Immune thrombocytopenic purpura (ITP) – adult - Version 3.2 Criteria

Name	Indication/Section	Changes	Date change made in this document	Changed in BloodSTAR date
[redacted]	Qualifying Criteria 4 – inability to leave comment	Comment section added to Qualifying criteria 4 for evidence item 'There is a risk of clinically significant bleeding'	04/08/2023	30/11/2023
[redacted]	Indication	BSS release 3 2024 introduced the functionality to automatically approve Ig requests for the listed indication. This was done via data fix so no change to criteria version.	22/11/2024	08/12/2024

	Version 3.2 Criteria	Comments
Condition Name	Immune thrombocytopenic purpura (ITP) — adult	
Condition Short Name	Immune thrombocytopenic purpura (ITP) - adult	
Specialty	Haematology	
Keywords	Evans; persistent; Acute; Chronic; Newly diagnosed; thrombocytopenia; idiopathic; HIV; haematology; autoimmune.	
Chapter	5 – Established therapeutic role	
Specific conditions	• Newly Diagnosed immune thrombocytopenic purpura (ITP) • Persistent immune thrombocytopenic purpura (ITP) • Chronic immune thrombocytopenic purpura (ITP) • Evans syndrome, with significant immune thrombocytopenic purpura (ITP) – adult	
Level of Evidence	Evidence of probable benefit (Category 2a).	
Description and Diagnostic Criteria	Immune thrombocytopenic purpura (ITP) is a reduction in platelet count (thrombocytopenia) resulting from shortened platelet survival due to anti-platelet antibodies, reduced platelet production due to immune induced reduced megakaryopoiesis and/or immune mediated direct platelet lysis. When counts are very low (less than 30 x 10^9/L), bleeding into the skin (purpura) and mucous membranes can occur. Bone marrow platelet production (megakaryopoiesis) is morphologically normal. In some cases, there is additional impairment of platelet function related to antibody binding to glycoproteins on the platelet surface. It is a common finding in patients with human immunodeficiency virus (HIV) disease, and while it may be found	

	at any stage of the infection, its prevalence increases as HIV disease advances. Around 80 percent of adults with ITP have the chronic form of disease. The highest incidence of chronic ITP is in women aged 15 to 50 years, although some reports suggest increasing incidence with age. Chronic ITP may relapse and remit spontaneously and the course may be difficult to predict. If the platelet count can be maintained at a level that prevents spontaneous bleeding or bruising, the outlook is good. The terminology from the ITP International Consensus Report (Provan et al, 2010) for the phases and severity of ITP disease are used in these Criteria. Newly diagnosed is used for all cases within three months of diagnosis; Persistent ITP relates to patients not achieving spontaneous remission within 3 to 12 months from diagnosis or not maintaining a response to treatment during this time; chronic ITP indicates patients with ITP lasting greater than 12 months. Severe ITP relates to patients with clinically relevant bleeding mandating treatment or new bleeding mandating a change in therapy. In the context of these Criteria, refractory refers to patients where splenectomy has failed to correct the ITP or splenectomy is contraindicated and second line therapy has been unsuccessful. Evans syndrome is a rare but serious autoimmune disease defined by the simultaneous or sequential occurrence of autoimmune haemolytic anaemia (AIHA) and ITP without underlying aetiology. As such, it is a diagnosis of exclusion and other disorders, such as collagen vascular diseases, especially systemic lupus erythematosus (SLE) and scleroderma should be ruled out. The 2005 review by Norton and Roberts provided perspective on diagnosis, clinical features and management.	
Justification for Evidence Category	Five small prospective studies, including three randomised studies, demonstrated equivalent efficacy of intravenous immunoglobulin (IVIg) in comparison to prednisone 1 mg/kg/day and high-dose dexamethasone regimen. Overall, the studies found a dose response with more rapid increment in platelet counts at scheduling greater than or equal to 0.8 g/kg on day one compared with 0.4 g/kg/day for three days. A small, controlled study (10 patients in each arm) of HIV-positive patients with severe thrombocytopenia reported possible benefit for the restoration and maintenance of platelet count for the duration of the haemorrhagic disorder (Biotext 2004). An international consensus statement from January 2010 (Provan et al 2010) reported on new data and provided consensus-based recommendations relating to diagnosis and treatment of immune thrombocytopenic purpura (ITP) in adults, in children, and during pregnancy. This statement concluded that few randomised controlled trials (RCTs) have been conducted and that multi-centre, prospective RCTs are required. A 2005 review on the management of Evans syndrome, based on Massachusetts Hospital data and a literature review, showed a transient response in all patients unless IVIg was given every three weeks (Norton and Roberts 2006). The review concluded that the data supported a role for IVIg in first-line therapy. It was not clear whether it was important for steroids to be given at the same time, although this is common practice. A total dose of 2g/kg in divided doses appeared to be sufficient.	

	The review also stated that there might be a role for IVIg in preference to steroids in the acute setting in very young children. A recent meta-analysis of low to medium quality evaluated outcomes of 13 small RCTs comparing high dose (2g/kg) to lower dose (1g/kg) IVIg in acute ITP. The analysis demonstrated equivalent efficacy for all endpoints studied including platelet responses and control of bleeding (Qin YH et al 2010) in both high dose and low dose groups.			
Diagnosis is required	Yes	By which speciality	Haematologist, Paediatrician or General Medicine Physician	
Diagnosis must be verified	No	By which speciality		
Exclusion Criteria	Evans syndrome – where predominant feature is AIHA (link)			
Indications	Newly diagnosed ITP — initial Ig therapy ITP in pregnancy — initial Ig therapy ITP with life-threatening haemorrhage or the potential for life-threatening haemorrhage - Can be auto approved Newly diagnosed or persistent ITP — subsequent therapy (diagnosis < 12 months) Refractory persistent or chronic ITP – splenectomy failed or contraindicated and second-line agent unsuccessful Subsequent or ongoing treatment for ITP responders during pregnancy and the postpartum period ITP and inadequate platelet count for planned surgery HIV-associated ITP			

Indication 1	Newly diagnosed ITP — Initial Ig therapy	

Qualifying Criteria 1	Newly diagnosed ITP — Initial Ig therapy	
Qualifying Criteria 1	Preamble This indication should be used to request one-off treatment in patients who have been diagnosed with ITP in the last three months. For patients requiring subsequent or ongoing therapy, where the diagnosis was made in the last 3 to 12 months, use indication: Newly diagnosed or persistent ITP – subsequent therapy (diagnosis < 12 months). For refractory or chronic ITP patients use indication: Refractory persistent or chronic ITP – splenectomy failed or contraindicated and second-line agent unsuccessful. [Group 1] Current platelet count is less than $30x10^9/L$ • Current platelet count (Number) [EI-2] Internal evaluation: compliance with qualifying range Unit: x $10^9/L$ Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 29 Prompt for a date: single Date prompt text: date of assessment Allow attachments upload Attachment prompt text: Upload results Allow commentary Decision support text "...current platelet count". Assessment Instructions: To qualify the current platelet count must be less than $30x10^9/L$ AND [Group 2] There is evidence of clinically significant bleeding • Clinically significant bleeding (Multi-LOV) [EI-1] Internal evaluation: count of qualifying values	

Qualifying Criteria 1	Newly diagnosed ITP — Initial Ig therapy	
	Minimum qualifying count required: 1 Minimum selection of count required: N/A i. Skin bruising or petechiae (qualifies) ii. Mucosal bleeding (oral, GIT) (qualifies) iii. Frank haemorrhage multiple sites (qualifies) iv. Other, please specify in comments (qualifies) Allow commentary Decision support text "...a description of the clinically significant bleeding". Assessment Instructions: To qualify clinically significant bleeding must be present. Any from the list will qualify, use judgement with other. OR There is a risk of clinically significant bleeding • Please describe the risk of bleeding (Multi-LOV) [EI-3] Internal evaluation: count of qualifying values Minimum qualifying count required: 1 Minimum selection of count required: 1 i. Trauma (qualifies) ii. Recent surgery (qualifies) iii. Other, please specify in comments (qualifies) Allow commentary Decision support text "...a description of the risk of clinically significant bleeding". Assessment Instructions: To qualify there must be a risk of clinically significant bleeding. Any from the list will qualify, use judgement with other. AND [Group 3] No improvement in response to conventional doses of corticosteroid therapy for at least 14 days (unless a valid reason is provided). • Corticosteroid treatment period and if less than 14 days please state reason in comments (Number) Unit: days Internal evaluation: compliance with qualifying range Lowest valid value: 0 Highest valid value: 1000 Lowest qualifying value: 14	

Qualifying Criteria 1	Newly diagnosed ITP — Initial Ig therapy	
	Highest qualifying value: 1000 Prompt for a date: N/A Allow commentary Decision Support text "...the number of days corticosteroid therapy was trialled or a valid contraindication reason" Assessment instructions: Corticosteroid treatment must be greater than or equal to 14 days unless a valid reason is provided. Use judgement with the reason if less than 14 days. OR Corticosteroid therapy is contraindicated. • Please select the contraindication reason (Multi-LOV) [EI-7] Internal evaluation: count of compliance with qualifying values Minimum qualifying count required: 1 Minimum selection count required: 1 i. Unstable diabetes (qualifies) ii. Psychosis or mood disorder (qualifies) iii. Significant infection including sepsis (qualifies) iv. Severe osteoporosis (qualifies) v. Myopathy (qualifies) vi. Active gastrointestinal bleeding (qualifies) vii. History of avascular necrosis (qualifies) viii. Other, please specify in comments (qualifies) Allow commentary Assessment instructions: To qualify any from the list must be selected. Use judgement with other.	

Review Criteria 1	Newly diagnosed ITP — Initial Ig therapy	
Review Criteria 1	Initial authorisation period (max): 7 days Review can be completed: Yes Continuing Treatment is permitted: No Review preamble Review is not mandated for this indication however the following criteria may be useful in assessing the effectiveness of therapy. Resolution of active bleeding, or a reduction in evidence of bleeding correlating with a doubling of platelet count or an increment in platelet count greater than $10x10^9$/L within seven days	

Review Criteria 1	Newly diagnosed ITP — Initial Ig therapy	
	• Please select the type of bleeding resolved or reduced (Multi-LOV) [EI-9] Is mandatory: No Internal evaluation: count of selected values Minimum qualifying count required: N/A Minimum selection of count required: 1 i. Mucosal bleeding (oral, GIT) reduced / resolved ii. Intracranial bleeding reduced or resolved iii. Wound or other active skin bleeding resolved iv. Mild bruising or petechiae resolved v. Mucosal bleeding reduced / resolved vi. Wound or other active bleeding resolved vii. No change in bleeding viii. Other, please specify in comments Allow commentary Decision support text: N/A Assessment instructions: N/A • Platelet count and response following (within seven days) Ig therapy (Number) Is mandatory: No Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: single Date prompt text: date of assessment Show interpretation of results: Yes Interpretation of Results values: i. Doubling of baseline platelet count (qualifies) ii. Increment in platelet count of greater than 10x10^9/L (does not qualify) iii. Increment in platelet count greater than 10x10^9/L and doubled (does not qualify) Allow attachments: Upload results Allow commentary: yes Decision support text: Not required Assessment instructions: Not required • Please describe the date of, and response to the most recent Ig infusion (Text) [EI-12]	

Review Criteria 1	Newly diagnosed ITP — Initial Ig therapy	
	Is mandatory: No Max characters: 2500 Max lines: 5 Assessment instructions: Not required. OR In patients without active bleeding a doubling of baseline platelet count and a rise in platelet count to greater than $30x10^9$/L was demonstrated within seven days of Ig therapy • Platelet count and response following (within seven days) Ig therapy (number) Is mandatory: No Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: single Date prompt text: date of assessment Show interpretation of results: Yes Interpretation of results values: i. Double from baseline platelet count but not above $30x10^9$/L (qualifies) ii. Double from baseline platelet count and above $30x10^9$/L (does not qualify) iii. Did not double from baseline but was above $30x10^9$/L (does not qualify) Allow commentary: yes Allow attachments: Upload results Decision support text: Not required Assessment instructions: N/A • Please provide the date of, and response to the most recent Ig infusion (Text) [EI-12] Is mandatory: No Max characters: 2500 Max lines: 5 Assessment instructions: N/A	

<table>
<tr><td>Dose 1</td><td>Newly diagnosed ITP — Initial Ig therapy</td><td></td></tr>
<tr><td>Dose 1</td><td>Max dose per authorisation period per kg: 2.0 g/kg

Initial dose

<table>
<tr><td>Dose text</td><td>0.8 - 2g/kg in a single or divided dose</td></tr>
<tr><td>Infusion method</td><td>IVIg</td></tr>
<tr><td>Dose type</td><td>One off dose</td></tr>
<tr><td>Requests at which this dose may be proposed</td><td>Initial</td></tr>
<tr><td>Dose may be requested during the course of authorisation</td><td>Yes</td></tr>
<tr><td>Max number of additional doses allowed during the course of an authorisation period</td><td>99</td></tr>
<tr><td>Conditions for additional dose</td><td>The remainder of the 2g/kg dose may be requested provided the total dose of 2g/kg is not exceeded.</td></tr>
<tr><td>Min Dose per kg</td><td>0.8 g/kg</td></tr>
<tr><td>Max Dose per kg</td><td>2.0 g/kg</td></tr>
<tr><td>Max Total per Dose</td><td>N/A</td></tr>
<tr><td>Administer in a divided dose</td><td>Yes</td></tr>
<tr><td>Min divisions</td><td>2</td></tr>
<tr><td>Max divisions</td><td>5</td></tr>
<tr><td>Assessment instructions</td><td>N/A</td></tr>
<tr><td>Dose type postscript</td><td>N/A</td></tr>
</table>

Dose Postscript

The objective of IVIg therapy in ITP is to maintain a safe platelet count while other therapeutic options are explored.

The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient.

Refer to the current product information sheet for further information on dose, administration and contraindications.</td><td></td></tr>
</table>

Indication 2	ITP in pregnancy - Initial Ig therapy	

Qualifying Criteria 2	ITP in pregnancy - Initial Ig therapy	Applies to not male
Qualifying Criteria 2	Qualifying preamble IVIg therapy is used to avoid corticosteroids, immunosuppressive agents and splenectomy during pregnancy. A total dose up to 2g/kg is available under this indication. If a response is achieved but not maintained with this initial Ig therapy, a subsequent induction dose prior to impending procedure or delivery or a maintenance dose titrated to maintain a platelet count above $30x10^9$/L may be administered every three to four weeks throughout pregnancy. To access the subsequent induction or maintenance dose use the indication: Subsequent or ongoing treatment for ITP responders during pregnancy and the postpartum period. Pregnant patient and current platelet count represents potential risk: ○ Less than $30x10^9$/L with risk of haemorrhage ○ Less than $80x10^9$/L with life-threatening haemorrhage ○ Less than $100x10^9$/L and impending delivery. • Estimated date of confinement (Date) [EI-14] Internal evaluation: compliance with qualifying range Earliest valid date 5 days before request Latest valid date 42 weeks after request Earliest qualifying date 5 days before request Latest qualifying date 42 weeks after request Allow commentary Decision support text: "...estimated date of confinement" Assessment Instructions: The expected date of confinement will indicate the potential cessation date. Any date within a current pregnancy will qualify e.g. less than 42 weeks from date of request. • Current platelet count (Number) [EI-15] Internal evaluation: interpretation compliance Unit: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 100 Prompt for a date: single Date prompt text: date of assessment Show interpretation of results: Yes Interpretation of results values: i. <$30x10^9$/L with risk of haemorrhage (qualifies)	

Qualifying Criteria 2	ITP in pregnancy - Initial Ig therapy	Applies to not male
	ii. <80x10^9/L with life threatening haemorrhage (qualifies) iii. <100x10^9/L and impending delivery (qualifies) iv. Other, please specify in comments (qualifies) Allow commentary Allow attachments: Upload results Decision support text: "...platelet count and bleeding risk" Assessment Instructions: To qualify the platelet count should fall into one of the listed categories. Please use judgement with other. Platelet counts above 100 should not qualify.	

Review Criteria 2	ITP in pregnancy - Initial Ig therapy	
Review Criteria 2	Initial authorisation period (max): 7 days Review can be completed: Yes Continuing Treatment is permitted: No Review preamble Review is not mandated for this indication however the following criteria may be useful in assessing the effectiveness of therapy. Resolution of active bleeding, or a reduction in evidence of bleeding correlating with a doubling of platelet count or an increment in platelet count greater than 10x10^9/L within seven days • Please select the type of bleeding resolved or reduced (Multi-LOV) [EI-9] Is mandatory: No Internal evaluation: count of selected values Minimum qualifying count required: N/A Minimum selection of count required: 1 i. No evidence of bleeding prior to Ig ii. Mucosal bleeding (oral, GIT) reduced / resolved iii. Intracranial bleeding reduced or resolved iv. Wound or other active skin bleeding resolved v. Mild bruising or petechiae resolved vi. Mucosal bleeding reduced / resolved vii. Wound or other active bleeding resolved viii. No change in bleeding ix. Other, please specify in comments Allow commentary Decision support text: N/A Assessment instructions: N/A	

Review Criteria 2	ITP in pregnancy - Initial Ig therapy	
	• Platelet count and response following (within seven days) Ig therapy (number) Is mandatory: No Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: single Date prompt text: date of assessment Show Interpretation of results: Yes Interpretation of results values i. Doubling of baseline platelet count (qualifies) ii. Increment in platelet count of greater than 10x10^9/L (does not qualify) iii. Increment in platelet count less than 10x10^9/L and did not double (does not qualify) Allow commentary: Allow attachments: Upload results Decision support text: N/A Assessment Instructions: N/A • Please provide the date of, and response to most recent Ig infusion (Text) [EI-12] Is mandatory: No Max characters: 2500 Max lines: 5 Assessment Instructions: N/A OR In patients without active bleeding a doubling of baseline platelet count and a rise in platelet count to greater than 30x10^9/L was demonstrated within seven days of Ig therapy • Platelet count and response following (within seven days) Ig therapy (number) Is mandatory: No Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500	

Review Criteria 2	ITP in pregnancy - Initial Ig therapy	
	Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: Date of assessment Show interpretation of results: Yes Interpretation of results values i. Double from baseline platelet count but not above 30x10^9/L (qualifies) ii. Double from baseline platelet count and above 30x10^9/L (does not qualify) iii. Did not double from baseline but was above 30x10^9/L (does not qualify) Prompt for a date: single Date prompt text: date of assessment Allow commentary Allow attachments: Upload results Decision support text: Not required Assessment Instructions: N/A • Please provide the date of, and response to most recent Ig treatment (Text) [EI-12] Is mandatory: No Max characters: 2500 Max lines: 5 Assessment Instructions: N/A	

Dose 2	ITP in pregnancy - Initial Ig therapy	
Dose 2	Max dose per authorisation period per kg: 2.0 g/kg Induction dose	

Dose text	0.8 - 2g/kg as a single or divided dose
Infusion method	IVIg
Dose type	One off dose
Requests at which this dose may be proposed	Initial
Dose may be requested during the course of authorisation	Yes
Max number of additional doses allowed during the course of an authorisation period	99
Conditions for additional dose	The remainder of the 2g/kg dose may be requested provided the total dose of 2g/kg is not exceeded.
Min Dose per kg	0.8 g/kg
Max Dose per kg	2.0 g/kg

Dose 2	ITP in pregnancy - Initial Ig therapy	

Max Total per Dose	N/A
Administer in a divided dose	Yes
Min divisions	2
Max divisions	5
Assessment instructions	N/A
Dose type postscript	A total dose up to 2g/kg is available under this indication. If a response is achieved but not maintained with this initial Ig therapy, a subsequent induction dose prior to impending procedure or delivery or a maintenance dose titrated to maintain a platelet count above $30x10^9$/L may be administered every three to four weeks throughout pregnancy. To access the subsequent induction or maintenance dose use the indication –Subsequent or ongoing treatment for ITP responders during pregnancy and the postpartum period.

Dose Postscript

The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient.

Refer to the current product information sheet for further information on dose, administration and contraindications.

Indication 3	ITP with life-threatening haemorrhage or the potential for life-threatening haemorrhage	

Qualifying Criteria 3	ITP with life-threatening haemorrhage or the potential for life-threatening haemorrhage	
Qualifying Criteria 3	[Group 1] Life threatening bleeding or the potential for life threatening bleeding • Please select the bleeding risk (Multi LOV) [EI-16] Internal evaluation: count of selected values Minimum qualifying count required: N/A Minimum selection of count required: 1 i. Severe mucosal or GIT haemorrhage (qualifies) ii. Multiple sites frank haemorrhage (qualifies) iii. Intracranial bleeding (qualifies) iv. Trauma (qualifies) v. Recent surgery (qualifies) vi. Other, please specify in comments (qualifies) Prompt for a date: no Allow commentary Decision support text "...the bleeding risk". Assessor Instructions: Any from the list will qualify. Please use judgement with other. You will need to use this in conjunction with the platelet count to determine appropriate cut-off AND Current platelet count is: ○ Less than 100 x 10^9/L in patients with intracranial haemorrhage ○ Less than 50x 10^9/L in patients with life-threatening haemorrhage ○ Less than 30 x 10^9/L in patients with a risk of haemorrhage. • Current platelet count (Number) [EI-15] Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 100 Prompt for a date: single	

Qualifying Criteria 3	ITP with life-threatening haemorrhage or the potential for life-threatening haemorrhage	
	Date prompt text: date of assessment Show interpretation of results: Yes Interpretation of results values: i. <30x10^9/L with risk of haemorrhage (qualifies) ii. <50x10^9/L with life threatening haemorrhage (qualifies) iii. <100x10^9/L and intracranial haemorrhage (qualifies) iv. Other, please specify in comments (qualifies) Allow attachments upload Attachment prompt text: Upload results Allow commentary Decision support text: "...platelet count and bleeding risk" Assessment Instructions: To qualify the platelet count must fall into one of the categories listed. You can use the response from the previous evidence item to help determine the risk. AND [Group 2] A rapid response is required • Please provide the reason for rapid response (Text*) [EI-17] Max characters: 2500 Max lines: 5 Decision support text "...confirmation that a rapid response is required". Assessment Instructions: A valid reason for a rapid response must be provided. OR Conventional doses of corticosteroids have failed to improve count (unless a valid reason is provided). • Corticosteroid treatment period and if less than 14 days please state reason in comments (Number) [EI-5] Internal evaluation: compliance with qualifying range Unit of measure: days Number of decimals: 0 Lowest valid value: 0 Highest valid value: 1000 Lowest qualifying value: 14 Highest qualifying value: 1000 Prompt for a date: N/A Allow commentary	

Qualifying Criteria 3	ITP with life-threatening haemorrhage or the potential for life-threatening haemorrhage	
	Decision Support text "...the number of days corticosteroid therapy was trialled or a valid contraindication reason Assessment instructions: Corticosteroid treatment must be greater than or equal to 14 days unless a valid reason is provided. Use judgement with the reason if less than 14 days. OR Corticosteroid therapy is contraindicated. • Corticosteroid contraindication reason (Multi-LOV) [EI-7] Internal evaluation: count of selected values Minimum qualifying count required: N/A Minimum selection count required: 1 i. Unstable diabetes (qualifies) ii. Psychosis or mood disorder (qualifies) iii. Significant infection including sepsis (qualifies) iv. Severe osteoporosis (qualifies) v. Myopathy (qualifies) vi. Pregnancy (qualifies) vii. Active gastrointestinal bleeding (qualifies) viii. History of avascular necrosis (qualifies) ix. Other, please specify in comments (qualifies) Prompt for a date: N/A Allow commentary Decision support text "...the contraindications to corticosteroid therapy". Assessment instructions: Any from the list will qualify. Use judgement with other.	

Review Criteria 3	ITP with life-threatening haemorrhage or the potential for life-threatening haemorrhage	
Review Criteria 3	Initial authorisation period: 7 days Review can be completed: Yes Continuing treatment is permitted: No Review preamble Review is not mandated for this indication however the following criteria may be useful in assessing the effectiveness of therapy.	.

Review Criteria 3	ITP with life-threatening haemorrhage or the potential for life-threatening haemorrhage	
	Resolution of, or a reduction in evidence of bleeding correlating with a doubling of platelet count or an increment in platelet count greater than $10x10^9$/L within seven days of Ig therapy • Please select the type of bleeding resolved or reduced (Multi-LOV) [EI-9] Is mandatory: No Internal evaluation: count of selected values Minimum qualifying count required: N/A Minimum selection of count required: 1 i. No evidence of bleeding prior to Ig ii. Mucosal bleeding (oral, GIT) reduced / resolved iii. Intracranial bleeding reduced or resolved iv. Wound or other active skin bleeding resolved v. Mild bruising or petechiae resolved vi. Mucosal bleeding reduced / resolved vii. Wound or other active bleeding resolved viii. No change in bleeding ix. Other, please specify in comments Allow commentary Decision support text: N/A Assessment Instructions: N/A • Platelet count and response following (within seven days) Ig therapy (number) Is mandatory: No Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: single Date prompt text: date of assessment Show interpretation of results: Yes Interpretation of results values: i. Doubling of baseline platelet count (qualifies) ii. Increment in platelet count of greater than $10x10^9$/L (does not qualify) iii. Increment in platelet count less than $10x10^9$/L and did not double (does not qualify) Allow attachment upload Attachment prompt text: Upload results Allow commentary	

Review Criteria 3	ITP with life-threatening haemorrhage or the potential for life-threatening haemorrhage	
	Decision support text: Not required Assessment Instructions: N/A • Please provide the date of, and response to most recent Ig infusion (Text) [EI-12] Is mandatory: No Max characters: 2500 Max lines: 5 lines Assessment Instructions: N/A OR In patients without active bleeding a doubling of baseline platelet count and a rise in platelet count of greater than 30x10^9/L was demonstrated within seven days of Ig therapy • Platelet count and response following (within seven days) previous Ig therapy (Number) Is mandatory: No Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: single Date prompt text: date of assessment Show interpretation of results: Yes Interpretation of results values i. Doubling of baseline platelet count but not above 30x10^9/L (qualifies) ii. Double from baseline platelet count and above 30x10^9/L (does not qualify) iii. Did not double from baseline but was above 30x10^9/L (does not qualify) Allow attachments Attachment prompt text: upload results Allow commentary Decision support text: N/A Assessment Instructions: N/A • Please provide the date of, and response to the most recent Ig infusion (Text) [EI-12] Is mandatory: No Max characters: 2500 Max lines: 5	

Review Criteria 3	ITP with life-threatening haemorrhage or the potential for life-threatening haemorrhage	
	Assessment Instructions: Not required.	

Dose 3	ITP with life-threatening haemorrhage or the potential for life-threatening haemorrhage	
Dose 3	Max dose per authorisation period per kg: 2.0 g/kg Induction dose	

Dose text	1 - 2g/kg as a single or divided dose
Infusion method	IVIg
Dose type	One off dose
Requests at which this dose may be proposed	Initial
Dose may be requested during the course of authorisation	Yes
Max number of additional doses allowed during the course of an authorisation period	99
Conditions for additional dose	The remainder of the 2g/kg dose may be requested provided the total dose of 2g/kg is not exceeded.
Min Dose per kg	1.0 g/kg
Max Dose per kg	2.0 g/kg
Max Total per Dose	N/A
Administer in a divided dose	Yes
Min divisions	2
Max divisions	5
Assessment instructions	N/A
Dose type postscript	N/A

Dose Postscript

The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient.

Refer to the current product information sheet for further information on dose, administration and contraindications.

Indication 4	Newly diagnosed or persistent ITP – subsequent therapy (diagnosis < 12 months)	

Qualifying Criteria 4	Newly diagnosed or persistent ITP – subsequent therapy (diagnosis < 12 months)	
Qualifying Criteria 4	Preamble This indication should be used to request maintenance therapy for patients who have been diagnosed within the past 12 months. Where the diagnosis was made greater than 12 months ago a request should be submitted using the indication Refractory Persistent or Chronic ITP— splenectomy failed or contraindicated and second-line agent unsuccessful [Group 1] A diagnosis of ITP has been made within the last 12 months • Please provide the date of initial ITP diagnosis (text) [EI-26] Max characters: 2500 Max lines: 5 Prompt for a date: No Decision support text: "...date of diagnosis" Assessment Instructions: To qualify generally diagnosis should be within the last 12 months. If greater, the authorisation may qualify under Refractory Persistent or Chronic ITP— splenectomy failed or contraindicated and second-line agent unsuccessful. AND The current platelet count is less than $30x10^9$/L • Current platelet count (Number) [EI-2] Internal evaluation: compliance with qualifying range Unit: x 10^9/L Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 29 Prompt for a date: single Date prompt text: date of assessment Allow attachments upload Attachment prompt text "Upload results" Allow commentary Decision support text "...current platelet count". Assessment Instructions: To qualify the current platelet count must be less than $30x10^9$/L	

Qualifying Criteria 4	Newly diagnosed or persistent ITP – subsequent therapy (diagnosis < 12 months)	
	AND [Group 2] There is evidence of clinically significant bleeding • Please select the type of clinically significant bleeding (Multi-LOV) [EI-1] Internal evaluation: count of selected values Minimum qualifying count required: N/A Minimum selection of count required: 1 i. Skin bruising or petechiae (qualifies) ii. Mucosal bleeding (oral, GIT) (qualifies) iii. Frank haemorrhage multiple sites (qualifies) iv. Other, please specify in comments (qualifies) Allow commentary Decision support text "…a description of the clinically significant bleeding". Assessment Instructions: To qualify clinically significant bleeding must be present. Any from the list will qualify, use judgement with other. OR There is a risk of clinically significant bleeding • Please select the type of bleeding risk (Multi-LOV) [EI-3] Internal evaluation: count of selected values Minimum qualifying count required: N/A Minimum selection of count required: 1 i. Trauma (qualifies) ii. Recent surgery (qualifies) iii. Other, please specify in comments (qualifies) Allow commentary Internal evaluation: count of selected values Decision support text: "…a description of the risk of clinically significant bleeding." Assessment Instructions: To qualify there must be a risk of clinically significant bleeding. Any from the list will qualify, use judgement with other. AND [Group 3]	

Qualifying Criteria 4	Newly diagnosed or persistent ITP – subsequent therapy (diagnosis < 12 months)	
	No improvement in response to conventional doses of corticosteroid therapy for at least 14 days (unless a valid reason is provided). • Corticosteroid treatment period and if less than 14 days please state reason in comments (Number) [EI-5] Internal evaluation: compliance with qualifying range Unit: days Lowest valid value: 0 Highest valid value: 1000 Lowest qualifying value: 14 Highest qualifying value: 1000 Allow commentary Decision support text: "...the number of days corticosteroid therapy was trialled or a valid reason provided." Assessment instructions: Corticosteroid treatment must be greater than or equal to 14 days unless a valid reason is provided e.g. unacceptable side effects or significant toxicity. Use judgement with the reason if less than 14 days. OR Corticosteroid therapy is contraindicated. • Please select the contraindication reason (Multi-LOV) [EI-7] Internal evaluation: count of selected values Minimum qualifying count required: N/A Minimum selection count required: 1 – Unstable diabetes (qualifies) – Psychosis or mood disorder (qualifies) – Significant infection including sepsis (qualifies) – Severe osteoporosis (qualifies) – Myopathy (qualifies) – Active gastrointestinal bleeding (qualifies) – History of avascular necrosis (qualifies) – Other, please specify in comments (qualifies) Allow commentary Decision support text: N/A Assessment instructions: To qualify one of the following must be selected. Use judgement with other. AND [Group 4]	

Qualifying Criteria 4	Newly diagnosed or persistent ITP – subsequent therapy (diagnosis < 12 months)	
	At least one second line agent has been unsuccessful in raising the platelet count above $30x10^9$/L • Please select the second line agent trialled (Multi -LOV) [EI-18] Internal evaluation: count of selected values Minimum qualifying count required: N/A Minimum selection of count required: 1 i. Azathioprine (qualifies) ii. Danazol (qualifies) iii. Dapsone (qualifies) iv. Rituximab (qualifies) v. Thrombopoietin receptor agonist (qualifies) vi. Other, please specify in comments (qualifies) Allow commentary Decision support text: "...the second-line agent(s) that have been unsuccessful in raising the platelet count above $30x10^9$/L. Assessor instructions: Any agent from the list will qualify. Please use judgement with other. Qualifying Postscript Review must be undertaken six monthly by a haematologist, paediatrician or general physician. Documentation of clinical effectiveness is necessary for continuation of IVIg therapy. Ongoing use of IVIg should be primarily to prevent bleeding while other treatment options are explored, including splenectomy.	

Review Criteria 4	Newly diagnosed or persistent ITP – subsequent therapy (diagnosis < 12 months)	
Review Criteria 4	Initial authorisation period: 6 months Review can be completed: Yes Continuing treatment is permitted: Yes Continuing authorisation period: 6 months Total treatment period for an authorisation (max): 12 months Initial review to be undertaken by: Specialist – Haematologist, Paediatrician, General Medicine Physician Continuing review to be undertaken by: Specialist – Haematologist, Paediatrician, General Medicine Physician	.

Review Criteria 4	Newly diagnosed or persistent ITP – subsequent therapy (diagnosis < 12 months)	
	Review preamble Review must be undertaken six monthly by a haematologist, paediatrician or general physician. Documentation of clinical effectiveness is necessary for continuation of IVIg therapy. Ongoing use of IVIg should be primarily to prevent bleeding while other treatment options are explored, including splenectomy. On review of the initial authorisation period: [Group 1] Current platelet count is less than $30x10^9/L$ • Current platelet count (Number) Is mandatory: Yes Internal evaluation: compliance with qualifying range Unit of measure: x 10^9/L Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 29 Prompt for a date: single Date prompt text: date of assessment Allow attachments upload Attachment prompt text: Upload results Allow commentary Decision support text: N/A Assessment Instructions: To qualify the current platelet count must be less than $30x10^9/L$. AND [Group 2] Ig therapy resulted in a resolution of active bleeding or a reduction in evidence of bleeding correlating with a doubling of baseline platelet count or an increment in platelet count of greater than $10x10^9/L$ within seven days of Ig therapy • Please select the type of bleeding resolved or reduced (Multi-LOV) [EI-19]	

Review Criteria 4	Newly diagnosed or persistent ITP – subsequent therapy (diagnosis < 12 months)	
	Is mandatory: Yes Internal evaluation: compliance with qualifying values Minimum qualifying count: 1 Minimum selection count: N/A i. Mucosal bleeding (oral, GIT) reduced /resolved (qualifies) ii. Intracranial bleeding reduced or resolved (qualifies) iii. Wound or other active skin bleeding resolved (qualifies) iv. Mild bruising or petechiae resolved (qualifies) v. Mucosal bleeding reduced /resolved (qualifies) vi. Wound or other active bleeding resolved (qualifies) vii. No change in active bleeding (does not qualify) viii. Other, please specify in comments (qualifies) Prompt for a date: None Allow commentary Decision support text N/A Assessment Instructions: To qualify there must be a reduction in bleeding with Ig therapy, if bleeding was present initially. Please use judgement with other. • Platelet count and response following (within seven days) Ig therapy (Number) Is mandatory: Yes Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: single Date prompt text: date of assessment Show interpretation of results: Yes Interpretation of results values i. Doubling of baseline platelet count (qualifies) ii. Increment in platelet count of greater than 10x10^9/L (qualifies) iii. Increment in platelet count less than 10x10^9/L and did not double (does not qualify) iv. Other, describe in comments (does not qualify) Allow attachment upload Attachment prompt text: Upload results Allow commentary: Yes Decision support text: N/A	

Review Criteria 4	Newly diagnosed or persistent ITP – subsequent therapy (diagnosis < 12 months)	
	Assessment Instructions: To qualify at least one qualifying value must be selected. Assessors to check qualifying platelet count value. • Please provide date of, and response to most recent Ig infusion (text) [EI-22] Is mandatory: Yes Max characters: 2500 Max lines: 5 Prompt for a date: single Date prompt text: date of most recent Ig infusion Decision support text: N/A Assessment Instructions: The post treatment platelet count must have been within 7 days of the date of the most recent Ig infusion. See previous evidence item for post-treatment platelet date. There must be a demonstrated response to Ig therapy including a reduction or resolution in bleeding and a post treatment platelet count rise of >10x10^9/L or double the pre-treatment count (i.e. if <10x10^9/L pre-treatment) within 7 days of previous Ig therapy. OR In patients without active bleeding a doubling of baseline platelet count and a rise in platelet count to greater than 30x10^9/L was demonstrated within seven days of Ig therapy • Platelet count and response following (within seven days) previous Ig therapy (Number) Is mandatory: No Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: single Date prompt text: date of assessment Show interpretation of results: Yes Interpretation of results values: – Double from baseline platelet count but not above 30x10^9/L (does not qualify) – Double from baseline platelet count and above 30x10^9/L (qualifies) Did not double from baseline but was above 30x10^9/L (does not qualify) Allow commentary Decision support text: N/A Assessment Instructions: To qualify at least one qualifying value must be selected.	

Review Criteria 4	Newly diagnosed or persistent ITP – subsequent therapy (diagnosis < 12 months)	
	• Please provide date of, and response to most recent Ig infusion (text) [EI-22] Is mandatory: Yes Max characters: 2500 Max lines: 5 Prompt for a date: single Date prompt text: date of assessment Decision support text: N/A Assessment Instructions: The post treatment platelet count must have been within 7 days of the date of the most recent Ig infusion. See previous evidence item for post-treatment platelet date. There must be a demonstrated response to Ig therapy including a doubling of baseline platelet count and a rise in platelet count to greater than 30x10^9/L within 7 days of previous Ig therapy. On review of a transitioning authorisation [Group 1] Group preamble Severity of disease prior to Ig therapy Prior to Ig therapy, the platelet count was less than 30x10^9/L • Platelet count prior to Ig therapy (Number) [EI-2] Interpretation evaluation: compliance with qualifying range Unit: x 10^9/L Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 29 Prompt for a date: single Date prompt text: date of assessment Allow attachments upload Attachment prompt text: “Upload results” Allow commentary Decision support text: N/A Assessment Instructions: To qualify the platelet count must be less than 30x10^9/L AND Prior to Ig therapy, there was actual, or risk of, clinically significant bleeding	

Review Criteria 4	Newly diagnosed or persistent ITP – subsequent therapy (diagnosis < 12 months)	
	• Please select the type of clinically significant bleeding or bleeding risk prior to Ig therapy (Multi-LOV) [EI-1] Internal evaluation: count of selected values Minimum qualifying count required: N/A Minimum selection of count required: 1 – Skin bruising or petechiae (qualifies) – Mucosal bleeding (oral, GIT) (qualifies) – Frank haemorrhage multiple sites (qualifies) – Trauma (qualifies) – Recent surgery (qualifies) – Other or unknown, please describe in comments (qualifies) Allow commentary Decision support text: N/A Assessment Instructions: To qualify clinically significant bleeding must have been present or a risk prior to therapy. Any selection will qualify, use judgement with other. While the patient may have been under the care of a different TMS at the time of diagnosis, every endeavour should have been made to confirm the key elements of the diagnosis, for example the clinician may reference a referral letter that confirms the original diagnosis. AND Prior to Ig therapy, there was no improvement in response to conventional doses of corticosteroids (unless unacceptable side effects, significant toxicity or contraindicated) • Please describe the response to corticosteroid treatment including the treatment period, or provide details as to why any treatment may have been less than 14 days (Text) [EI-5] Is mandatory: Yes Max characters: 2500 Max lines: 5 Decision support text: N/A Assessment instructions: Corticosteroid treatment must be greater than or equal to 14 days unless a valid reason is provided e.g. unacceptable side effects or significant toxicity or contraindicated. Use judgement with the reason if less than 14 days. This may be unknown if the patient was under the care of a different TMS at the time of diagnosis. AND Prior to Ig therapy, at least one second line agent was unsuccessful in raising the platelet count above $30x10^9$/L. • Please select the second line agent(s) trialled (Multi-LOV) [EI-18]	

Review Criteria 4	Newly diagnosed or persistent ITP – subsequent therapy (diagnosis < 12 months)	
	Internal evaluation: count of selected values Minimum qualifying count required: N/A Minimum selection of count required: 1 – Azathioprine (qualifies) – Danazol (qualifies) – Dapsone (qualifies) – Rituximab (qualifies) – Thrombopoietin receptor agonist (qualifies) – Other, please specify in comments (qualifies) Allow commentary Decision support text: N/A Assessor instructions: Any unsuccessful agent from the list will qualify. Please use judgement with other. AND [Group 2] Group preamble Current requirement for continued Ig therapy Current platelet count is less than 30x10^9/L • Current platelet count (Number) [EI-2] Internal evaluation: compliance with qualifying range Unit: x 10^9/L Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 29 Prompt for a date: single Date prompt text: date of assessment Allow attachment upload Attachment prompt text: Upload results Allow commentary Decision support text: N/A Assessment Instructions: To qualify the current platelet count must be less than 30x10^9/L AND [Group 3]	

Review Criteria 4	Newly diagnosed or persistent ITP – subsequent therapy (diagnosis < 12 months)	
	Group preamble Response to Ig therapy Ig therapy resulted in a resolution of active bleeding or a reduction in evidence of bleeding, correlating with a doubling of baseline platelet count or an increase in platelet count increment of greater than $10x10^9$/L within seven days of Ig therapy • Please select the type of bleeding resolved or reduced (Multi-LOV) [EI-19] Is mandatory: Yes Internal evaluation: count of compliance with qualifying ranges Min qualifying count: 1 Min selection count: N/A i. Mucosal bleeding (oral, GIT) reduced / resolved (qualifies) ii. Intracranial bleeding reduced or resolved (qualifies) iii. Wound or other active skin bleeding resolved (qualifies) iv. Mild bruising or petechiae resolved (qualifies) v. Mucosal bleeding reduced / resolved (qualifies) vi. Wound or other active bleeding resolved (qualifies) vii. No change in active bleeding (does not qualify) viii. Other, please specify in comments (qualifies) Allow commentary Decision support text N/A Assessment Instructions: To qualify there must be a reduction in bleeding with Ig therapy, if bleeding was present. Please use judgement with other. • Platelet count and response following (within seven days) Ig therapy (Number) Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: single Date prompt text: date of assessment Show interpretation of results: Yes Interpretation of results values i. Doubling of baseline platelet count (qualifies)	

Review Criteria 4	Newly diagnosed or persistent ITP – subsequent therapy (diagnosis < 12 months)	
	ii. Increment in platelet count of greater than $10x10^9$/L (qualifies) iii. Increment in platelet count less than $10x10^9$/L and did not double (does not qualify) Allow attachment upload Attachment prompt text: Upload results Allow commentary Decision support text: N/A Assessment Instructions: To qualify at least one qualifying value must be selected. • Please provide the date of, and response to most recent Ig infusion (text) [EI-22] Is mandatory: Yes Max characters: 2500 Max lines: 5 Prompt for a date: single Date prompt text: date of assessment Decision support text: N/A Assessment Instructions: The post treatment platelet count must have been within 7 days of the date of the most recent Ig infusion. See previous evidence item for post-treatment platelet date There must be a demonstrated response to Ig therapy to qualify: a reduction or resolution in bleeding and a post treatment platelet count rise of >$10x10^9$/L or double the pre-treatment count. i.e. if <$10x10^9$/L pre-treatment within 7 days of previous Ig therapy. OR In patients without active bleeding, a doubling of baseline platelet count and a rise in platelet count to greater than $30x10^9$/L was demonstrated within seven days of previous Ig therapy • Platelet count following (within seven days) Ig therapy Is mandatory: Yes Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: single Date prompt text: date of assessment Show interpretation of results: Yes Interpretation of results values – Double from baseline platelet count but not above $30x10^9$/L (does not qualify)	

Review Criteria 4	Newly diagnosed or persistent ITP – subsequent therapy (diagnosis < 12 months)	
	– Double from baseline platelet count and above 30x10^9/L (qualifies) – Did not double from baseline but was above 30x10^9/L (does not qualify) Allow attachments Attachment prompt text: Upload results Allow commentary Decision support text: N/A Assessment Instructions: To qualify the platelet response must be both double from baseline AND greater than 30x10^9/L. • Please provide the date of, and response to the most recent Ig infusion (text) [EI-22] Max characters: 2500 Max lines: 5 Prompt for a date: None Decision support text: N/A Assessment Instructions: The post treatment platelet count must have been within 7 days of the date of the most recent Ig infusion. See previous evidence item for post-treatment platelet date. There must be a demonstrated response to Ig therapy to qualify: a reduction or resolution in bleeding and a post treatment platelet count rise to >30x10^9/L and double the pre-treatment count On review of a continuing authorisation request [Group 1] Current platelet count is less than 30x10^9/L • Current platelet count (Number) [EI-2] Internal evaluation: compliance with qualifying range Unit: x 10^9/L Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 29 Prompt for a date: single Date prompt text: date of assessment Allow attachment upload Attachment prompt text: Upload results Allow commentary Decision support text: N/A Assessment Instructions: To qualify the current platelet count must be less than 30x10^9/L	

Review Criteria 4	Newly diagnosed or persistent ITP – subsequent therapy (diagnosis < 12 months)	
	AND [Group 2] Ig therapy resulted in resolution of active bleeding or a reduction in evidence of bleeding, correlating with a doubling of baseline platelet count or an increment in platelet count of greater than $10x10^9/L$ within seven days of Ig therapy • Please select the type of bleeding resolved or reduced (Multi-LOV) [EI-19] Internal evaluation: count of selected values Minimum qualifying count required: N/A Minimum selection of count required: 1 i. Mucosal bleeding (oral, GIT) reduced / resolved (qualifies) ii. Intracranial bleeding reduced or resolved (qualifies) iii. Wound or other active skin bleeding resolved (qualifies) iv. Mild bruising or petechiae resolved (qualifies) v. Mucosal bleeding reduced / resolved (qualifies) vi. Wound or other active bleeding resolved (qualifies) vii. No change in active bleeding (does not qualify) viii. Other, please specify in comments (qualifies) Prompt for a date: None Allow commentary Decision support text: N/A Assessment Instructions: To qualify for ongoing Ig there must have been a response within 7 days of previous Ig therapy. Bleeding must have either reduced or resolved. Please use judgement with other. • Platelet count within seven days post Ig therapy (Number) Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: single Date prompt text: date of assessment Show interpretation of results: Yes Interpretation of results values: – Doubling of baseline platelet count (qualifies)	

Review Criteria 4	Newly diagnosed or persistent ITP – subsequent therapy (diagnosis < 12 months)	
	– Increment in platelet count of greater than 10x10^^{9}/L (qualifies) – Increment in platelet count greater than 10x10^^{9}/L and doubling of baseline (qualifies) – Other – describe in comments (does not qualify) Allow attachments upload Attachment prompt text: Upload results Allow commentary Decision support text: N/A Assessment Instructions: To qualify any qualifying value must be selected. • Please provide the date of, and response to, most recent Ig infusion (text) [EI-22] Max characters: 2500 Max lines: 5 Prompt for a date: single Date prompt text: date of most recent Ig infusion Decision support text N/A Assessment Instructions: The post treatment platelet count must have been within 7 days of the date of the most recent Ig infusion. See previous evidence item for post-treatment platelet date. There must be a demonstrated response to Ig therapy to qualify: a reduction or resolution in bleeding and a post treatment platelet count rise of >10x10^9/L or double the pre-treatment count (i.e. if <10x10^9/L pre-treatment). OR In patients without active bleeding, a doubling of baseline platelet count and a rise in platelet count to greater than 30x10^9/L was demonstrated within seven days of previous Ig therapy • Platelet count and response following (within seven days) most recent Ig therapy (Number) Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: single Date prompt text: date of assessment Show interpretation of results: Yes Interpretation of results values – Double from baseline platelet count but not above 30 x 10^9/L (does not qualify) – Double from baseline platelet count and above 30x10^9/L (qualifies)	

Review Criteria 4	Newly diagnosed or persistent ITP – subsequent therapy (diagnosis < 12 months)	
	– Did not double from baseline but was above 30x10^9/L (does not qualify) – Did not double from baseline and was below 30x10^9/L (does not qualify) Allow attachments upload Attachment prompt text: Upload results Allow commentary Decision support text: N/A Assessment Instructions: To qualify the platelet response must be both double from baseline AND greater than 30x10^9/L. • Please provide the date of, and response to, the most recent Ig infusion (text) [EI-22] Max characters: 2500 Max lines: 5 Prompt for a date: None Decision support text: N/A Assessment Instructions: The post treatment platelet count must have been within 7 days of the date of the most recent Ig infusion. There must be a demonstrated response to Ig therapy to qualify: a reduction or resolution in bleeding and a post treatment platelet count rise to >30x10^9/L and double the pre-treatment count.	

Dose 4	Newly diagnosed or persistent ITP – subsequent therapy (diagnosis < 12 months)	
Dose 4	Maintenance dose **Dose text:** 0.4 - 2g/kg as a single or divided dose at 4 to 6 weekly intervals titrated to symptoms and platelet count, up to a maximum of 2g/kg/4 week period **Infusion method:** IVIg **Dose type:** Maintenance dose **Requests at which this dose may be proposed:** Initial, continuing **Min Dose per kg:** 0.4 g/kg **Max Dose per kg:** 2.0 g/kg **Max Total per Dose:** N/A **Administer in a divided dose:** Yes **Min divisions:** 2 **Max divisions:** 5 **Minimum frequency:** 2 **Maximum frequency:** 6	

<table>
<tr><td>Dose 4</td><td>Newly diagnosed or persistent ITP – subsequent therapy (diagnosis < 12 months)</td><td></td></tr>
<tr><td></td><td>
<table>
<tr><td>Frequency unit</td><td>Weeks</td></tr>
<tr><td>Max dose per period per kg</td><td>2.0 g/kg every 4 weeks</td></tr>
<tr><td>Assessment instructions</td><td>n/A</td></tr>
<tr><td>Dose type postscript</td><td>N/A</td></tr>
</table>

Dose Postscript

The objective of IVIg therapy in ITP is to maintain a safe platelet count while other therapeutic options are explored.

The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient.

Refer to the current product information sheet for further information on dose, administration and contraindications.</td><td></td></tr>
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Indication 5	Refractory Persistent or Chronic ITP — splenectomy failed or contraindicated and second-line agent unsuccessful	

Qualifying Criteria 5	Refractory Persistent or Chronic ITP — splenectomy failed or contraindicated and second-line agent unsuccessful	
Qualifying Criteria 5	Preamble This indication should be used to request maintenance therapy for patients where a diagnosis was made greater than 12 months ago. For patients who have been diagnosed within the past 12 months a request should be submitted using the indication Newly diagnosed or persistent ITP – subsequent therapy (diagnosis < 12 months) [Group 1] Date of initial ITP diagnosis is greater than 12 months in the past. • Date of initial ITP diagnosis (text) [EI-26] Max characters: 2500 Max lines: 5 Decision support text: "...date of diagnosis" Assessment Instructions: To qualify generally diagnosis should be at least 12 months previously. If less authorisation should be under Newly diagnosed or persistent ITP - subsequent therapy (diagnosis < 12 months). AND Current platelet count less than 30x10^9/L in a patient with persistent or chronic ITP • Please provide the current platelet count (Number) [EI-2] Internal evaluation: compliance with qualifying range Units: x 10^9/L Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 29 Prompt for a date: single Date prompt text: date of assessment Allow attachments upload Attachment prompt text: Upload results Allow commentary Decision support text "...current platelet count". Assessment Instructions: To qualify the current platelet count must be less than 30x10^9/L.	

Qualifying Criteria 5	Refractory Persistent or Chronic ITP — splenectomy failed or contraindicated and second-line agent unsuccessful	
	AND [Group 2] There is clinically significant bleeding • Please select the type of clinically significant bleeding (Multi-LOV) [EI-1] Internal evaluation: count of selected values Minimum qualifying count required: N/A Minimum selection of count required: 1 i. Skin bruising or petechiae (qualifies) ii. Mucosal bleeding (oral, GIT) (qualifies) iii. Frank haemorrhage multiple sites (qualifies) iv. Other, please describe in comments (qualifies) Allow commentary Decision support text "...a description of the clinically significant bleeding". Assessment Instructions: To qualify clinically significant bleeding must be present. Any from the list will qualify, use judgement with other. OR There is a risk of clinically significant bleeding • Please select the type of bleeding risk (Multi-LOV) [EI-3] Internal evaluation: count of selected values Minimum qualifying count required: N/A Minimum selection of count required: 1 i. Trauma (qualifies) ii. Recent surgery (qualifies) iii. Other, please specify in comments (qualifies) Allow commentary Decision support text "...a description of the risk of clinically significant bleeding". Assessment Instructions: To qualify there must be a risk of clinically significant bleeding. Any from the list will qualify, use judgement with other. AND [Group 3]	

Qualifying Criteria 5	Refractory Persistent or Chronic ITP — splenectomy failed or contraindicated and second-line agent unsuccessful	
	Previous Ig therapy resulted in a resolution of active bleeding or a reduction in evidence of bleeding, correlating with a doubling of baseline platelet count and/or an increase in platelet count increment of greater than $10x10^9$/L within seven days • Please select the type of bleeding resolved or reduced (Multi-LOV) [EI-19] Internal evaluation: count of compliance with qualifying values Minimum qualifying count required: 1 Minimum selection of count required: N/A i. Mucosal bleeding (oral, GIT) reduced or resolved (qualifies) ii. Intracranial bleeding reduced or resolved (qualifies) iii. Wound or other active skin bleeding resolved or reduced (qualifies) iv. Mild bruising or petechiae resolved or reduced (qualifies) v. Mucosal bleeding reduced or resolved (qualifies) vi. Wound or other active bleeding resolved or reduced (qualifies) vii. No change in bleeding (does not qualify) viii. Other, please specify in comments (qualifies) Allow commentary Decision Support text: "...a description of the response to Ig therapy" Assessment Instructions: To qualify for ongoing Ig there must have been a response within 7 days of previous Ig therapy. Bleeding must have either reduced or resolved. Please use judgement with other. • Please provide the pre-treatment platelet count (Number) Internal evaluation: compliance with qualifying range Unit: x 10^9/L Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 29 Prompt for a date: single Date prompt text: date of assessment Allow attachments upload Attachment prompt text: Upload results Allow commentary Decision support text "...pre-treatment platelet count". Assessment Instructions: To qualify the current platelet count must be less than $30x10^9$/L • Platelet count and response following (within seven days) of Ig therapy (Number) Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0	

Qualifying Criteria 5	Refractory Persistent or Chronic ITP — splenectomy failed or contraindicated and second-line agent unsuccessful	
	Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: single Date prompt text: Date of assessment Show interpretation of results: Yes Interpretation of results values i. Doubling of baseline platelet count (qualifies) ii. Increment in platelet count of greater than 10x10^9/L (qualifies) iii. Doubling of baseline platelet count and increment of greater than 10x10^9/L (qualifies) iv. Other, please specify in comments (does not qualify) Allow attachments Attachment prompt text: Upload results Allow commentary Decision support text: "…the platelet response within 7 days of most recent Ig therapy" Assessment Instructions: To qualify the platelet response must be one of the first three in the list. Use judgement with other. • Please describe date of, and response to the most recent Ig infusion (text) [EI-22] Max characters: 2500 Max lines: 5 Decision support text "…date of, and response to the most recent Ig infusion" Assessment Instructions: The post-treatment platelet count must have been within 7 days of the date of the most recent Ig infusion. See previous evidence item for post-treatment platelet date. There must be a demonstrated response to Ig therapy to qualify including: a reduction or resolution in bleeding and a post treatment platelet count rise of >10x10^9/L or double the pre-treatment count (i.e. if <10x10^9/L pre-treatment) or an increase in platelet increment by at least 10x10^9/L. OR In patients without active bleeding, a doubling of baseline platelet count and a rise in platelet count to greater than 30x10^9/L was demonstrated within seven days of previous Ig therapy • Please provide the pre-treatment platelet count Internal evaluation: compliance with qualifying range Unit: x 10^9/L Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0	

Qualifying Criteria 5	Refractory Persistent or Chronic ITP — splenectomy failed or contraindicated and second-line agent unsuccessful	
	Highest qualifying value: 29 Prompt for a date: single Date prompt text: date of assessment Allow attachments upload Attachment prompt text: Upload results Allow commentary Decision support text "...pre-treatment platelet count". Assessment Instructions: To qualify the pre-treatment platelet count must be less than $30x10^9$/L • Platelet count and response following (within seven days) Ig therapy (Number) Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Show interpretation of results: Yes Interpretation of results values i. Double from baseline platelet count AND above $30x10^9$/L (qualifies) ii. Other (does not qualify) Date of assessment: single Date prompt: date of test Allow commentary: Allow attachments: Upload results Decision support text: "...the platelet response within 7 days of Ig therapy" Assessment Instructions: To qualify the platelet response must be both double from baseline AND greater than $30x10^9$/L. • Please describe the date of, and response to the most recent Ig infusion (text) [EI-22] Max characters: 2500 Max lines: 5 Decision support text: "...date of, and response to the most recent Ig infusion" Assessment Instructions: The post treatment platelet count must have been within 7 days of the date of the most recent Ig infusion. See previous evidence item for post-treatment platelet date. There must be a demonstrated response to Ig therapy to qualify including: a reduction or resolution in bleeding and a post treatment platelet count rise to >$30x10^9$/L and double the pre-treatment count AND	

Qualifying Criteria 5	Refractory Persistent or Chronic ITP — splenectomy failed or contraindicated and second-line agent unsuccessful	
	[Group 4] Splenectomy has failed to correct thrombocytopenia. • Please comment regarding the patient's thrombocytopenia post-splenectomy (Text*) [EI-27] Max characters: 2500 Max lines: 5 Decision support text: "...the response to splenectomy." Assessment instructions: A valid comment is required regarding the failed correction of thrombocytopenia following splenectomy. OR Splenectomy is contraindicated. • Please select the splenectomy contraindication reason (Multi -LOV) [EI-28] Internal evaluation: count of selected values Minimum qualifying count required: N/A Minimum selection of count required: 1 i. Extra-medullary haematopoiesis (qualifies) ii. Surgically contraindicated (qualifies) iii. Other, please specify in comments (qualifies) Allow commentary Decision support text "...the splenectomy contraindication reason." Assessment instructions: Any reason from the list will qualify. Please use judgement with other. AND [Group 5] Therapy with a second-line agent has been unsuccessful in raising the platelet count above $30x10^9$/L. • Please select the second line agent trialled (Multi -LOV) [EI-18] Internal evaluation: count of selected values Minimum qualifying count required: N/A Minimum selection of count required: 1 i. Azathioprine (qualifies) ii. Danazol (qualifies) iii. Dapsone (qualifies) iv. Rituximab (qualifies) v. TPO (qualifies)	

Qualifying Criteria 5	Refractory Persistent or Chronic ITP — splenectomy failed or contraindicated and second-line agent unsuccessful	
	vi. Other, please specify in comments (qualifies) Allow commentary Decision support text "...the second-line agent that has not been successful in raising the platelet count above $30x10^9$/L. Assessment instructions: Any unsuccessful agent from the list will qualify. Please use judgement with other. Qualifying Postscript With ongoing therapy, IVIg may be administered to achieve a platelet count of greater than $30x10^9$/L. Review must be undertaken six monthly by a haematologist, paediatrician, or general physician. Documentation of clinical effectiveness is necessary for continuation of IVIg therapy.	

Review Criteria 5	Refractory Persistent or Chronic ITP — splenectomy failed or contraindicated and second-line agent unsuccessful	
Review Criteria 5	Initial authorisation period: 6 months Review can be completed: Yes Continuing Treatment is permitted: Yes Continuing authorisation period (max): 6 months Initial review to be undertaken by: Specialist - Haematologist, Paediatrician, General Medicine Physician Continuing Review to be undertaken by: Specialist - Haematologist, Paediatrician, General Medicine Physician Review preamble Review must be undertaken six monthly by a haematologist, paediatrician, or general physician. Documentation of clinical effectiveness is necessary for continuation of IVIg therapy. On review of an initial authorisation request [Group 1] The platelet count responds to Ig therapy but cannot be maintained above $30x10^9$/L • Lowest maintenance platelet count (Number) [EI-2] Internal evaluation: compliance with qualifying range Unit: x 10^9/L Lowest valid value: 0 Highest valid value: 500	

Review Criteria 5	Refractory Persistent or Chronic ITP — splenectomy failed or contraindicated and second-line agent unsuccessful	
	Lowest qualifying value: 0 Highest qualifying value: 29 Prompt for a date: single Date prompt text: date of assessment Allow attachments upload Attachment prompt text: Upload results Allow commentary Decision support text: N/A Assessment Instructions: To qualify the lowest maintenance platelet count cannot be maintained above $30x10^9/L$ AND [Group 2] Ig therapy resulted in resolution of active bleeding or a reduction in evidence of bleeding, correlating with a doubling of baseline platelet count or an increase in platelet count by an increment of greater than $10x10^9/L$ within seven days of Ig therapy • Please select the type of bleeding resolved or reduced (Multi-LOV) [EI-19] Internal evaluation: count of compliance with qualifying values Minimum qualifying count required: 1 Minimum selection of count required: N/A – Mucosal bleeding (oral, GIT) reduced / resolved (qualifies) – Intracranial bleeding reduced or resolved (qualifies) – Wound or other active skin bleeding resolved (qualifies) – Mild bruising or petechiae resolved (qualifies) – Mucosal bleeding reduced / resolved (qualifies) – Wound or other active bleeding resolved (qualifies) – No change in active bleeding (does not qualify) – Other, please specify in comments (qualifies) Prompt for a date: None Allow commentary Decision support text: N/A Assessment Instructions: To qualify for ongoing Ig there must have been a response within 7 days of previous Ig therapy. Bleeding must have either reduced or resolved unless no active bleeding was evident at diagnosis. Please use judgement with other. • Please provide the platelet count and response following (within seven days) Ig therapy (Number)	

Review Criteria 5	Refractory Persistent or Chronic ITP — splenectomy failed or contraindicated and second-line agent unsuccessful	
	Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: single Date prompt text: date of assessment Show interpretation of results: Yes Interpretation of results values – Doubling of baseline platelet count (qualifies) – Increment in platelet count of greater than 10x10^9/L (qualifies) – Increment in platelet count greater than 10x10^9/L and doubling of baseline (qualifies) – Other – describe in comments (does not qualify) Allow attachments upload Attachment prompt text: Upload results Allow commentary: yes Decision support text: N/A Assessment Instructions: To qualify any qualifying value must be selected. Use judgement with other. • Please provide the date of, and response to the most recent Ig infusion (text) [EI-22] Max characters: 2500 Max lines: 5 Prompt for a date: single Date prompt text: date of most recent Ig infusion Decision support text: N/A Assessment Instructions: The post treatment platelet count must have been within 7 days of the date of the most recent Ig infusion. See previous evidence item for post-treatment platelet date. There must be a demonstrated response to Ig therapy to qualify including: a reduction or resolution in bleeding and a post treatment platelet count rise of >10x10^9/L or double the pre-treatment count (i.e. if <10x10^9/L pre-treatment) OR In patients without active bleeding, a doubling of baseline platelet count and a rise in platelet count to greater than 30x10^9/L was demonstrated within seven days of the most recent Ig therapy • Please provide the platelet count and response following (within seven days) the most recent Ig therapy (Number)	

Review Criteria 5	Refractory Persistent or Chronic ITP — splenectomy failed or contraindicated and second-line agent unsuccessful	
	Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: single Date prompt text: date of assessment Show interpretation of results: Yes Interpretation of results values – Double from baseline platelet count AND above 30x10^9/L (qualifies) – Other (does not qualify) Allow attachments Attachment prompt text: Upload results Allow commentary Decision support text: N/A Assessment Instructions: To qualify the platelet response must be both double from baseline AND greater than 30x10^9/L. • Please provide the date of, and response to the most recent Ig infusion (text) [EI-22] Max characters: 2500 Max lines: 5 Prompt for a date: None Decision support text: N/A Assessment Instructions: The post treatment platelet count must have been within 7 days of the date of the most recent Ig infusion. See previous evidence item for post-treatment platelet date. There must be a demonstrated response to Ig therapy to qualify including: a reduction or resolution in bleeding and a post treatment platelet count rise to >30x10^9/L and double the pre-treatment count On review of a transitioning authorisation [Group 1] Group preamble Prior to Ig therapy Prior to Ig therapy, there was actual, or risk of, clinically significant bleeding	

Review Criteria 5	Refractory Persistent or Chronic ITP — splenectomy failed or contraindicated and second-line agent unsuccessful	
	• Please select the type of clinically significant bleeding or bleeding risk prior to Ig therapy (Multi-LOV) [EI-1] Internal evaluation: count of selected values Minimum qualifying count required: N/A Minimum selection of count required: 1 – Skin bruising or petechiae (qualifies) – Mucosal bleeding (oral, GIT) (qualifies) – Frank haemorrhage multiple sites (qualifies) – Trauma (qualifies) – Recent surgery (qualifies) – Other or unknown, please describe in comments (qualifies) Prompt for a date: None Allow commentary Decision support text: N/A Assessment Instructions: To qualify clinically significant bleeding must be present or a risk. Any selection will qualify, use judgement with other. While the patient may have been under the care of a different TMS at the time of diagnosis, every endeavour should have been made to confirm the key elements of the diagnosis, for example the clinician may reference a referral letter that confirms the original diagnosis. AND Splenectomy failed to correct thrombocytopenia or splenectomy is contraindicated • Please comment regarding the patient's thrombocytopenia post-splenectomy or advise the reason splenectomy is contraindicated (Text*) [EI-27] Max characters: 2500 Max lines: 5 Prompt for a date: None Decision support text: N/A Assessor instructions: A valid comment is required regarding the failed correction of thrombocytopenia following splenectomy or a contraindication reason is provided (e.g. extra-medullary haematopoiesis, surgical contraindication) AND Therapy with a second-line agent has been unsuccessful in raising the platelet count above $30x10^9$/L. • Please select the second line agent therapy trialled (Multi -LOV) [EI-18] Internal evaluation: count of selected values	

Review Criteria 5	Refractory Persistent or Chronic ITP — splenectomy failed or contraindicated and second-line agent unsuccessful	
	Minimum qualifying count required: N/A Minimum selection of count required: 1 – Azathioprine (qualifies) – Danazol (qualifies) – Dapsone (qualifies) – Rituximab (qualifies) – TPO (qualifies) – Other, please specify in comments (qualifies) Allow commentary Decision support text N/A Assessor instructions: Any unsuccessful agent from the list will qualify. Please use judgement with other. AND The platelet count responds to Ig therapy but cannot be maintained above $30x10^9$/L • Please provide the lowest maintenance platelet count (Number) [EI-2] Internal evaluation: compliance with qualifying range Unit: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 29 Prompt for a date: single Date prompt text: date of assessment Allow attachments upload Attachment prompt text "Upload results" Allow commentary Decision support text N/A Assessment Instructions: To qualify the lowest maintenance platelet count must be less than $30x10^9$/L AND [Group 2] Group preamble Response to Ig therapy	

Review Criteria 5	Refractory Persistent or Chronic ITP — splenectomy failed or contraindicated and second-line agent unsuccessful	
	Previous Ig therapy resulted in resolution of active bleeding or a reduction in evidence of bleeding, correlating with a doubling of baseline platelet count or an increase in platelet count increment of greater than 10x10^9/L within seven days of Ig therapy • Please select the type of bleeding resolved or reduced (Multi-LOV) [EI-19] Internal evaluation: count of compliance with qualifying values Minimum qualifying count required: 1 Minimum selection of count required: N/A i. Mucosal bleeding (oral, GIT) reduced / resolved (qualifies) ii. Intracranial bleeding reduced or resolved (qualifies) iii. Wound or other active skin bleeding resolved (qualifies) iv. Mild bruising or petechiae resolved (qualifies) v. Mucosal bleeding reduced / resolved (qualifies) vi. Wound or other active bleeding resolved (qualifies) vii. No change in active bleeding (does not qualify) viii. Other, please specify in comments (qualifies) Allow commentary Assessment Instructions: To qualify for ongoing Ig there must have been a response within 7 days of previous Ig therapy. Bleeding must have either reduced or resolved unless no active bleeding was evident at diagnosis. Please use judgement with other. • Please provide the platelet count and response following (within seven days) Ig therapy (Number) Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: single Date prompt text: date of assessment Show Interpretation of Results: Yes Interpretation of results values: – Doubling of baseline platelet count (qualifies) – Increment in platelet count of greater than 10x10^9/L (qualifies) – Increment in platelet count greater than 10x10^9/L and doubling of baseline (qualifies) – Other – describe in comments (does not qualify) Allow commentary Allow attachments: Upload results	

Review Criteria 5	Refractory Persistent or Chronic ITP — splenectomy failed or contraindicated and second-line agent unsuccessful	
	Decision support text: N/A Assessment Instructions: To qualify any qualifying value must be selected. • Please provide date of, and response to the most recent Ig infusion (text) [EI-22] Max characters: 2500 Max lines: 5 Prompt for a date: single Date prompt text: date of assessment Decision support text: N/A Assessment Instructions: The post treatment platelet count must have been within 7 days of the date of the most recent Ig infusion. See previous evidence item for post-treatment platelet date. There must be a demonstrated response to Ig therapy to qualify including a reduction or resolution in bleeding and a post treatment platelet count rise of >10x10^9/L or double the pre-treatment count (i.e. if <10x10^9/L pre-treatment was demonstrated) within 7 days of the most recent Ig therapy OR In patients without active bleeding, a doubling of baseline platelet count and a rise in platelet count to greater than 30x10^9/L was demonstrated within seven days of previous Ig therapy • Please provide the platelet count and response following (within seven days) the most recent Ig therapy Internal evaluation: Interpretation compliance Unit of measure: x10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Show Interpretation of Results: Yes Interpretation of Results Values – Double from baseline platelet count AND above 30x10^9/L (qualifies) – Other (does not qualify) Prompt for a date: single Date prompt text: date of assessment Allow attachments upload Attachment prompt text: Upload results Allow commentary Decision support text: N/A Assessment Instructions: To qualify the platelet response must be both double from baseline AND greater than 30x10^9/L.	

Review Criteria 5	Refractory Persistent or Chronic ITP — splenectomy failed or contraindicated and second-line agent unsuccessful	
	• Please describe the date of, and response to the most recent Ig infusion (text) [EI-22] Max characters: 2500 Max lines: 5 Prompt for a date: none Decision support text: N/A Assessment Instructions: The post treatment platelet count must have been within 7 days of the date of the most recent Ig infusion. There must be a demonstrated response to Ig therapy to qualify including: a reduction or resolution in bleeding and a post treatment platelet count rise to greater than $30x10^9$/L and double the pre-treatment count On review of a continuing authorisation request [Group 1] The platelet count responds to Ig therapy but cannot be maintained above $30x10^9$/L • Please provide the lowest maintenance platelet count (Number) [EI-2] Internal evaluation: compliance with qualifying range Unit: x 10^9/L Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 29 Prompt for a date: single Date prompt text: date of assessment Allow attachments upload Attachment prompt text: upload results Allow commentary Decision support text: N/A Assessment Instructions: To qualify the lowest maintenance platelet count must be less than $30x10^9$/L AND [Group 2] Ig therapy resulted in resolution of active bleeding or a reduction in evidence of bleeding, correlating with a doubling of baseline platelet count or an increase in platelet count by increment of greater than $10x10^9$/L within seven days of Ig therapy	

Review Criteria 5	Refractory Persistent or Chronic ITP — splenectomy failed or contraindicated and second-line agent unsuccessful	
	• Please select the type of bleeding resolved or reduced (Multi-LOV) [EI-19] Internal evaluation: count of selected values Minimum qualifying count required: N/A Minimum selection of count required: 1 i. Mucosal bleeding (oral, GIT) reduced / resolved (qualifies) ii. Intracranial bleeding reduced or resolved (qualifies) iii. Wound or other active skin bleeding resolved (qualifies) iv. Mild bruising or petechiae resolved (qualifies) v. Mucosal bleeding reduced / resolved (qualifies) vi. Wound or other active bleeding resolved (qualifies) vii. No change in active bleeding (does not qualify) viii. Other, please specify in comments (qualifies) Prompt for a date: None Allow commentary Decision support text: N/A Assessment Instructions: To qualify for ongoing Ig there must have been a response within 7 days of previous Ig therapy. Bleeding must have either reduced or resolved. Please use judgement with other. • Please provide the platelet count and response following (within seven days) Ig therapy (Number) Internal evaluation: interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: single Date prompt text: date of assessment Show Interpretation of Results: Yes Interpretation of Results Values: – Doubling of baseline platelet count (qualifies) – Increment in platelet count of greater than 10x10^9/L (qualifies) – Increment in platelet count greater than 10x10^9/L and doubling of baseline (qualifies) – Other – describe in comments (does not qualify) Allow attachment upload Attachment prompt text: Upload results Allow commentary: Decision support text: N/A Assessment Instructions: To qualify any qualifying value must be selected.	

Review Criteria 5	Refractory Persistent or Chronic ITP — splenectomy failed or contraindicated and second-line agent unsuccessful	
	OR In patients without active bleeding, a doubling of baseline platelet count and a rise in platelet count to greater than $30x10^9$/L was demonstrated within seven days of previous Ig therapy • Please provide the platelet count and response following (within seven days) the most recent Ig therapy (Number) Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: single Date prompt text: date of assessment Show Interpretation of Results: Yes Interpretation of Results Values – Double from baseline platelet count AND above $30x10^9$/L (qualifies) – Other (does not qualify) Allow attachment upload Attachment prompt text: upload results Allow commentary Decision support text: N/A Assessment Instructions: To qualify the platelet response must be both double from baseline AND greater than $30x10^9$/L. • Please describe the date of, and response to the most recent Ig infusion (text) [EI-22] Max characters: 2500 Max lines: 5 Prompt for a date: none Decision support text: N/A Assessment Instructions: The post treatment platelet count must have been within 7 days of the date of the most recent Ig infusion. There must be a demonstrated response to Ig therapy to qualify including: a reduction or resolution in bleeding and a post treatment platelet count rise to >$30x10^9$/L and double the pre-treatment count. Review Postscript	

Review Criteria 5	Refractory Persistent or Chronic ITP — splenectomy failed or contraindicated and second-line agent unsuccessful	
	The objective of therapy is to maintain a safe platelet count while other treatment options are explored.	

Dose 5	Refractory Persistent or Chronic ITP — splenectomy failed or contraindicated and second-line agent unsuccessful	
Dose 5	Maintenance dose **Dose text:** 0.4 - 2g/kg as a single or divided dose at 4 to 6-weekly intervals titrated to symptoms and platelet count, up to a maximum of 2g/kg/4-week period **Infusion method:** IVIg **Dose type:** Maintenance dose **Requests at which this dose may be proposed:** Initial, continuing **Min Dose per kg:** 0.4 g/kg **Max Dose per kg:** 2.0 g/kg **Max Total per Dose:** N/A **Administer in a divided dose:** Yes **Min divisions:** 2 **Max divisions:** 5 **Minimum frequency:** 2 **Maximum frequency:** 6 **Frequency unit:** Weeks **Max dose per period per kg:** 2.0 g/kg every 4 weeks **Assessment instructions:** N/A **Dose type postscript:** N/A Dose Postscript The objective of IVIg therapy in ITP is to maintain a safe platelet count while other therapeutic options are explored. The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient. Refer to the current product information sheet for further information on dose, administration and contraindications.	

Indication 6	Subsequent or ongoing treatment for ITP responders during pregnancy and the postpartum period	

Qualifying Criteria 6	Subsequent or Ongoing treatment for ITP responders during pregnancy and the postpartum period	
Qualifying Criteria 6	Qualifying Preamble IVIg therapy is used to avoid corticosteroids, immunosuppressive agents and splenectomy during pregnancy. A dose up to 2g/kg is available under the ITP in pregnancy - initial therapy indication. If a response is achieved following this initial therapy but not maintained, a maintenance dose titrated to maintain a platelet count above $30x10^9$/L may be administered every three to four weeks throughout pregnancy under this indication. A subsequent one-off induction dose of up to 2g/kg prior to impending procedure or delivery is also available under this indication. [Group 1] Pregnant patient and current platelet count represents potential risk: ○ Less than $30x10^9$/L and risk of haemorrhage ○ Less than $80x10^9$/L and life-threatening haemorrhage ○ Less than $100x10^9$/L and impending delivery. • Please select the current platelet count and risk potential (Number) EI-15] Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 100 Prompt for a date: single Date prompt text: date of assessment Show Interpretation of Results: Yes Interpretation of Results Values: i. < $30x10^9$/L with risk of haemorrhage (qualifies) ii. <$80x10^9$/L with life threatening haemorrhage (qualifies) iii. <$100x10^9$/L and impending delivery (qualifies) iv. Other, please specify in comments (qualifies) Allow attachments upload Attachment prompt text: Upload results Allow commentary Decision support text: “...platelet count and bleeding risk”	

Qualifying Criteria 6	Subsequent or Ongoing treatment for ITP responders during pregnancy and the postpartum period	
	Assessment Instructions: To qualify the platelet count should fall into one of these categories. Please use judgement with other. • Please provide the estimated date of confinement (Date) EI-14] Earliest valid date: 5 days before request Latest valid date: 42 weeks after request Earliest qualifying date: 5 days before request Latest qualifying date: 42 weeks after request Allow commentary Decision support text: "...the estimated date of confinement" Assessment Instructions: The expected date of confinement will indicate the potential cessation date noting that Ig therapy may extend beyond delivery to cover post partum bleeding risks. Any date within a current pregnancy will qualify e.g. less than 42 weeks from date of request. AND [Group 2] Previous Ig therapy resulted in resolution of active bleeding or a reduction in evidence of bleeding, correlating with a doubling of baseline platelet count or an increase in platelet count by an increment of greater than $10x10^9$/L within seven days of Ig therapy • Please select the type of bleeding reduced or resolved (Multi-LOV) [EI-19] Count of compliance with qualifying values Minimum qualifying count required: 1 Minimum selection count required: N/A – Mucosal bleeding (oral, GIT) reduced /resolved (qualifies) – Intracranial bleeding reduced or resolved (qualifies) – Wound or other active skin bleeding resolved (qualifies) – Mild bruising or petechiae resolved (qualifies) – Mucosal bleeding reduced /resolved (qualifies) – Wound or other active bleeding resolved (qualifies) – No change in bleeding (does not qualify) – Other, please specify in comments (qualifies) Allow commentary Decision support text "...a description of the patient's response to Ig in regards to bleeding symptoms". Assessment Instructions: To qualify there must be a reduction in bleeding with Ig therapy, if bleeding was present. Please use judgement with other.	

Qualifying Criteria 6	Subsequent or Ongoing treatment for ITP responders during pregnancy and the postpartum period	
	• Please provide the pre-Ig treatment platelet count Internal evaluation: compliance with qualifying range Unit: x 10^9/L Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 100 Prompt for a date: single Date prompt text: date of assessment Allow attachments upload Attachment prompt text: Upload results Allow commentary Decision support text: "...pre-Ig treatment platelet count". Assessment Instructions: To qualify the platelet count must be less than 100x10^9/L • Platelet count and response following (within seven days) previous Ig therapy (number) Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: single Date prompt text: date of assessment Show Interpretation of Results: Yes Interpretation of Results Values – Doubling of baseline platelet count (qualifies) – Increment in platelet count of greater than 10x10^9/L (qualifies) – Doubling of baseline platelet count and increment of greater than 10x10^9/L(qualifies) – Other – describe in comments (does not qualify) Allow attachments upload Attachment prompt text: Upload results Allow commentary Decision support text: "...the platelet response within 7 days of Ig therapy" Assessment Instructions: To qualify the platelet response must be in one of the categories of qualifying values. • Please provide the date of, and response to the most recent Ig infusion (text)[EI-22] Max characters: 2500	

Qualifying Criteria 6	Subsequent or Ongoing treatment for ITP responders during pregnancy and the postpartum period	
	Max lines: 5 Prompt for a date: none Decision support text: "...date of and response to the most recent Ig infusion" Assessment Instructions: The post treatment platelet count must have been within 7 days of the date of the most recent Ig infusion. See previous evidence item for post-treatment platelet count. There must be a demonstrated response to Ig therapy to qualify including: a reduction or resolution in bleeding and a post treatment platelet count rise of >10x10^9/L or double the pre-treatment count (i.e. if <10x10^9/L pre-treatment). OR In patients without active bleeding, the most recent Ig therapy resulted in a doubling of baseline platelet count and a rise in platelet count to greater than 30x10^9/L within seven days of therapy • Platelet count and response following (within seven days) most recent Ig therapy) (number) Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: single Date prompt text: date of assessment Show Interpretation of Results: Yes Interpretation of Results Values – Double from baseline platelet count AND above 30x10^9/L (qualifies) – Other (does not qualify) Allow commentary Allow attachments: Upload results Decision support text: "...the platelet response within 7 days of Ig therapy" Assessment Instructions: To qualify the platelet response must be both double from baseline AND greater than 30x10^9/L. • Please provide the date of, and response to the most recent Ig infusion (text) EI-22] Max characters: 2500 Max lines: 5 Prompt for a date: none Decision support text: "...date of, and response to the most recent Ig infusion"	

Qualifying Criteria 6	Subsequent or Ongoing treatment for ITP responders during pregnancy and the postpartum period	
	Assessment Instructions: The post treatment platelet count must have been within 7 days of the date of the most recent Ig infusion. See previous evidence item for post-treatment platelet count. There must be a demonstrated response to Ig therapy to qualify including: a reduction or resolution in bleeding and a post treatment platelet count rise to >30x10^9/L and double the pre-treatment count.	

Review Criteria 6	Subsequent or ongoing treatment for ITP responders during pregnancy and the postpartum period	
Review Criteria 6	Initial authorisation period: 12 months Review can be completed: Yes Continuing Treatment is permitted: No Review preamble Review is not mandated for this indication however the following criteria may be useful in assessing the effectiveness of therapy. Resolution of, or a reduction in evidence of bleeding correlating with a doubling of platelet count or increase in platelet count by an increment greater than 10x10^9/L within seven days • Resolution of, or reduction in bleeding (Multi-LOV) [EI-9] Is mandatory: No Internal evaluation: count of selected values Minimum qualifying count required: N/A Minimum selection of count required: 1 i. No evidence of bleeding prior to Ig ii. Mucosal bleeding (oral, GIT) reduced / resolved iii. Intracranial bleeding reduced or resolved iv. Wound or other active skin bleeding resolved v. Mild bruising or petechiae resolved vi. Mucosal bleeding reduced / resolved vii. Wound or other active bleeding resolved viii. No change in bleeding ix. Other, please specify in comments Prompt for a date: None Allow commentary Decision support text: N/A Assessment Instructions: N/A • Platelet count and response following (within seven days) most recent Ig therapy (number)	

Review Criteria 6	Subsequent or ongoing treatment for ITP responders during pregnancy and the postpartum period	
	Is mandatory: No Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: single Date prompt text: date of assessment Show Interpretation of Results: Yes Interpretation of results values i. Double from baseline platelet count but not above 30x10^9/L (does not qualify) ii. Double from baseline platelet count and above 30x10^9/L (qualifies) iii. Did not double from baseline but was above 30x10^9/L (does not qualify) iv. Did not double from baseline and was below 30x10^9/L (does not qualify) Allow attachments upload Attachment prompt text: Upload results Allow commentary Decision support text: N/A Assessment Instructions: N/A • Please describe the date of, and response to the most recent Ig infusion (Text) [EI-12] Max characters: 2500 Max lines: 5 Prompt for a date: none Decision support text: N/A Assessment Instructions: N/A OR In patients without active bleeding a doubling of baseline platelet count and a rise in platelet count to greater than 30x10^9/L was demonstrated within seven days of previous Ig therapy • Platelet count and response following (within seven days) most recent Ig therapy (number) Is mandatory: No Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0	

Review Criteria 6	Subsequent or ongoing treatment for ITP responders during pregnancy and the postpartum period	
	Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: single Date prompt text: date of assessment Show Interpretation of Results: Yes Interpretation of Results Values i. Double from baseline platelet count AND above $30x10^9$/L (qualifies) ii. Other – describe in comments (does not qualify) Allow attachments upload Attachment prompt text: upload results Allow commentary Decision support text: N/A Assessment Instructions: N/A • Please provide the date of, and response to the most recent IG infusion (Text) [EI-12] Max characters: 2500 Max lines: 5 Prompt for a date: none Decision support text: N/A Assessment Instructions: N/A	

Dose 6	Subsequent or ongoing treatment for ITP responders during pregnancy and the postpartum period	
Dose 6	[Dose 1] Maintenance dose	

Dose text	0.4 - 2g/kg as a single or divided dose at 4 to 6-weekly intervals titrated to symptoms and platelet count, up to a maximum of 2g/kg/4-week period
Infusion method	IVIg
Dose type	Maintenance dose
Requests at which this dose may be proposed	Initial
Min Dose per kg	0.4 g/kg
Max Dose per kg	2.0 g/kg
Max Total per Dose	N/A

Dose 6	Subsequent or ongoing treatment for ITP responders during pregnancy and the postpartum period	

Administer in a divided dose	Yes
Min divisions	2
Max divisions	5
Minimum frequency	2
Maximum frequency	6
Frequency unit	Weeks
Max dose per period per kg	2.0 g/kg every 4 weeks
Assessment instructions	N/A
Dose type postscript	The frequency and dose should be titrated to maintain a platelet count of at least 30 x 10^9/L

[Dose 2]

Induction dose prior to impending procedure or delivery

Dose text	0.8 - 2g/kg in single or divided dose
Infusion method	IVIg
Dose type	One off dose
Requests at which this dose may be proposed	Initial
Dose may be requested during the course of authorisation	Yes
Max number of additional doses allowed during the course of an authorisation period	1
Conditions for additional dose	A response to the initial dose must be demonstrated for approval of an additional dose of up to 2g/kg.
Min Dose per kg	0.8 g/kg
Max Dose per kg	2.0 g/kg
Max Total per Dose	N/A
Administer in a divided dose	Yes
Min divisions	2
Max divisions	5
Assessment instructions	A response to the first dose (of up to 2g/kg) is required to approve a second dose of up to 2g/kg. In pregnancy the patient's weight should be capped at 100kg for dose calculation purposes. A second dose of up to 2g/kg is anticipated only in rare circumstances e.g. an unexpected timelapse between the initial dose and a rescheduled procedure or a good but incomplete response to the initial therapy.

<table>
<tr><td>Dose 6</td><td colspan="2">Subsequent or ongoing treatment for ITP responders during pregnancy and the postpartum period</td><td></td></tr>
<tr><td></td><td colspan="2">
<table>
<tr><td>Dose type postscript</td><td>In rare circumstances a second induction dose of up to 2g/kg may be required (e.g. where the procedure was postponed/rescheduled after the initial induction dose). A second dose of up to 2g/kg will only be approved if a response to the initial induction dose was achieved.</td></tr>
</table>
<u>Dose Postscript</u>
The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient.
Refer to the current product information sheet for further information on dose, administration and contraindications.</td><td></td></tr>
</table>

Indication 7	ITP and inadequate platelet count for planned surgery	

Qualifying Criteria 7	ITP and inadequate platelet count for planned surgery.	
Qualifying Criteria 7	Qualifying preamble IVIg may be used to achieve a platelet count considered safe for surgery. The safe threshold will vary with the nature of the surgery and whether there is a concurrent bleeding risk. Recommended platelet counts for patients without concurrent risks of bleeding: ○ minor dental work (greater than $30x10^9$/L ○ major dental work (greater than $50x10^9$/L) ○ minor surgery (greater than $50x10^9$/L) ○ major surgery (greater than $80x10^9$/L) ○ major neurosurgery (greater than $100x10^9$/L) [Group 1] Surgery is planned • Type of Surgery (Multi-LOV) [EI-29] Internal evaluation: count of selected values Minimum qualifying count required: N/A Minimum selection of count required: 1 – Minor dental work (qualifies) – Major dental (qualifies) – Minor surgery (qualifies) – Major surgery (qualifies) – Major neurosurgery (qualifies) – Other, please specify in comments (qualifies) Allow commentary Decision support text "type and date of planned surgery." Assessment Instructions: Any from the list will qualify. Please use judgement with other". • Name of operation and date of surgery (if scheduled) (Text*) [EI-30] Max characters: 2500 Max lines: 5 Prompt for a date: none Decision support text: N/A Assessment Instructions: Any response will qualify. Please consider the type of surgery with the platelet range in the list. Recommended platelet counts: ○ minor dental work (>$30x10^9$/L ○ major dental work (>$50x10^9$/L)	

Qualifying Criteria 7	ITP and inadequate platelet count for planned surgery.	
	○ minor surgery (>50x10^9/L) ○ major surgery (>80x10^9/L) ○ major neurosurgery (>100x10^9/L) AND [Group 2] Platelet count is below the accepted cut-off for the intended surgery • Please provide the current platelet count (describe concurrent risk factors in comments) (Number) [EI-34] Internal evaluation: interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 150 Prompt for a date: single Date prompt text: date of assessment Show Interpretation of Results: Yes Interpretation of Results Values – minor dental work (<30x10^9/L) (qualifies) – major dental work (<50x10^9/L) (qualifies) – minor surgery (<50x10^9/L) (qualifies) – major surgery (<80x10^9/L) (qualifies) – major neurosurgery (<100x10^9/L) (qualifies) – other – describe in comments (qualifies) Allow attachments upload Attachment prompt text: upload results Allow commentary Decision support text: "...the current platelet count" Assessment Instructions: To qualify the platelet count should fall into one of the listed categories for patients without risk factors. Higher platelet counts are acceptable for patients with concurrent bleeding risk factors (e.g. warfarin therapy, aspirin therapy, factor deficiencies, anticoagulation or surgical factors) platelet counts higher than those suggested for patients without risk factors will be allowed. An acceptable platelet count will depend on the nature of the risk factor and the surgery.	

Review Criteria 7	ITP and inadequate platelet count for planned surgery	
Review Criteria 7	Initial authorisation period: 1 month Review can be completed: yes Continuing Treatment is permitted: No Review preamble Review Is not mandated for this indication however the following criteria may be useful in assessing the effectiveness of Ig therapy. Platelet count is above the accepted cut-off for the intended surgery for patients without concurrent risk factors: • Surgery was able to proceed as planned (Boolean) Is Mandatory: No Internal evaluation: compliance with qualifying values Qualifying value: unticked Prompt for a date: single Date prompt text: date of surgery Allow commentary Assessment instructions: N/A • Please provide the pre-surgery platelet count following Ig therapy (Number) [EI-34] Is mandatory: No Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Prompt for a date: single Date prompt text: date of assessment Show Interpretation of Results: Yes Interpretation of Results Values – minor dental work (>30x10^9/L) (does not qualify) – major dental work (>50x10^9/L) (does not qualify) – minor surgery (>50x10^9/L) (does not qualify) – major surgery (>80x10^9/L) (qualifies) – major neurosurgery (>100x10^9/L) (does not qualify) Allow attachments upload Attachment prompt text: upload results Allow commentary Decision support text: N/A Assessment Instructions: N/A	

Review Criteria 7	ITP and inadequate platelet count for planned surgery	
	• Please provide the date of, and response to the last Ig infusion (single date text) [EI-12] Max characters: 2500 Max lines: 5 Prompt for a date: none Decision support text: N/A Assessment Instructions: Not required. OR Platelet count is above the accepted cut-off for the intended surgery for patients with concurrent risk factors: • Surgery was able to proceed as planned (Boolean) Is Mandatory: No Internal evaluation: compliance with qualifying values Qualifying value: unticked Prompt for a date: single Date prompt text: date of surgery Allow commentary Assessment Instructions: N/A • Pre-surgery platelet count following Ig therapy (Number) [EI-34] Is mandatory: No Internal evaluation: compliance with qualifying range Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: single Date prompt text: date of assessment Allow attachments upload Attachment prompt text: Upload results Allow commentary Assessment Instructions: N/A • Please provide the date of, and response to the last Ig infusion (single date text) [EI-12] Max characters: 2500 Max lines: 5	

Review Criteria 7	ITP and inadequate platelet count for planned surgery	
	Prompt for a date: none Decision support text: N/A Assessment instructions: N/A	

Dose 7	ITP and inadequate platelet count for planned surgery	
Dose 7	Induction dose **Dose text:** 1 - 2g/kg as a single or divided dose **Infusion method:** IVIg **Dose type:** One off dose **Requests at which this dose may be proposed:** Initial **Dose may be requested during the course of authorisation:** Yes **Max number of additional doses allowed during the course of an authorisation period:** 99 **Conditions for additional dose:** A response to the initial dose must be demonstrated for approval of an additional dose of up to 2g/kg. **Min Dose per kg:** 1.0 g/kg **Max Dose per kg:** 2.0 g/kg **Max Total per Dose:** N/A **Administer in a divided dose:** Yes **Min divisions:** 2 **Max divisions:** 5 **Assessment instructions:** A response to the first dose (of up to 2g/kg) is required to approve an additional dose. The total of both doses must not exceed 2g/kg. **Dose type postscript:** N/A Dose Postscript While a dose of 1-2g/kg is suggested, a lower dose may be appropriate if the patient has previously responded to a lower dose. IVIg may be used to achieve a platelet count considered safe for surgery.	

Dose 7	ITP and inadequate platelet count for planned surgery	
	The safe threshold will vary with the nature of the surgery. If an additional induction dose is required prior to a surgical procedure where there has been a response to IVIg, but the platelet count falls to below safe levels for that procedure, a new application is required. The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient. Refer to the current product information sheet for further information on dose, administration, and contraindications.	

Indication 8	HIV-associated ITP	

Qualifying Criteria 8	HIV-associated ITP	
Qualifying Criteria 8	Failure of antiretroviral therapy with intracranial haemorrhage and platelet count less than $80x10^9$/L • Please describe the failure of antiviral therapy (text) Max characters: 2500 Max lines: 5 Prompt for a date: none Decision support text: "...confirmation that antiviral therapy has failed". Assessment Instructions: To qualify, the antiviral therapy should be stated and there must be confirmation that this therapy has failed. • Please describe the intracranial haemorrhage (text) Max characters: 2500 Max lines: 5 Prompt for a date: none Decision support text: "...confirmation that the patient has suffered an intracranial haemorrhage". Assessment Instructions: To qualify there must be confirmation that the patient has suffered an intracranial haemorrhage, sub-dural haematoma. • Please provide the current platelet count (Number) [EI-36] Internal evaluation: compliance with qualifying range Unit: $x10^9$/L Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 79 Prompt for a date: single	

Qualifying Criteria 8	HIV-associated ITP	
	Date prompt text: date of assessment Allow attachments upload Attachment prompt text: Upload results Allow commentary Decision support text: "...current platelet count". Assessment Instructions: To qualify the current platelet count must be less than $80x10^9/L$ OR Failure of antiretroviral therapy and other life-threatening haemorrhage with a platelet count of less than $50x10^9/L$ • Please describe the failure of antiviral therapy (text) Max characters: 2500 Max lines: 5 Prompt for a date: none Decision support text: "...confirmation that antiviral therapy has failed and the patient has suffered an intracranial haemorrhage. Assessment Instructions: To qualify, the antiviral therapy should be stated and there must be confirmation that antiviral therapy has failed. Life-threatening bleeding may also have occurred in the context of commencement of Highly Active Antiretroviral Therapy (HAART) but there has been an insufficient timeframe for this therapy to become effective. • Type of life-threatening haemorrhage (Multi-LOV) [EI-38] Internal evaluation: count of selected values Minimum qualifying count required: N/A Minimum selection count required: 1 i. Severe mucosal or GIT haemorrhage (qualifies) ii. Multiple sites frank haemorrhage (qualifies) iii. Trauma (qualifies) iv. Pregnancy (qualifies) v. Other please specify in comments (qualifies) Allow commentary Decision support text "...the type of life-threatening haemorrhage". Assessment Instructions: Any from the list will qualify. Please use judgement with other. • Please provide the current platelet count (Number) [EI-36] Internal evaluation: compliance with qualifying range Unit: x $10^9/L$ Lowest valid value: 0	

Qualifying Criteria 8	HIV-associated ITP	
	Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 49 Prompt for a date: single Date prompt text: date of assessment Allow attachments upload Attachment prompt text "Upload results" Allow commentary Decision support text "...current platelet count". Assessment Instructions: To qualify the current platelet count must be less than $50x10^9/L$ OR Failure of antiretroviral therapy and risk of clinically significant bleeding and platelet count less than $30x10^9/L$ • Please describe the failure of antiviral therapy (text) Max characters: 2500 Max lines: 5 Prompt for a date: none Decision support text: "...confirmation that antiviral therapy has failed and the patient has suffered an intracranial haemorrhage. Assessment Instructions: To qualify there must be confirmation that antiviral therapy has failed • Please select the type of bleeding risk (Mulit-LOV) [EI-3] Internal evaluation: count of selected values Minimum qualifying count required: N/A Minimum selection of count required: 1 – Trauma (qualifies) – Recent surgery (qualifies) – Other, please specify in comments (qualifies) Allow commentary Decision support text "...a description of the risk of clinically significant bleeding". Assessment Instructions: To qualify there must be a risk of clinically significant bleeding. Any from the list will qualify, use judgement with other. • Please provide the current platelet count (Number) [EI-2] Internal evaluation: compliance with qualifying range Unit: x $10^9/L$ Lowest valid value: 0 Highest valid value: 500	

Qualifying Criteria 8	HIV-associated ITP	
	Lowest qualifying value: 0 Highest qualifying value: 29 Prompt for a date: single Date prompt text: date of assessment Allow attachments upload Attachment prompt text “Upload results” Allow commentary Decision support text: “...current platelet count”. Assessment Instructions: To qualify the current platelet count must be less than $30x10^9$/L	

Review Criteria 8	HIV-associated ITP	
Review Criteria 8	Initial authorisation period: 7 days Review can be completed: Yes Continuing treatment is permitted: No Review preamble Review is not mandated for this indication however the following criteria may be useful in assessing the effectiveness of Ig therapy. Resolution of, or a reduction in evidence of bleeding correlating with a doubling of platelet count or in platelet count of greater than $10x10^9$/L within seven days of Ig therapy • Please select the type of bleeding that has resolved or reduced (Multi-LOV) [EI-9] Is mandatory: No Internal evaluation: count of selected values Minimum qualifying count required: 0 Minimum selection of count required: 1 – No evidence of bleeding prior to Ig – Mucosal bleeding (oral, GIT) reduced / resolved – Intracranial bleeding reduced or resolved – Wound or other active skin bleeding resolved – Mild bruising or petechiae resolved Mucosal bleeding reduced / resolved – Wound or other active bleeding resolved – No change in bleeding – Other, please specify in comments	

Review Criteria 8	HIV-associated ITP	
	Prompt for a date: None Allow commentary Decision support text: N/A Assessment Instructions: N/A • Platelet count and response following (within seven days) most recent Ig therapy (number) Is mandatory: No Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: single Date prompt text: date of assessment Show Interpretation of Results: Yes Interpretation of Results Values – Double from baseline platelet count but not above 30x10^9/L (qualifies) – Double from baseline platelet count and above 30x10^9/L (does not qualify) – Did not double from baseline but was above 30x10^9/L (does not qualify) Allow attachments upload Attachment prompt text: Upload results Allow commentary Decision support text: N/A Assessment Instructions: N/A • Please describe the date of, and response to the most recent Ig infusion (Text) [EI-12] Max characters: 2500 Max lines: 5 Prompt for a date: none Decision support text: N/A Assessment Instructions: N/A OR In patients without active bleeding a doubling of baseline platelet count and a rise in platelet count to greater than 30x10^9/L was demonstrated within seven days of Ig therapy • Platelet count and response following (within seven days) Ig therapy (Number)	

Review Criteria 8	HIV-associated ITP	
	Is mandatory: no Internal evaluation: Interpretation compliance Unit of measure: x 10^9/L Number of decimals: 0 Lowest valid value: 0 Highest valid value: 500 Lowest qualifying value: 0 Highest qualifying value: 500 Prompt for a date: single Date prompt text: date of assessment Show Interpretation of Results: Yes Interpretation of Results Values – Double from baseline platelet count but not above 30x10^9/L (qualifies) – Double from baseline platelet count and above 30x10^9/L (does not qualify) – Did not double from baseline but was above 30x10^9/L (does not qualify) Allow attachments upload Attachment prompt text: Upload results Allow commentary Decision support text: N/A Assessment Instructions: N/A • Please provide the date of, and response to most recent Ig treatment (Text) [EI-12] Is mandatory: No Max characters: 2500 Max lines: 5 Prompt for a date: none Decision support text: N/A Assessment Instructions: N/A	

Dose 8	HIV-associated ITP	
Dose 8	Max dose per authorisation period per kg: 2.0 g/kg Induction dose Dose text: 1 - 2g/kg as a single or divided dose Infusion method: IVIg Dose type: One off dose	

<table>
<tr><td>Dose 8</td><td>HIV-associated ITP</td><td></td></tr>
<tr><td></td><td>
<table>
<tr><td>Requests at which this dose may be proposed</td><td>Initial</td></tr>
<tr><td>Dose may be requested during the course of authorisation</td><td>Yes</td></tr>
<tr><td>Max number of additional doses allowed during the course of an authorisation period</td><td>99</td></tr>
<tr><td>Conditions for additional dose</td><td>The remainder of the 2 g/kg dose may be requested provided the total dose of 2 g/kg is not exceeded.</td></tr>
<tr><td>Min Dose per kg</td><td>1.0 g/kg</td></tr>
<tr><td>Max Dose per kg</td><td>2.0 g/kg</td></tr>
<tr><td>Max Total per Dose</td><td>N/A</td></tr>
<tr><td>Administer in a divided dose</td><td>Yes</td></tr>
<tr><td>Min divisions</td><td>2</td></tr>
<tr><td>Max divisions</td><td>5</td></tr>
<tr><td>Assessment instructions</td><td>N/A</td></tr>
<tr><td>Dose type postscript</td><td>N/A</td></tr>
</table>
Dose Postscript
The objective of IVIg therapy in ITP is to maintain a safe platelet count while other therapeutic options are explored.
The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient.
Refer to the current product information sheet for further information on dose, administration, and contraindications.
</td><td></td></tr>
</table>

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