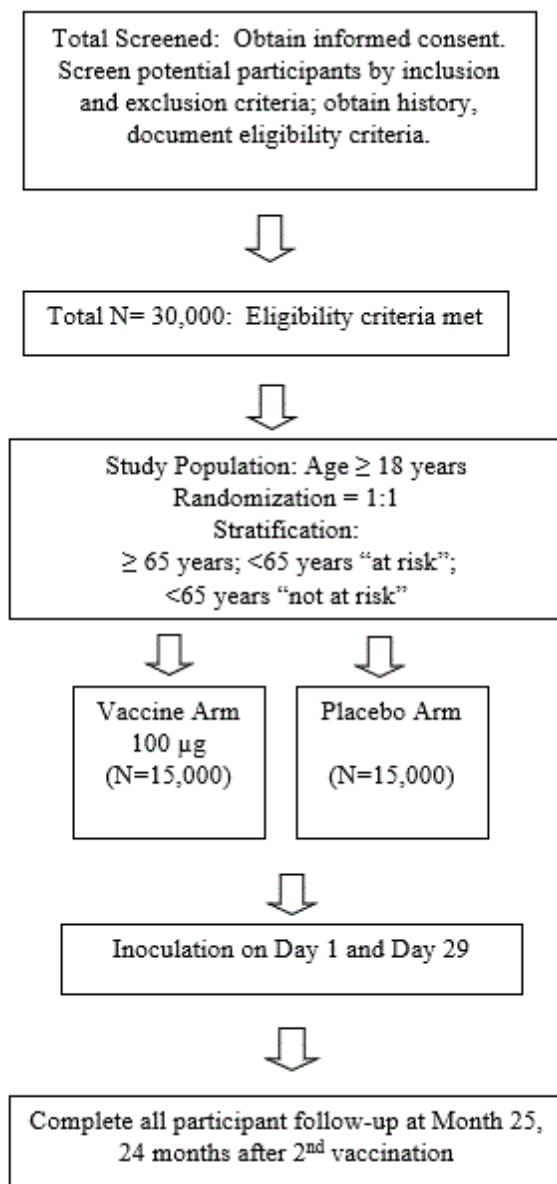
Randomization will be stratified based on age and, for participants < 65 years of age, based on the presence or absence of risk factors for severe illness from COVID-19, as determined by current CDC recommendation ([CDC 2020b](#)). There will be 3 strata for randomization:  $\geq 65$  years, < 65 years and categorized to be at increased risk (“at risk”) for the complications of COVID-19, and < 65 years “not at risk.” Risk will be defined based on a study participant’s relevant past and current medical history. At least 25% of enrolled participants, but not to exceed 40%, will be either  $\geq 65$  years of age or < 65 years of age and at risk at Screening.

Participants who are < 65 years old will be categorized as at risk for severe COVID-19 illness if they have at least 1 of the following risk factors at Screening:

- Chronic lung disease (e.g., emphysema and chronic bronchitis), idiopathic pulmonary fibrosis and cystic fibrosis) or moderate to severe asthma
- Significant cardiac disease (e.g., heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)
- Severe obesity (body mass index  $\geq 40$  kg/m<sup>2</sup>)
- Diabetes (Type 1, Type 2 or gestational)
- Liver disease

Thus, there will be 3 strata for randomization:  $\geq 65$  years,  $< 65$  years at risk, and  $< 65$  years not at risk.

**Figure 1: Study Flow Diagram**



### Study Vaccine:

The mRNA-1273 vaccine is a lipid nanoparticle (LNP) dispersion of an mRNA encoding the prefusion stabilized S protein of SARS-CoV-2 formulated in LNPs composed of 4 lipids (1 proprietary and 3 commercially available): the proprietary ionizable lipid SM-102; cholesterol; 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC); and

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1-monomethoxypolyethyleneglycol-2,3-dimyristylglycerol with polyethylene glycol of average molecular weight 2000 (PEG2000-DMG). mRNA-1273 Injection is provided as a sterile liquid for injection, white to off white dispersion in appearance, at a concentration of 0.5 mg/mL in 20 mM Tris buffer containing 87 mg/mL sucrose and 10.7 mM sodium acetate at pH 7.5.

The placebo is 0.9% sodium chloride (normal saline) injection, United States Pharmacopeia (USP).

Further details on the physical, chemical, and pharmaceutical properties of mRNA-1273 can be found in the Investigator's Brochure (IB).

## 2. Objectives and endpoints

**Table 1: Objectives and Endpoints**

<b>Objectives and Endpoints</b>	
<b>Primary Objective</b>	<b>Primary Endpoints</b>
<b>Efficacy Objective (Primary):</b> To demonstrate the efficacy of mRNA-1273 to prevent COVID-19.	<p><b>Efficacy Endpoints (Primary):</b> Vaccine efficacy (VE) of mRNA-1273 to prevent the first occurrence of COVID-19 starting 14 days after the second dose of investigational product (IP), where COVID-19 is defined as symptomatic disease based on the following criteria:</p> <ul style="list-style-type: none"> <li>• The participant must have experienced at least TWO of the following systemic symptoms: Fever (<math>\geq 38^{\circ}\text{C}</math>), chills, myalgia, headache, sore throat, new olfactory and taste disorder(s), OR</li> <li>• The participant must have experienced at least ONE of the following respiratory signs/symptoms: cough, shortness of breath or difficulty breathing, OR clinical or radiographical evidence of pneumonia; AND</li> <li>• The participant must have at least one nasopharyngeal (NP) swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) positive for SARS-CoV-2 by RT-PCR.</li> </ul> <p>The primary endpoint will be based on assessment of the adjudication committee if the assessments are available. The adjudication committee will be blinded to treatment assignment.</p>

<p><b>Safety Objective (Primary):</b>          To evaluate the safety and reactogenicity of 2 injections of the mRNA-1273 vaccine given 28 days apart.</p>	<p><b>Safety Endpoint (Primary):</b></p> <ul style="list-style-type: none"> <li>• Solicited local and systemic adverse reactions (ARs) through 7 days after each dose of IP.</li> <li>• Unsolicited AEs through 28 days after each dose of IP.</li> <li>• Medically attended adverse events (MAAEs) or AEs leading to withdrawal throughout the entire study period.</li> <li>• SAEs throughout the entire study period.</li> <li>• Pregnancy and perinatal outcomes.</li> </ul>
<p><b>Efficacy Objectives (Secondary)</b></p>	<p><b>Efficacy Endpoints (Secondary)</b></p>
<p>To evaluate the efficacy of mRNA-1273 to prevent severe COVID-19.</p>	<ul style="list-style-type: none"> <li>• Vaccine efficacy of mRNA-1273 to prevent severe COVID-19, defined as first occurrence of COVID-19 starting 14 days after the second dose of IP, (as per the primary endpoint) AND any of the following:             <ul style="list-style-type: none"> <li>○ Clinical signs indicative of severe systemic illness; Respiratory Rates <math>\geq 30</math> per minute, Heart Rate <math>\geq 125</math> beats per minute, <math>SpO_2 \leq 93\%</math> on room air at sea level or <math>PaO_2/FIO_2 &lt; 300</math> mm Hg, OR</li> <li>○ Respiratory failure or Acute Respiratory Distress Syndrome (ARDS), (defined as needing high-flow oxygen, non-invasive or mechanical ventilation, or ECMO), evidence of shock (systolic blood pressure <math>&lt; 90</math> mmHg, diastolic BP <math>&lt; 60</math> mmHg or requiring vasopressors), OR</li> <li>○ Significant acute renal, hepatic or neurologic dysfunction, OR</li> <li>○ Admission to an intensive care unit or death.</li> </ul> </li> </ul>

To evaluate the efficacy of mRNA-1273 to prevent serologically confirmed SARS-CoV-2 infection or COVID-19 regardless of symptomatology or severity.	Vaccine efficacy of mRNA-1273 to prevent the first occurrence of either COVID-19 or SARS-CoV-2 infection starting 14 days after the second IP dose. This endpoint is a combination of COVID-19, defined as for the primary endpoint, and asymptomatic SARS-CoV-2 infection, determined by seroconversion assessed by bAb levels against SARS-CoV-2 as measured by a ligand-binding assay specific to the SARS-CoV-2 nucleocapsid protein and with a negative NP swab sample for SARS-CoV-2 at Day 1 (Section 8.1.1 of protocol).
To evaluate VE against a secondary definition of COVID-19.	Vaccine efficacy of mRNA-1273 to prevent the secondary case definition of COVID-19 starting 14 days after the second IP dose. The secondary case definition of COVID-19 is defined as at least one of the following systemic symptoms: fever (temperature $\geq 38^{\circ}\text{C}$ ) or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle aches or body aches, headache, new loss of taste or smell, sore throat, nasal congestion or rhinorrhea, nausea or vomiting, or diarrhea AND a positive NP swab, nasal swab, or saliva sample for SARS-CoV-2 by RT-PCR.
To evaluate VE to prevent death caused by COVID-19.	Vaccine efficacy of mRNA-1273 to prevent death due to a cause directly attributed to a complication of COVID-19, starting 14 days after the second IP dose.
To evaluate the efficacy of mRNA-1273 to prevent COVID-19 after the first dose of IP.	Vaccine efficacy of mRNA-1273 to prevent the first occurrence of COVID-19 starting 14 days after the first dose of IP.
To evaluate the efficacy of mRNA-1273 to prevent COVID-19 in all study participants, regardless of evidence of prior SARS-CoV-2 infection.	Vaccine efficacy of mRNA-1273 to prevent the first occurrence of COVID-19 starting 14 days after the second dose of IP regardless of evidence of prior SARS-CoV-2 infection determined by a baseline serologic titer against SARS-CoV-2 nucleocapsid (FAS analysis population, see Section 9.4 of protocol).
To evaluate the efficacy of mRNA-1273 to prevent asymptomatic SARS-CoV-2 infection.	Vaccine efficacy to prevent the first occurrence of SARS-CoV-2 infection in the absence of symptoms defining COVID-19 starting 14 days after the second IP dose. SARS-CoV-2 infection determined by seroconversion assessed by bAb levels against SARS-CoV-2 as measured by a ligand-binding assay specific to the SARS-CoV-2 nucleocapsid protein and with a negative NP swab sample for SARS-CoV-2 at Day 1 (Section 8.1.1 of protocol).



Immunogenicity Objective (Secondary):	Immunogenicity Endpoints (Secondary):
To evaluate the immunogenicity of 2 doses of mRNA-1273 given 28 days apart.	<ul style="list-style-type: none"> <li>• Geometric mean titer (GMT) of SARS-CoV-2-specific neutralizing antibody (nAb) on Day 1, Day 29, Day 57, Day 209, Day 394, and Day 759.</li> <li>• Geometric mean fold rise (GMFR) of SARS-CoV-2-specific nAb relative to Day 1 on Day 29, Day 57, Day 209, Day 394, and Day 759.</li> <li>• Quantified levels or GMT of S protein-specific binding antibody (bAb) on Day 1, Day 29, Day 57, Day 209, Day 394, and Day 759.</li> <li>• GMFR of S protein-specific bAb relative to Day 1 on Day 29, Day 57, Day 209, Day 394, and Day 759.</li> </ul>
<b>Exploratory Objectives</b>	
To evaluate the effect of mRNA-1273 on the viral infection kinetics, as measured by viral load at SARS-CoV-2 infection diagnosis by RT-PCR and number of days from the estimated date of SARS-CoV-2 infection until undetectable SARS-CoV-2 infection by RT-PCR.	
To assess VE to reduce the duration of symptoms of COVID-19.	
To assess VE against burden of disease (BOD) due to COVID-19.	
To evaluate VE against all-cause mortality.	
To evaluate the genetic and/or phenotypic relationships of isolated SARS-CoV-2 strains to the vaccine sequence.	
To evaluate immune response markers after dosing with IP as correlates of risk of COVID-19 and as correlates of risk of SARS-CoV-2 infection.	
To conduct additional analyses related to furthering the understanding of SARS-CoV-2 infection and COVID-19, including analyses related to the immunology of this or other vaccines, detection of viral infection, and clinical conduct.	

Abbreviations: AE = adverse event; AR = adverse reaction; bAb = binding antibody; GMFR = geometric mean fold rise; GMT = geometric mean titer; ICU = intensive care unit; MAAE = medically attended adverse event; nAb = neutralizing antibody; NP = nasopharyngeal; SAE = serious adverse event; VE = vaccine efficacy.

### 3. Responsibilities of the Data and Safety Monitoring Board (DSMB)

An independent DSMB will periodically review blinded and unblinded data, including both safety and cases of COVID-19 at scheduled data review meetings and at 2 planned interim analyses. The DSMB will make recommendations to an Oversight Group (OG), such as continuation or termination of vaccinations or follow-up, or other design modifications,

either due to persuasive evidence of efficacy, non-efficacy, vaccine harm, or unacceptable safety issues, guided by pre-specified formal statistical monitoring boundaries if applicable. The responsibilities of the DSMB and the OG are to safeguard the interest of study participants and to enhance the integrity of the study. The independent DSMB review unblinded data, i.e. are unblinded to the treatment group assignments. The OG consists of representatives from the SPONSOR, BARDA, and NIAID. The members of the OG are blinded to the treatment assignments, i.e. review treatment-group blinded data.

- In addition to blinded and unblinded review of safety data, at each data review meeting, the DSMB will review the numbers and rate of COVID-19 cases, including rate of severe COVID disease with prespecified thresholds for imbalance in the treatment groups which would trigger halting rules.
- At the interim analyses (IAs), the DSMB will review the interim analyses results. If early efficacy has been achieved based on the boundaries as described in Section 3.1, the DSMB will make recommendations to the OG. Based on DSMB and OG's recommendation, the SPONSOR will make decisions in terms of study results reporting and unblinding of limited SPONSOR and CRO personnel to enable the SPONSOR to prepare for CSR and regulatory interaction.
- At the IAs, the DSMB will also monitor the study for non-efficacy. The boundary for non-efficacy is non-binding and is based on the nominal confidence interval (CI) of VE to prevent stopping the study early before the vaccine effect ramps up. The boundary for non-efficacy is based on the nominal CI of VE of mRNA-1273 to prevent COVID-19 (the primary objective). If the CI falls below 0%, i.e., upper bound < 0%, the boundary for non-efficacy is considered met.
- The DSMB will monitor the study for vaccine harm based on both COVID-19 and severe COVID-19. Continuous harm monitoring will be provided for COVID-19 and severe COVID-19 separately. For harm monitoring, cases will be counted starting after the first vaccination according to the IP subjects actually received regardless of the treatment group subjects were randomized to. The monitoring boundaries are provided based on the exact binomial test conditional on the total number of cases, each test is performed at an one-sided type I error rate of 0.05. Monitoring using the harm bounds for COVID-19 will start with 9 cases; monitoring using harm bounds for severe COVID-19 will start with 5 such cases. Details are provided in [Section 3.3](#).
- The boundaries are considered guidelines, i.e., a recommendation to modify the study would not be based solely on statistical rules, as many other factors (i.e.,

totality of the data from the study including additional efficacy, safety and immunogenicity endpoints as well as data external to the study) may be part of the decision process. In the case when a recommendation is made to continue the trial despite crossing the boundaries for efficacy or inefficacy, the reason for disregarding the boundary must be documented in the meeting minutes and communicated to the OG.

After each data review meeting or IA, the DSMB will make a recommendation to the OG, and based on the DSMB and OG's recommendation, the Sponsor may take one of the following courses of action:

- Unblind the study (i.e. limited SPONSOR personnel will be unblinded), or stop further enrollment, if applicable, to facilitate filing if criteria for early efficacy are met.
- Pause the study or stop further enrollment due to a safety concern or non-efficacy if the criteria for non-efficacy are met.
- Pause enrollment and consider a change in study design.
- Continue the study as is.

The Sponsor or the Protocol Safety Review Team (PSRT) may also request that the DSMB conduct ad hoc reviews of safety events from this study or other data, including new nonclinical or clinical information related to mRNA-1273 external to this study. The DSMB will review all available study data to adjudicate such events in accordance with the DSMB charter.

### 3.1 Efficacy at Interim Analyses

For the primary efficacy objective, the null hypothesis of this study is that the VE of mRNA-1273 to prevent first occurrence of COVID-19 is  $\leq 30\%$  (i.e.,  $H_0^{\text{efficacy}}: \text{VE} \leq 0.3$ ).

The study will be considered to meet the primary efficacy objective if the corresponding CI of VE rules out 30% (i.e., the lower bound of the CI  $> 30\%$ ) at either one of the interim analyses or at the primary analysis based on the primary efficacy endpoint using the PP Set.

There are 2 planned IAs when 35% and 70% of total target cases towards the primary efficacy endpoint (approximately 151 cases at the primary analysis, Table 2) have accrued across the two vaccine groups. The primary objective of the IAs is for early detection of reliable evidence that VE is above 30%. The Lan-DeMets O'Brien-Fleming approximation spending function is used for calculating efficacy bounds and to preserve the (one-sided)

0.025 false positive error rate over the IAs and the primary analysis (when the target number of cases have been observed), relative to the hypothesis:

$H_0^{\text{efficacy}}$ :  $HR \geq 0.7$  (equivalently, proportional-hazards  $VE \leq 0.3$ ).

Vaccine efficacy is defined as the percent reduction in the hazard of the primary endpoint (mRNA-1273 vs placebo). The VE will be estimated using one minus the hazard ratio (HR) (mRNA-1273 vs placebo). A stratified Cox proportional hazard model will be used to assess the magnitude of the treatment group difference (i.e., HR) between mRNA-1273 and placebo. The HR and its 95% CI from the stratified Cox model with Efron's method of tie handling and with treatment group as the covariate will be reported. The same stratification factors used for randomization will be applied to the stratified Cox model.

The Per-Protocol (PP) Set will be used as the primary analysis population for analyses of efficacy. For the primary efficacy analysis, cases will be counted starting 14 days after the second vaccination. All numbers in this section pertain to the PP set and the primary efficacy analysis approach. Analyses of the primary endpoint will be also performed based on the modified intent-to-treat (mITT) Set using the same methods described above.

For the primary efficacy endpoint, sensitivity analyses with cases counted immediately after the second vaccination, and immediately after randomization will also be carried out.

There is no intention to stop the study early if the efficacy has been demonstrated at any of the IAs; the subjects will continue in the study per protocol, investigators, site staff, participants, and Sponsor and CRO staff with oversight of study conduct will remain blinded to treatment allocation for the study duration.

If efficacy is demonstrated at an IA, the subsequent IA or primary analysis will be considered supportive in nature. The DSMB will review the IA results and make recommendations to the OG. Based on DSMB and OG's recommendation, the SPONSOR will make decisions in terms of study results reporting and unblinding of limited SPONSOR and CRO personnel based on the boundaries of early efficacy as described in this section, safety data, and data external to this study. In addition to possible early efficacy at IAs, the DSMB will monitor for non-efficacy and vaccine harm; the guiding principles (non-binding) are provided in Section 3.2 and Section 3.3.

[Table 2](#) summarizes the timing, number of cases, and decision guidance at each IA and primary analysis.

The first IA will occur when approximately 35% of the total cases (53 cases) have been observed (across both treatment groups). The study will be considered positive at the first IA if the p-value for rejecting  $HR \geq 0.7$  is less than 0.0002 based on the Lan-DeMets O'Brien-Fleming approximation spending function.

The second IA will occur when approximately 70% of the total cases (106 cases) have been observed. The study will be considered positive (VE has been demonstrated) if the p-value for rejecting  $HR \geq 0.7$  is less than 0.0073 based on the Lan-DeMets O'Brien-Fleming approximation spending function.

Equivalently, at each IA, vaccine efficacy is considered demonstrated if the corresponding alpha-adjusted confidence interval of VE rules out 30% (i.e. lower bound of CI >30%).

If the study continues to the primary analysis, a prespecified group of study personnel within Moderna will be unblinded and responsible for conducting this analysis. Moderna study team personnel responsible for ongoing safety and efficacy until Month 25 (24 months after the 2<sup>nd</sup> vaccination) will remain blinded. The primary analysis will be performed when approximately 151 cases have been observed in the study. The study will be considered positive at the primary analysis if the one-sided p-value for rejecting  $HR \geq 0.7$  is less than 0.0227 hazard ratio, or equivalently, if the alpha-adjusted confidence interval rules out 30%.

**Table 2: Interim boundaries using O'Brien-Fleming spending function, calculation is based on the PP population for the primary efficacy endpoint (Table 12 of the protocol)**

Information fraction (% of total #cases)	Number of cases	Nominal Alpha	Efficacy Boundary Rejecting $H_0$ (VE $\leq$ 30%)	Probability (of crossing efficacy boundary if the true VE = 60%)
<b>IA1 35%</b>	53	0.0002	VE $\geq$ 0.741 (HR $\leq$ 0.259)	4.6%
<b>IA2 70%</b>	106	0.0073	VE $\geq$ 0.565 (HR $\leq$ 0.435)	61.5%
<b>Primary analysis 100%</b>	151	0.0227	VE $\geq$ 0.495 (HR $\leq$ 0.505)	90.0%

The proposed list of summary tables to be included in the DSMB package at the interim analyses is provided in [Appendix B](#). The DSMB package at each interim analysis will include results on disposition, baseline characteristics, efficacy and safety. For data review meetings prior to the first interim analysis, or between planned analyses, the DSMB package will include data on disposition, baseline characteristics, and safety.

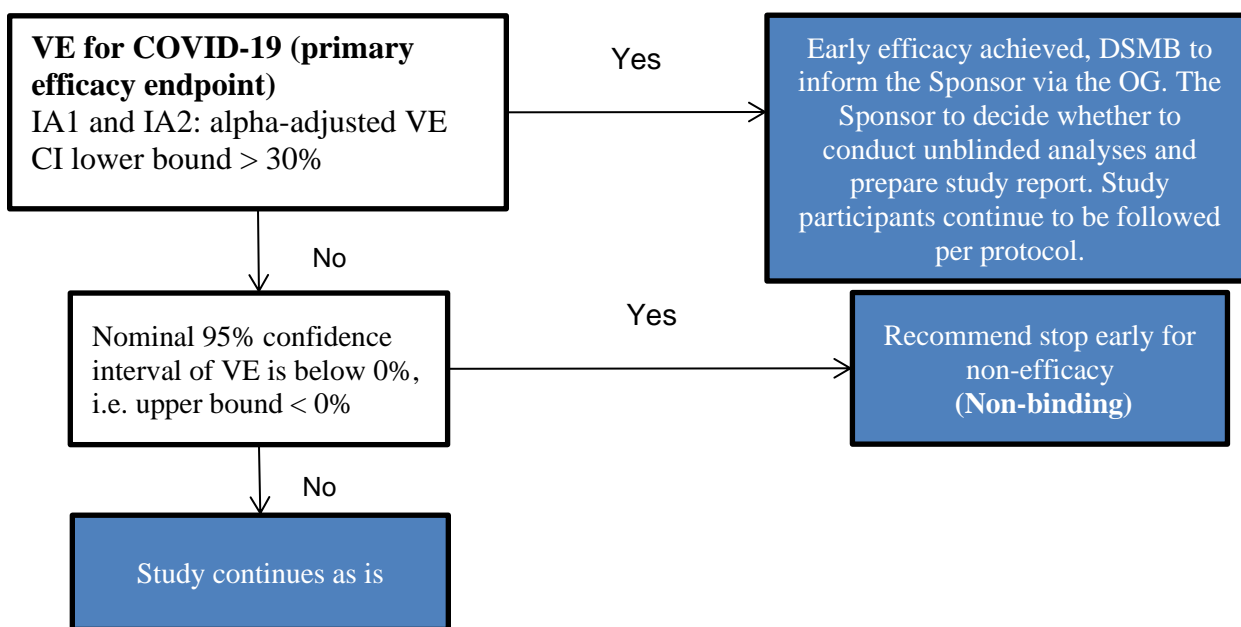
### 3.2 Monitoring for non-efficacy at the Interim Analyses

At the interim analyses, the DSMB will also monitor for non-efficacy. The boundary for non-efficacy is non-binding and is based on the nominal confidence interval (CI) of VE to prevent stopping the study early before the vaccine effect ramps up. The boundary for

non-efficacy is based on the nominal 95% confidence interval of VE of mRNA-1273 to prevent COVID-19 (the primary objective). If the CI falls below 0%, i.e., upper bound <0%, the boundary for non-efficacy is considered met. At the IAs, both alpha-adjusted confidence intervals and the nominal 95% CI of VE will be provided.

Figure 1 outlines the decision guidance at IAs. The boundaries are considered guidelines, i.e., a recommendation to modify the study would not be based solely on statistical rules, as many other factors (i.e., totality of the data from the study including efficacy, safety and immunogenicity as well as data external to the study) may be part of the decision process. In the case a recommendation is made disregarding the boundaries, the reason for disregarding them must be documented in the meeting minutes and communicated to the OG.

Figure 1. Decision guidelines at IAs



### 3.3 Monitor for Potential Vaccine Harm

The DSMB will monitor the study for potential vaccine harm based on imbalance between mRNA-1273 vs. placebo for both COVID-19 and severe COVID-19 case counts. Monitoring for vaccine harm will be based on the Safety Set, defined as all

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randomized participants who received at least one injection of study vaccination.

Participants will be analysed according to the IP that they actually received regardless of the group to which they were randomized. For harm monitoring, cases will be counted starting after the first dose of study vaccination.

The unblinded statisticians will inform and update the DSMB chair of each case of COVID-19 and severe COVID-19 on a continuous basis.

Potential vaccine harm is continuously monitored by evaluating number of COVID-19 and severe COVID-19 cases separately, in vaccine and placebo arm. The unblinded statisticians will continuously monitor the trial (i.e., examine the data after each COVID-19 case, and each severe COVID-19 case, respectively) for early evidence of a potential elevated rate of COVID-19 or severe COVID-19 in the mRNA-1273 group compared to the placebo group, in the FAS. If the prespecified stopping boundary is reached for either COVID-19 or severe COVID-19, then the unblinded statisticians will immediately inform the DSMB that the harm rules have been met. This monitoring guideline is chosen to allow stopping for prudence as early as possible, maximizing participant safety.

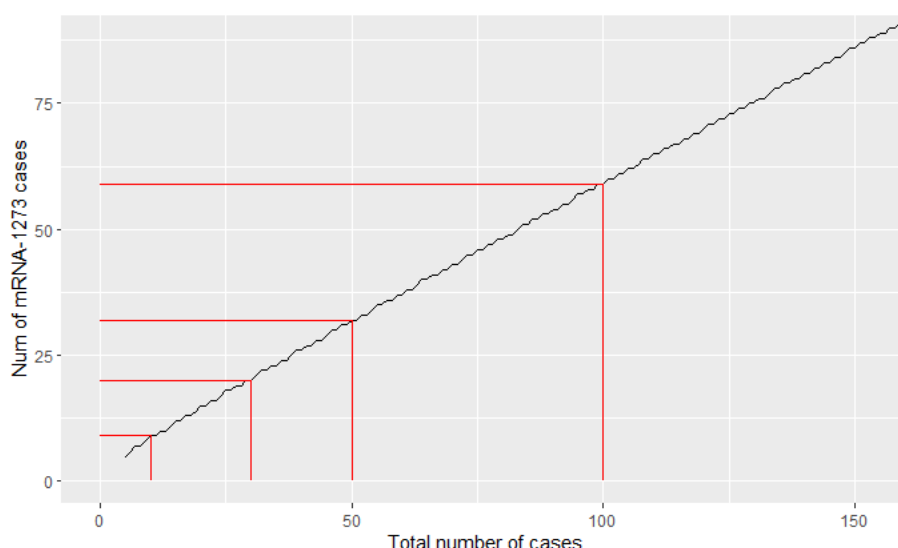
Harm monitoring will be based on COVID-19 and severe COVID-19 separately. The monitoring for each is implemented with exact one-sided binomial tests of  $H_0: p = 0.5$  versus  $H_1: p > 0.5$ , where  $p$  is the probability that a case participant would be in the vaccine group given the total number of cases. The bounds for harm monitoring are based on the assumption that  $VE=0\%$  (corresponds to  $p=0.5$ ).

For COVID-19, such analyses start at the 9th case confirmed after the first vaccination and continue at each additional case. Each test is performed at one-sided type I error rate of 0.05. At the first interim analysis both efficacy and non-efficacy will be evaluated. After the 1<sup>st</sup> interim analysis, the DSMB can decide whether to continue to monitor using the harm bound provided up to 153 cases; or to use analysis for non-efficacy at the interim analyses.

For severe COVID-19, descriptive monitoring of severe COVID-19 cases will be provided starting from the 1<sup>st</sup> severe case, and a formal guideline for potential harm is also provided starting from 5 severe cases, using a similar approach as that for COVID-19, to allow early stopping if there is evidence of an elevated rate of severe disease in the mRNA-1273 vs. placebo group. The monitoring for potential harm based on the number of severe COVID-19 cases will continue at least until the primary analysis.

Table A-1 in Appendix A shows the stopping bounds and probability of crossing the bounds if the true vaccine efficacy =0 (corresponding to  $p=0.5$ ) starting from a total of 5 cases and up to 153 cases. The same table can be used for harm monitoring based on COVID-19 and severe COVID-19, with monitoring using the bounds for COVID-19 starts at 9 cases; and monitoring using the bounds for severe COVID-19 starts at 5 cases. The stopping bounds are also illustrated in Figure 2.

Figure 2. Stopping bounds for potential vaccine harm, based on exact binomial test conditional on the total number of cases, each test to be performed at one-sided alpha of 0.05



### 3.4 Additional Monitoring for Disease Enhancement

In addition to monitoring the imbalance in COVID-19 and severe COVID-19 between mRNA-1273 and placebo group, exploratory analysis on burden of disease (BOD) will be provided to the DSMB to assess potential disease enhancement.

A BOD score is defined based on the post SARS-CoV-2 infection follow-up to reflect the severity of symptoms (Table 3).

**Table 3: Burden of Disease Score**

Patient State (Worst Category Following Disease Detection)	BOD Score
Without COVID-19 (Uninfected/Asymptomatic infection)	0



COVID-19 without hospitalization (Symptomatic without hospitalization)	1
COVID-19 with Hospitalization	2
Death	3

Summary of BOD score, number and percentage of subject with each level of BOD score, will be provided by treatment group. A non-parametric Wilcoxon test based on the ranks of the BOD scores will be performed to compare mRNA-1273 vs. placebo group.

BOD score will be summarized by periods of follow-up time, subjects who are un-diseased at the beginning of each period will be included in the summary for the corresponding period. There will be 4 periods: from randomization through 6 months; 6 months through 12 months; 12 months through 18 months; and 18 months through completion. To assess impact of baseline risk of severe disease on the vaccine effect regarding disease severity, summary of BOD will be provided by randomization strata (i.e.  $\geq 65$  years,  $< 65$  years at risk, and  $< 65$  years not at risk).

In order to assess the disease burden in subjects with COVID-19, the above analyses will also be performed in participants with COVID-19, i.e. subjects with BOD score of zero will be excluded from the analysis.

These tables will be provided to the DSMB at each interim analysis.

While transparent, the proportions in the summary table will change with increased follow-up time as more subjects inevitably acquire disease. This makes comparisons across different periods of follow-up difficult. To augment this analysis, a proportional means model may be used to assess the treatment effect on BOD between mRNA-1273 and placebo in terms of ratio of mean severity score. The proportional means model allows for direct comparisons across different periods of follow-up, unaffected by differential follow-up.

To fully understand the impact of vaccination on disease severity, asymptomatic infections should also be evaluated. Similarly, a burden of infection (BOI) score will be used to understand the impact. Because asymptomatic infection is identified by seroconversion only at months 1, 2, 7, 13 and 25, summary of BOI will be provided for relevant periods (i.e. M1 through M2, M2 through M7, M7 through M13, and M13 through M25) only using subjects who have serological data for that period. A non-parametric Wilcoxon test based on the ranks of the BOI scores will be performed to compare mRNA-1273 vs. placebo group. Similarly, in order to assess the infection/disease burden in subjects with infection

regardless of symptoms, the above analyses will also be performed in participants with infection regardless of symptoms, i.e. subjects with BOI score of zero will be excluded from such analysis.

**Table 4: Burden of Infection Score**

<b>Patient State (Worst Category Following Disease Detection)</b>	<b>BOI Score</b>
No infection	0
Asymptomatic infection	1/2
COVID-19 without hospitalization (Symptomatic without hospitalization)	1
COVID-19 with Hospitalization	2
Death	3

#### **4. Statistical Considerations for DSMB**

This section describes the planned statistical analysis strategy and procedures for DSMB review. A detailed comprehensive statistical analysis plan (SAP) will be developed for the study and will be finalized before the clinical database lock for the study and treatment unblinding.

Additional DSMB requests will be documented in DSMB minutes, and, if required, additional statistical methods may be provided as appendix to the DSMB package or this document may be amended to document additional statistical methods or procedures used to address DSMB's requests.

##### **4.1 Blinding and Responsibility for Analyses**

The Sponsor Biostatistics department or designee is responsible for analyses to be reviewed by the DSMB. There are two planned interim analyses and a primary analysis in this study, as described in [Section 3.1](#). Participant-level unblinding will be restricted to an independent unblinded statistician and, as needed, a statistical programmer performing the IAs, who will have no other responsibilities associated with the study.

The DSMB will review treatment-level results of the IAs, provided by the independent unblinded statistician. Limited additional Sponsor personnel may be unblinded to the treatment-level results of the IAs, if required, in order to act on the recommendations of

the DSMB. The extent to which individuals are unblinded with respect to results of IAs will be documented. Depending on the recommendation of the DSMB, the Sponsor may prepare a regulatory submission after an IA. In this case, pre-identified Sponsor members, including the analysis and reporting team, will be unblinded to treatment assignments and remain unblinded for the remainder of the study. Participants and investigators will remain blinded.

## 4.2 Statistical Hypotheses

For the primary efficacy objective, the null hypothesis of this study is that the VE of mRNA-1273 to prevent first occurrence of COVID-19 is  $\leq 30\%$  (i.e.,  $H_0^{\text{efficacy}}: \text{VE} \leq 0.3$ ).

The study will be considered to meet the primary efficacy objective if the corresponding CI of VE rules out 30% (i.e. the lower bound of the CI of  $\text{VE} > 30\%$ ) at either one of the interim analyses or at the primary analysis.

## 4.3 Sample Size Determination

The sample size is driven by the total number of cases to demonstrate VE (mRNA-1273 vs. placebo) to prevent COVID-19. Under the assumption of proportional hazards over time and with 1:1 randomization of mRNA-1273 and placebo, a total of 151 COVID-19 cases will provide 90% power to detect a 60% reduction in hazard rate (60% VE), rejecting the null hypothesis  $H_0: \text{VE} \leq 30\%$ , with 2 IAs pre-specified when 35% and 70% of the target total number of cases have been accrued, using a 1-sided O'Brien-Fleming boundary for efficacy and a log-rank test statistic with a 1-sided false positive error rate of 0.025. The total number of cases pertains to the PP Set accruing at least 14 days after the second dose. Up to approximately 30,000 participants will be randomized with the following assumptions:

- The target VE against COVID-19 is 60% (with 95% CI lower bound ruling out 30%, rejecting the null hypothesis  $H_0: \text{VE} \leq 30\%$ )
- A 6-month COVID-19 incidence rate of 0.75% in the placebo arm
- An annual dropout rate of 2% (loss of evaluable participants)
- Fifteen percent of the participants are seropositive at baseline, are non-compliant with injection assessments, or have major protocol deviations
- Two IAs will be performed when 35% and 70% of the total target number of cases have been accrued across the 2 groups with O'Brien-Fleming boundaries for efficacy monitoring
- 3-month uniform accrual

- Approximately 15% of participants will be excluded from the PP population, and participants are at risk for COVID-19 starting 14 days after the second dose

Table 5 provides sample size with 90% power to demonstrate VE on COVID-19.

**Table 5: Conditions and Sample Size to Demonstrate Vaccine Efficacy**

Target VE	Lower Bound	Randomization Ratio	Total # of Cases	6-Month Incidence Rate		Total Sample Size*
				Placebo	mRNA-1273	
60%	30%	1:1	151	0.75%	0.30%	30,000

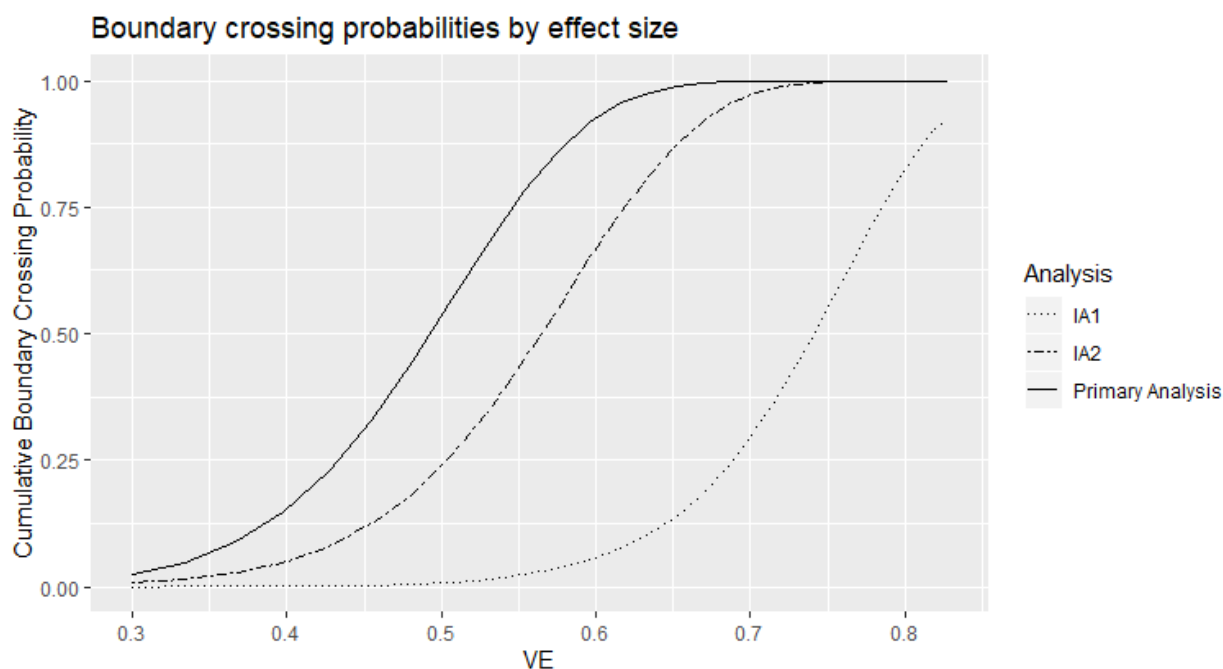
\*Sample size to account for 15% participants to be excluded from the PP Set (e.g., seropositive at baseline, have not received planned IP)

The sample size is calculated using R package gsDesign (Anderson 2020)

Under these above assumptions, including 6-month incidence rate of 0.75% on placebo, with 30,000 participants, it will take approximately 5, 8, and 10 months from study start (first subject first dose), respectively, to accrue 35% (approximately 53), 70% (approximately 106) and 100% (151) of the target number of cases in the PP Set.

Figure 4 shows the power of the primary efficacy endpoint under true VE at the 2 planned IAs and the primary efficacy analysis assuming a total of 151 events.

**Figure 4: Boundary Crossing Probabilities by Effect Size**



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The Sponsor may adjust the size of the study or duration of follow-up based on the blinded review of the total number of cases of COVID-19 accrued during the study, in addition to the estimated percentages of study participants with serologic evidence of SARS-CoV-2 infection at baseline.

#### **4.4 Analysis Populations**

Analysis populations for statistical analyses are Randomization Set, Full Analysis Set (FAS), modified intent-to-treat (mITT) set, Per Protocol (PP) Set, Immunogenicity Subset, Solicited Safety Set, and Safety Set, as shown in [Table 6](#).

**Table 6: Populations for Analyses**

<b>Population</b>	<b>Description</b>
Randomization Set	All participants who are randomized, regardless of the participants' treatment status in the study.
Full Analysis Set (FAS)	All randomized participants who received at least one dose of IP. Participants will be analyzed according to the group to which they were randomized.
Modified Intent-to-Treat (mITT) Set	All participants in the FAS who had no immunologic or virologic evidence of prior COVID-19 (i.e. negative NP swab test at Day 1, and/or bAb against SARS-CoV-2 nucleocapsid below LOD or LLOQ) at Day 1 before the first dose of IP. Participants will be analyzed according to the group to which they were randomized.
Per-protocol (PP) Set	All participants in the mITT Set who received planned doses of IP per schedule and have no major protocol deviations. Participants will be analyzed according to the group to which they were randomized.
Immunogenicity Subset	All participants in the FAS who had a valid immunogenicity test result prior to the first dose of IP and at least 1 valid result after the first dose of IP.
Solicited Safety Set	The Solicited Safety Set consists of all randomized participants who received at least one dose of IP and contributed any solicited AR data. The Solicited Safety Set will be used for the analyses of solicited ARs and participants will be included in the treatment group corresponding to the IP that they actually received.
Safety Set	All randomized participants who received at least one dose of IP. The Safety Set will be used for all analyses of safety except for the solicited ARs. Participants will be included in the treatment group corresponding to the IP that they actually received.

## 4.5 Statistical Analyses

This section provides a summary of the planned statistical analyses of the primary and secondary endpoints.

The overall Type I error rate for the primary endpoint at the IAs and the primary analysis is strictly controlled at 2.5% (1-sided) based on the Lan-DeMets O'Brien-Fleming approximation spending function. The primary efficacy results that will be considered statistically significant after consideration of the strategy for controlling the Type I error as described in [Section 3.1](#). Statistical significance of the primary efficacy endpoint can be achieved at either one of the interim analyses or at the primary analysis. A sequential/hierarchical testing procedure will be used to control type 1 error rate over the primary efficacy endpoint and the secondary efficacy endpoints. Secondary efficacy endpoints will only be tested when the primary efficacy endpoint achieves statistical significance. Multiplicity adjustments among the secondary efficacy endpoints may be performed, in which case, they will be specified in the more detailed SAP.

#### 4.5.1 Efficacy Analyses

Efficacy analyses will be performed using the FAS, mITT and PP populations, and participants will be included in the treatment group to which they are randomized. The primary analysis population will be the PP Set. In the primary efficacy analysis approach, cases will be counted starting 14 days after the second vaccination.

[Table 7](#) summarizes the analysis approach for primary and secondary efficacy endpoints. Sensitivity analysis methods are described for each endpoint as applicable.

**Table 7: Statistical Analysis Methods of Efficacy Endpoints to be presented to DSMB**

Endpoint	Statistical Analysis Methods
<b>Primary endpoint:</b> Vaccine Efficacy (VE) of mRNA-1273 to prevent COVID-19	<ul style="list-style-type: none"> <li>Primary analysis: VE will be estimated with <math>1 - \text{HR}</math> (mRNA-1273 vs placebo) using a Cox proportional hazard regression model with treatment group as a fixed effect and adjust for the stratification factor based on the PP Set, with cases counted starting 14 days after the second dose of IP.</li> <li>Analysis using the same model based on the mITT Set.</li> <li>Sensitivity analysis using the same model based on the PP Set, with cases counted starting either immediately after the second dose of IP or immediately after the first dose of IP</li> <li>Subgroup analysis of the primary efficacy endpoint will be performed to assess consistency of VE, such as in the age groups <math>\geq 18</math> and <math>&lt; 65</math> years and <math>\geq 65</math> years</li> <li>Supportive analysis of VE to be estimated with <math>1 - \text{ratio of incidence rates}</math> with 95% CI using the exact method conditional upon the total number of cases</li> </ul>
<b>Secondary endpoints:</b>	Similar analysis method as for the primary endpoint analysis.

<ul style="list-style-type: none"> <li>• Vaccine efficacy of mRNA-1273 to prevent severe COVID-19</li> <li>• Vaccine efficacy of mRNA-1273 to prevent serologically confirmed SARS-CoV-2 infection or COVID-19 regardless of symptomatology or severity</li> <li>• Vaccine efficacy of mRNA-1273 to prevent COVID-19 using a secondary definition of symptoms</li> <li>• Vaccine efficacy of mRNA-1273 to prevent death due to COVID-19</li> <li>• Vaccine efficacy of mRNA-1273 to prevent COVID-19 after the first dose of IP</li> <li>• Vaccine efficacy of mRNA-1273 to prevent asymptomatic SARS-CoV-2 infection</li> </ul>	<p>For each of the secondary endpoints:</p> <ul style="list-style-type: none"> <li>• Primary analysis: VE will be estimated with <math>1 - \text{HR}</math> (mRNA-1273 vs placebo) using a Cox proportional hazard regression model with treatment group as a fixed effect and adjusting for the stratification factor based on the PP Set, with cases counted starting 14 days after the second dose of IP.</li> <li>• Analysis using the same model based on the mITT Set.</li> <li>• Sensitivity analyses with cases counted starting immediately after the second dose of IP, 14 days after the first dose of IP, immediately after the first dose of IP, and immediately after randomization.</li> <li>• Vaccine efficacy and 95% CI will be estimated with <math>1 - \text{ratio of incidence rates}</math> using the exact method conditional upon the total number of cases.</li> </ul>
<ul style="list-style-type: none"> <li>• Vaccine efficacy of mRNA-1273 to prevent COVID-19 in all study participants, regardless of evidence of prior SARS-CoV-2 infection</li> </ul>	<p>The FAS population will be used for this secondary objective, using similar analysis methods as for the primary endpoint analysis.</p> <ul style="list-style-type: none"> <li>• Primary analysis: VE will be estimated with <math>1 - \text{HR}</math> (mRNA-1273 vs placebo) using a Cox proportional hazard regression model with treatment group as a fixed effect and adjusting for the stratification factor based on the FAS, with cases counted starting 14 days after the second dose of IP.</li> <li>• Sensitivity analyses with cases counted starting immediately after the second dose of IP, 14 days after the first dose of IP, immediately after the first dose of IP, and immediately after randomization.</li> </ul>

#### 4.5.1.1 Efficacy Analysis on Primary Endpoint

To assess the primary efficacy endpoint of VE of mRNA-1273 in preventing the first occurrence of COVID-19 from 14 days after second dose of IP, Cox proportional hazards regression will be used to estimate proportional hazards VE (PH VE), measured by one minus the HR (mRNA-1273 vs. placebo), with a 2-sided score-based 95% CI and 2-sided  $p$ -value for testing  $H_0: \text{VE} \leq 30\%$ .

Vaccine efficacy is defined as the percent reduction in the hazard of the primary endpoint (mRNA-1273 vs placebo). The VE will be estimated using one minus the HR (mRNA-1273 vs placebo) estimand. A stratified Cox proportional hazard model will be used to assess the magnitude of the treatment group difference (i.e., HR) between mRNA-1273 and placebo. The HR and its 95% CI from the stratified Cox model with Efron's method of tie handling and with treatment group as covariate will be reported. The same stratification factors used for randomization will be applied to the stratified Cox model.



For the primary efficacy endpoints, participants without documented COVID-19 will be censored at the last study assessment date. Potential intercurrent events may include:

- 1) withdrawal from the study or death unrelated to COVID-19, for which, the time to COVID-19 will be censored at the date of withdrawal from the study or death;
- 2) early COVID-19 up to 14 days after second study dose, for which, the time to COVID-19 will be censored at the time of early infection;
- 3) missing dose of IP; and
- 4) seropositive at baseline.

For the primary efficacy analysis, cases will be counted starting 14 days after the second dose of IP. Sensitivity analyses with cases counted starting immediately after the second dose of IP and starting immediately after randomization will also be carried out.

Subgroup analysis of the primary efficacy endpoint will be performed in selected subgroups, such as age groups  $\geq 18$  and  $< 65$  year and  $\geq 65$  years to assess consistency of VE as described in Section 9.5.5 of the protocol.

As a supportive analysis, VE will also be estimated by one minus the infection rate ratio, where the number of cases (i.e., participants with first occurrence of COVID-19) will be used and the CI will be computed using the exact method conditional upon the total number of cases.

For exploratory analysis of the vaccine effect on the COVID-19 primary endpoint over time, the instantaneous hazard ratio (mRNA-1273/placebo) of the endpoint will be estimated with pointwise and 95% confidence intervals, using nonparametric kernel smoothing estimation of each of the vaccine and placebo arm hazard functions over time, using the method of Gilbert et al. (2002, Biometrics) with optimal bandwidths selected using the analytical formula in Andersen et al. (1993). At each interim analysis, a plot of the hazard ratio results, as well as plots of the point estimates and pointwise and simultaneous 95% confidence interval estimates for the treatment-arm specific hazard functions, will be provided to the DSMB. If the number of severe COVID-19 events (protocol secondary endpoint) becomes large enough to warrant analysis (upon DSMB recommendation), the same analysis may be applied for this endpoint.

#### **4.5.1.2 Efficacy Analyses for Secondary Endpoints**

- Vaccine efficacy to prevent severe COVID-19

- Vaccine efficacy to prevent serologically confirmed SARS-CoV-2 infection or COVID-19 regardless of symptomology or severity
- Vaccine efficacy to prevent COVID-19 using a broad definition of symptoms
- Vaccine efficacy to prevent asymptomatic SARS-CoV-2 infection

For each of the above secondary objectives, the same Cox proportional hazard model described above for the primary objective will be applied using the PP Set, with cases counted starting 14 days after the second dose of IP. Sensitivity analyses with cases counted starting after the second dose of IP, 14 days after the first dose of IP, immediately after the first dose of IP, and immediately after randomization will also be performed.

The same model will be applied using the mITT population, with cases counted starting 14 days after the second dose of IP.

Vaccine efficacy will be estimated with 1- ratio of incidence rates with the 95% CI using the exact method conditional upon the total number of cases.

#### Vaccine efficacy to prevent COVID-19 after the first dose of IP

The same Cox proportional hazard model described above for the primary objective will be applied using the PP Set, with cases counted starting 14 days after the first dose of IP.

#### Vaccine efficacy to prevent COVID-19 regardless of prior SARS-CoV-2 infection

The FAS will be used for analysis to evaluate VE to prevent COVID-19 regardless of prior SARS-CoV-2 infection. The same methods described above for the primary objective will be applied with cases counted starting 14 days after the second dose of IP. Sensitivity analyses with cases counted starting immediately after the second dose of IP, 14 days after the first dose of IP, immediately after the first dose of IP, and from randomization will also be performed.

Vaccine efficacy will be estimated with 1- ratio of incidence rates with the 95% CI using the exact method conditional upon the total number of cases.

### **4.5.2 Safety Analyses**

All safety analyses will be based on the Safety Set, except summaries of solicited ARs, which will be based on the Solicited Safety Set. All safety analyses will be provided by treatment group and baseline SARS-CoV-2 serostatus, unless otherwise specified.

Safety and reactogenicity will be assessed by clinical review of all relevant parameters.

The number and percentage of participants with any solicited local AR, with any solicited systemic AR, and with any solicited AR during the 7-day follow-up period after each dose will be provided. A 2-sided 95% exact CI using the Clopper-Pearson method will be also provided for the percentage of participants with any solicited AR for each treatment group.

Number and percentage of participants with unsolicited AEs, SAEs, MAAEs, Grade 3 or higher ARs and AEs, and AEs leading to discontinuation from IP or withdrawal from the study will be summarized. Unsolicited AEs will be presented by MedDRA preferred term and system organ class.

Number of events of solicited ARs, unsolicited AEs/SAEs, and MAAEs will be reported in summarization tables accordingly.

For all other safety parameters, descriptive summary statistics will be provided, and [Table 8](#) summarizes analysis strategy for safety parameters.

**Table 8: Analysis Strategy for Safety Parameters**

<b>Safety Endpoint</b>	<b>Number and Percentage of Participants, Number of Events</b>	<b>95% CI</b>
Any Solicited AR (overall and by local, systemic)	X	X
Any Unsolicited AE	X	
Any SAE	X	
Any Unsolicited MAAE	X	
Any Unsolicited Treatment-Related AE	X	
Any Treatment-Related SAE	X	
Discontinuation due to AE	X	
Any Grade 3 and above AE	X	
Any Treatment-Related Grade 3 and above AE	X	

Notes: 95% CI using the Clopper-Pearson method, X = results will be provided. Unsolicited AEs will be summarized by SOC and PT coded by MedDRA.

Further details will be described in the SAP.

## APPENDIX A: Guidance for Monitoring for Potential Vaccine Harm

Table A-1: Stopping bounds for Harm monitoring with cases starting after Dose 1. Each test is based on exact binomial test given the total number of cases at one-sided alpha = 0.05 under  $H_0: p = 0.5$  (corresponds to  $VE=0$ ). For COVID-19 cases, bounds to be used starting at 9 cases; for severe COVID-19 cases, bounds to be used starting at 5 cases.

Total cases	Harm Bound (#cases on mRNA-1273 $\geq$ )	
	mRNA-1273	Placebo
5	5	0
6	6	0
7	7	0
8	7	1
9	8	1
10	9	1
11	9	2
12	10	2
13	10	3
14	11	3
15	12	3
16	12	4
17	13	4
18	13	5
19	14	5
20	15	5
21	15	6
22	16	6
23	16	7
24	17	7
25	18	7
26	18	8
27	19	8
28	19	9
29	20	9
30	20	10
31	21	10
32	22	10
33	22	11
34	23	11
35	23	12
36	24	12
37	24	13
38	25	13
39	26	13

40	26	14
41	27	14
42	27	15
43	28	15
44	28	16
45	29	16
46	30	16
47	30	17
48	31	17
49	31	18
50	32	18
51	32	19
52	33	19
53	33	20
54	34	20
55	35	20
56	35	21
57	36	21
58	36	22
59	37	22
60	37	23
61	38	23
62	38	24
63	39	24
64	40	24
65	40	25
66	41	25
67	41	26
68	42	26
69	42	27
70	43	27
71	43	28
72	44	28
73	45	28
74	45	29
75	46	29
76	46	30
77	47	30
78	47	31
79	48	31
80	48	32
81	49	32
82	49	33
83	50	33

84	51	33
85	51	34
86	52	34
87	52	35
88	53	35
89	53	36
90	54	36
91	54	37
92	55	37
93	55	38
94	56	38
95	57	38
96	57	39
97	58	39
98	58	40
99	59	40
100	59	41
101	60	41
102	60	42
103	61	42
104	61	43
105	62	43
106	62	44
107	63	44
108	64	44
109	64	45
110	65	45
111	65	46
112	66	46
113	66	47
114	67	47
115	67	48
116	68	48
117	68	49
118	69	49
119	69	50
120	70	50
121	71	50
122	71	51
123	72	51
124	72	52
125	73	52
126	73	53
127	74	53

128	74	54
129	75	54
130	75	55
131	76	55
132	76	56
133	77	56
134	78	56
135	78	57
136	79	57
137	79	58
138	80	58
139	80	59
140	81	59
141	81	60
142	82	60
143	82	61
144	83	61
145	83	62
146	84	62
147	84	63
148	85	63
149	86	63
150	86	64
151	87	64
152	87	65
153	88	65





**APPENDIX B: Proposed Tables for DSMB – Subject to update**

<b>Disposition and Baseline Characteristics</b>
Subject Disposition
Number of Subjects in Each Analysis Set
Baseline Demographics
<b>For Harm Monitoring</b>
For Harm Monitoring: Summary of COVID-19 and Severe COVID-19 cases Starting from Randomization Safety Set
<b>Efficacy- only to be provided at the planned IAs*</b>
Summary of Primary and Secondary Efficacy Endpoints
Summary of RT-PCR Test for SARS-CoV-2 <sup>1</sup>
Summary of COVID-19 Symptoms Assessment
Analysis of Vaccine Efficacy against COVID-19 - Primary Analysis Approach PP Set
Analysis of Vaccine Efficacy against COVID-19 - Sensitivity Analysis (cases starting from 2nd vaccination) PP Set
Analysis of Vaccine Efficacy against COVID-19 - Sensitivity Analysis (cases starting from randomization) PP Set
Analysis of Vaccine Efficacy against COVID-19 - Primary Analysis Approach mITT
Analysis of Vaccine Efficacy against COVID-19 - Sensitivity Analysis (cases starting from 2nd vaccination) mITT
Analysis of Vaccine Efficacy against COVID-19 - Sensitivity Analysis (cases starting from randomization) mITT
Analysis of Vaccine Efficacy against Severe COVID-19 - Primary Analysis Approach PP Set
Analysis of Vaccine Efficacy against Severe COVID-19 - Primary Analysis Approach mITT
Analysis of Vaccine Efficacy against Infection - Primary Analysis Approach PP Set
Analysis of Vaccine Efficacy against infection - Primary Analysis Approach mITT
Analysis of Vaccine Efficacy against COVID-19 using a Secondary Definition of Symptoms - Primary Analysis Approach PP Set
Analysis of Vaccine Efficacy against COVID-19 using a Secondary Definition of Symptoms - Primary Analysis Approach mITT
Analysis of Vaccine Efficacy against COVID-19 after 1st Vaccination - Primary Analysis Approach PP Set
Analysis of Vaccine Efficacy against COVID-19 after 1st Vaccination - Primary Analysis Approach mITT
Analysis of Vaccine Efficacy against asymptomatic COVID-19 - Primary Analysis Approach PP Set
Analysis of Vaccine Efficacy against asymptomatic COVID-19 - Primary Analysis Approach mITT
Analysis of Vaccine Efficacy against Death regardless of Cause - PP Set
Analysis of Vaccine Efficacy against Death regardless of Cause - mITT

Analysis of Vaccine Efficacy against Death regardless of Cause - FAS
Analysis of Vaccine Efficacy against COVID-19 regardless of Prior SARS-CoV-2 Infection- Primary Analysis Approach FAS
Analysis of Vaccine Efficacy against COVID-19 regardless of Prior SARS-CoV-2 Infection- Sensitivity Analysis (Cases Starting after Randomization) FAS
Analysis of Vaccine Efficacy against COVID-19 - Sensitivity Analysis (Cases Starting from Randomization) PP Set
Summary of Burden of Disease
Analysis of Burden of Disease
Summary of Burden of Infection
Analysis of Burden of Infection
Summary of Burden of Disease in Subjects with COVID-19
Analysis of Burden of Disease in Subjects with COVID-19
Summary of Burden of Infection in Subjects with COVID-19 Infection regardless of Symptoms
Analysis of Burden of Infection in Subjects with COVID-19 Infection regardless of Symptoms
<b>Safety</b>
Summary of Solicited Adverse Reactions by Grade After First Injection - First Injection Solicited Safety Set
Summary of Solicited Adverse Reactions by Grade After Second Injection - Second Injection Solicited Safety Set
Summary of Solicited Adverse Reactions by Grade After Any Injection - Solicited Safety Set
Summary of Solicited Adverse Reactions by Onset Day After First Injection - First Injection Solicited Safety Set
Summary of Solicited Adverse Reactions by Onset Day After Second Injection - Second Injection Solicited Safety Set
Summary of Solicited Adverse Reactions by Onset Day After Any Injection - Solicited Safety Set
Summary of Number of Days of Solicited Adverse Reactions After First Injection - First Injection Solicited Safety Set
Summary of Number of Days of Solicited Adverse Reactions After Second Injection -Second Injection Solicited Safety Set
Summary of Number of Days of Solicited Adverse Reactions After Any Injection - Solicited Safety Set
Summary of Solicited Adverse Reactions Persisting beyond 7 days After First Injection - First Injection Solicited Safety Set
Summary of Solicited Adverse Reactions Persisting beyond 7 days After Second Injection - Second Injection Solicited Safety Set

Summary of Solicited Adverse Reactions Persisting beyond 7 days After Any Injection - Solicited Safety Set
Summary of Unsolicited TEAE -Safety Set
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term
Subject Incidence of Serious Treatment-Related TEAE by System Organ Class and Preferred Term
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study by System Organ Class and Preferred Term
Subject Incidence of Unsolicited Grade $\geq 3$ TEAE by System Organ Class and Preferred Term
Subject Incidence of Unsolicited Treatment-Related Grade $\geq 3$ TEAE by System Organ Class and Preferred Term
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term
Subject Incidence of Unsolicited TEAE by Preferred Term in Subjects with SARS-CoV-2
Subject Incidence of Serious TEAE by Preferred Term in Subjects with SARS-CoV-2
Summary of Vital Signs and Change from Baseline by Visit
Shift from Baseline in Vital Signs Toxicity Grades by Visit
<b>Immunogenicity at baseline</b>
Summary of SARS-CoV-2 Results by RT-PCR at baseline

\*Efficacy tables will only be provided at the planned interim analyses except for Tables 1 that may be provided at the Data Review meetings upon DSMB's request

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**APPROVAL**

Protocol Number: mRNA-1273-P301  
Document Description: Analysis Plan for DSMB  
Version Number: 1.1  
Effective Date: 23 July 2020

Author(s):

Honghong Zhou, PhD, Senior Director, Biostatistics

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Signature Date

Approved by:

Han Shu, PhD, VP, Biostatistics

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Signature Date

Brett Leav, MD, VP, Clinical Development, Public Health Vaccines

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Signature Date

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Approved by:

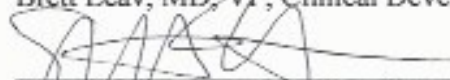
Han Shu, PhD, VP, Biostatistics

DocuSigned by:  
*Shu Han* 7-August-2020

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Signature	Date
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Brett Leav, MD, VP, Clinical Development, Public Health Vaccines

 7 AUGUST 2020

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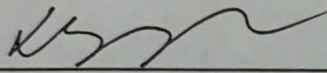
Signature	Date
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