

Proposed changes to the *Criteria for the clinical use of intravenous immunoglobulin in Australia, Second Edition*

ITEM	CRITERIA FOR THE CLINICAL USE OF INTRAVENOUS IMMUNOGLOBULIN IN AUSTRALIA, SECOND EDITION (CRITERIA)	PROPOSED REVISIONS TO THE CRITERIA	SWG RATIONALE FOR PROPOSED CHANGE (A) Administrative (B) Progressive (C) Programmed
Condition Name	Idiopathic (autoimmune) thrombocytopenic purpura (ITP) — adult	Idiopathic (autoimmune) thrombocytopenic purpura (ITP) — adult	
Specialty	Haematology	Haematology	
Chapter	5	5	
Specific Conditions		ITP –adult Evans Syndrome - autoimmune haemolytic anaemia (AIHA) with immune thrombocytopenia	Evans syndrome no longer exists as a separate condition and will be accessed under ITP- adult and ITP – children or AIHA.
Level of Evidence	Evidence of probable benefit (Category 2a).	Evidence of probable benefit (Category 2a).	
Justification for Evidence Category	Five small prospective studies, including three randomised studies, demonstrated equivalent efficacy of 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 ≥ 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	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 ≥ 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	

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	<p>thrombocytopenia reported possible benefit for the restoration and maintenance of platelet count for the duration of the haemorrhagic disorder (Biotext 2004).</p> <p>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 ITP in adults, in children, and during pregnancy. This statement concluded that few RCTs have been conducted and that multi-centre, prospective RCTs are required.</p>	<p>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).</p> <p>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 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.</p> <p>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 2 g/kg in</p>	

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		<p>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.</p> <p>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.</p>	
Description and Diagnostic Criteria	<p>ITP is a reduction in platelet count (thrombocytopenia) resulting from shortened platelet survival due to anti-platelet antibodies. When counts are very low ($<30 \times 10^9/L$), 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. ITP is divided into chronic and acute forms. It is a common finding in patients with HIV, and while it may be found at any stage of the infection, its</p>	<p>ITP is a reduction in platelet count (thrombocytopenia) resulting from shortened platelet survival due to anti-platelet antibodies. When counts are very low ($<30 \times 10^9/L$), 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. ITP is divided into chronic and acute forms. It is a common finding in patients with human immunodeficiency virus</p>	

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	<p>prevalence increases as HIV disease advances.</p> <p>Around 80% of adults with ITP have the chronic form of disease. The highest incidence of chronic ITP is in women aged 15–50 years, although some reports suggest increasing incidence with age.</p> <p>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.</p>	<p>(HIV), and while it may be found at any stage of the infection, its prevalence increases as HIV disease advances.</p> <p>Around 80% of adults with ITP have the chronic form of disease. The highest incidence of chronic ITP is in women aged 15–50 years, although some reports suggest increasing incidence with age.</p> <p>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.</p> <p>Evans syndrome is a rare but serious autoimmune disease defined by the simultaneous or sequential occurrence of AIHA and immune thrombocytopenia purpura (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</p>	

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		perspective on diagnosis, clinical features and management.			
Diagnosis is required	Refractory acute ITP <i>on the recommendation of a clinical haematologist</i>	Yes	Which Speciality	Haematologist or General Physician	Specialties of treating specialists are required to be identified within the Ig system. (A)
Diagnosis must be verified		No	Which Specialty		
Exclusion Criteria					
Indication for use	<p>1. Refractory acute ITP <i>on the recommendation of a clinical haematologist</i></p> <p>Patients with severe thrombocytopenia (platelets $<30 \times 10^9/L$) who have not responded to corticosteroid therapy.</p> <p>2. ITP with life-threatening haemorrhage or the potential for life-threatening haemorrhage</p> <p>Patients with severe thrombocytopenia ($<30 \times 10^9/L$) with clinical evidence of a haemostatic defect (e.g. mucous membrane haemorrhage) or active bleeding.</p>	<p>Refractory acute ITP — initial therapy.</p> <p>Refractory acute ITP — splenectomy failed or contraindicated and second-line agent unsuccessful.</p> <p>ITP with life-threatening haemorrhage or the potential for life-threatening haemorrhage.</p> <p>Initial therapy for ITP in pregnancy.</p> <p>Ongoing treatment for ITP responders during pregnancy and the postpartum period.</p>			Refractory ITP and pregnancy have each been split into 2 indications to support initial treatment and then ongoing therapy in those patients requiring monthly Ig treatment. Eg refractory ITP when splenectomy has failed and ongoing treatment for ITP responders during pregnancy.

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	<p>3. ITP in pregnancy</p> <p>a. Platelets $<30 \times 10^9/L$</p> <p>b. Impending delivery</p> <p>4. Specific circumstances</p> <p>a. Planned surgery</p> <p>b. Other concurrent risk factors for bleeding (e.g. concurrent anti-coagulant therapy)</p> <p>c. Severe ITP (platelets $<30 \times 10^9/L$) where corticosteroids and immunosuppression are contraindicated</p> <p>d. Chronic ITP under the guidance of a clinical haematologist, as adjunctive therapy or where other therapies have failed or are not appropriate</p> <p>5. HIV-associated ITP</p> <p>Patients with severe ITP associated with HIV infection.</p>	<p>ITP and inadequate platelet count for planned surgery.</p> <p>Severe ITP.</p> <p>Chronic ITP.</p> <p>HIV-associated ITP.</p>	
Qualifying Criteria	<p>1. Refractory acute ITP:</p> <p>1. Patients qualify for initial IVIg therapy</p>	<p>Refractory acute ITP — initial therapy.</p> <ul style="list-style-type: none"> Patients qualify for initial IVIg therapy 	<p>The qualifying criteria are largely unchanged with required timeframes for steroid therapy being defined and Steroid contra-indication reasons</p>

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	<p>when conventional doses of corticosteroids (0.5-2.0 mg/ kg prednisolone, or equivalent) have failed to improve the platelet count or stop bleeding within a clinically appropriate time frame, as assessed by a clinical haematologist. The objective of therapy is to induce a prompt increase in the platelet count (to $>30 \times 10^9/L$) while other therapies are introduced.</p> <p>2. Patients qualify for continuing doses when splenectomy has failed or is contraindicated AND where therapy with at least one second-line agent has been unsuccessful in maintaining a platelet count $>30 \times 10^9/L$.</p> <p>With ongoing therapy, IVIg may be administered to achieve a platelet count $>30 \times 10^9/L$. Further doses may be administered in responsive patients for up to 6 months (thereafter see Chronic refractory ITP). The frequency and dose should be titrated to maintain a platelet count of at least $30 \times 10^9/L$. The objective of therapy is to maintain a safe platelet count while other therapeutic</p>	<p>when current platelet count is $<30 \times 10^9/L$</p> <p>AND</p> <ul style="list-style-type: none"> There has been no improvement in response to conventional doses of corticosteroid therapy for at least 14 days (unless valid reason is provided) or corticosteroid therapy is contraindicated. <p>Refractory acute ITP — splenectomy failed or contraindicated and second-line agent unsuccessful.</p> <ul style="list-style-type: none"> Patients qualify for continuing doses when the current platelet count is $<30 \times 10^9/L$ <p>AND</p> <ul style="list-style-type: none"> At least a two-fold increase in platelet count (and platelet count $>30 \times 10^9/L$) was demonstrated within 72 hours of previous immunoglobulin (Ig) treatment and a reduction in evidence of bleeding (if relevant). <p>AND</p> <ul style="list-style-type: none"> Splenectomy has failed to correct thrombocytopenia or splenectomy is contraindicated. <p>AND</p> <ul style="list-style-type: none"> Therapy with a second-line agent has been unsuccessful in raising the platelet count above $30 \times 10^9/L$. 	<p>considered such as:</p> <ul style="list-style-type: none"> Unstable Diabetes Psychosis or mood disorder Significant infection including sepsis Severe osteoporosis Myopathy History of avascular necrosis <p>Evidence items supporting the eligibility criteria are formalised for each indication, eg failure to respond to steroid therapy is defined as being after 14 days treatment unless there is a valid reason. Data will be captured on all alternative therapies used and contraindication reason to steroids and immunosuppressive therapy are required to be provided. (A)</p> <p>SWG confirmed the measurement of maximum platelet count at 72 hours and that 'Response' was defined as level greater than 30 and at least a 2 fold increase in PLT count (in line with ITP IWG definition of response). (B)</p> <p>Splenectomy contraindication reasons include extramedullary haematopoiesis and surgical contraindications. (A)</p> <p>Second line agent therapy includes</p> <ol style="list-style-type: none"> Azathioprine Danazol Dapsone Rituximab

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	<p>options are explored.</p> <p>2. ITP with life-threatening haemorrhage or the potential for life-threatening haemorrhage:</p> <p>IVIg therapy may be given when conventional doses of corticosteroids have failed or in conjunction with steroids when a rapid response is required.</p> <p>3. ITP in pregnancy:</p> <ol style="list-style-type: none"> 1. Platelets $<30 \times 10^9/L$: IVIg therapy may be used to avoid corticosteroids, immunosuppressive agents and splenectomy. Further doses titrated to maintain a platelet count $>30 \times 10^9/L$ may be administered every three to four weeks throughout the pregnancy. 2. Impending delivery: IVIg therapy may be used to achieve a platelet count considered safe for delivery ($80\text{--}100 \times 10^9/L$). 	<p>With ongoing therapy, IVIg may be administered to achieve a platelet count of $>30 \times 10^9/L$. Further doses may be administered in responsive patients for up to 12 months (thereafter, see chronic refractory ITP).</p> <p>ITP with life-threatening haemorrhage or the potential for life-threatening haemorrhage.</p> <ul style="list-style-type: none"> IVIg therapy may be given to patients with life-threatening bleeding or potential for life threatening bleeding and the current platelet count is: <ul style="list-style-type: none"> $80\text{--}100 \times 10^9/L$ in patients with intracranial haemorrhage, $<50 \times 10^9/L$ in patients with life threatening haemorrhage $<30 \times 10^9/L$ in patients with a risk of haemorrhage. <p>AND</p> <ul style="list-style-type: none"> Ig therapy is given in conjunction with corticosteroids when a rapid response is required or when conventional doses of corticosteroids (for at least 14 days) have failed to improve count (unless a valid reason is provided) or when corticosteroid therapy is contraindicated. <p>Initial therapy for ITP in pregnancy IVIg therapy is used to avoid corticosteroids, immunosuppressive agents and splenectomy</p>	<p>v. Other (A)</p> <p>Qualifying platelet counts for different scenarios have been defined. (A)</p>

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	<p>4. Specific circumstances:</p> <p>1. Planned surgery: IVIg may be used to achieve a platelet count considered safe for surgery. The safe threshold will vary with the nature of the surgery <i>(Recommended platelet counts for patients without concurrent risks of bleeding: minor dental work $>30 \times 10^9/L$, minor surgery $>50 \times 10^9/L$, major surgery</i></p>	<p>during pregnancy. Once responder status has been demonstrated, doses titrated to maintain a platelet count $> 30 \times 10^9/L$ may be administered every three to four weeks throughout pregnancy.</p> <ul style="list-style-type: none"> Pregnant women are eligible when the current platelet count represents potential risk: <ul style="list-style-type: none"> $<30 \times 10^9/L$ with risk of haemorrhage $< 50 \times 30 \times 10^9/L$ with life-threatening haemorrhage or $<80-100 \times 10^9/L$ and impending delivery. <p>Ongoing treatment for ITP responders during pregnancy and the postpartum period. IVIg therapy is used to avoid corticosteroids, immunosuppressive agents and splenectomy during pregnancy. Further doses titrated to maintain a platelet count $>30 \times 10^9/L$ may be administered every three to four weeks throughout pregnancy.</p> <ul style="list-style-type: none"> Pregnant women are eligible when the current platelet count represents potential risk: <ul style="list-style-type: none"> $<30 \times 10^9/L$ with risk of haemorrhage $<50 \times 30 \times 10^9/L$ with life-threatening haemorrhage $<80-100 \times 10^9/L$ and impending 	

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	<p><i>>80x10⁹/L, major neurosurgery</i> <i>>100x10⁹/L.)</i></p> <p>2. Severe ITP: IVIg may be used where corticosteroids and immunosuppression are contraindicated.</p> <p>3. Chronic refractory ITP unresponsive to all other available therapies: These patients may be considered for long-term maintenance therapy with IVIg, subject to regular review by a haematologist.</p> <p>5. HIV-associated ITP:</p> <p>1. Failure of antiretroviral therapy with platelet count <30x10⁹/L;</p> <p>OR</p> <p>2. Life-threatening haemorrhage secondary to thrombocytopenia.</p>	<p>delivery.</p> <p>AND</p> <ul style="list-style-type: none"> The maximum platelet count achieved within 72 hours of the last Ig treatment was greater than 30 x 10⁹/L and at least double the pre-treatment count. <p>ITP and inadequate platelet count for planned surgery. 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.</p> <ul style="list-style-type: none"> Patients are eligible when surgery is planned and platelet count is below the accepted cut-off for the intended surgery: <ul style="list-style-type: none"> – minor dental work (>30 x 10⁹/L) – major dental work (>50 x 10⁹/L) – minor surgery (>50 x 10⁹/L) – major surgery (>80 x 10⁹/L) – major neurosurgery (>100 x 10⁹/L). <p>Severe ITP.</p> <ul style="list-style-type: none"> Severe ITP with platelet count <30 x 10⁹/L and corticosteroids and immunosuppression are contraindicated. 	<p>International working party on ITP have defined chronic ITP to commence after at least 12 months. The current version of criteria was based on 6 months. (A)</p> <p>Appropriate second line agents are:</p> <ol style="list-style-type: none"> TPO Azathioprine Danazol <p>(A)</p>

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		<p>Chronic ITP.</p> <ul style="list-style-type: none"> Chronic refractory ITP (at least 12 months from the first diagnosis of ITP) with platelet count $<30 \times 10^9/L$. <p>AND</p> <ul style="list-style-type: none"> Immunosuppressant therapy is contraindicated or conventional doses of steroids or immunosuppressant therapy have failed to correct the platelet count and therapy with at least one second-line agent has been unsuccessful in raising platelet count above $30 \times 10^9/L$. <p>AND</p> <ul style="list-style-type: none"> Splenectomy is contraindicated or splenectomy has failed to correct the low platelet count. <p>HIV-associated ITP.</p> <ul style="list-style-type: none"> Failure of antiretroviral therapy and a platelet count of $< 30 \times 10^9/L$ unless there is a risk of life-threatening haemorrhage secondary to thrombocytopenia ($<80-100 \times 10^9/L$ intracranial or $<50 \times 10^9/L$ other life-threatening haemorrhage). 	
Review Criteria	<ul style="list-style-type: none"> In chronic refractory ITP, six-month 	Refractory acute ITP — initial therapy.	For one-off requests, patient outcome data can

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	<p>review assessing evidence of clinical benefit;</p> <ul style="list-style-type: none"> • Resolution of bleeding; • Increment in platelet count. 	<p>Review Is not mandated for this indication however the following criteria may be useful in assessing the effectiveness of therapy.</p> <p>Outcome data to be measured</p> <ul style="list-style-type: none"> • maximum platelet count achieved within 72 hours after Ig treatment was greater than $30 \times 10^9/L$ and at least double the pre-treatment count • prevention of or reduction in bleeding, if prior bleeding. <p>Refractory acute ITP — splenectomy failed or contraindicated and second-line agent unsuccessful.</p> <p>Review must be undertaken six monthly by a Haematologist...</p> <p>Review criteria for assessing the effectiveness of IVIg use include:</p> <ul style="list-style-type: none"> • maintenance platelet count of greater than $30 \times 10^9/L$ • prevention of or reduction in bleeding, if prior bleeding. <p>Further IVIg doses may be administered in responsive patients for up to 12 months (thereafter see chronic refractory ITP). The frequency and dose should be titrated to maintain a platelet count of at least $30 \times 10^9/L$.</p>	<p>be entered but will not be mandatory.</p> <p>Review – Response to Ig therapy defined as Maximum platelet count of greater than $30 \times 10^9/L$ and doubling of count within 72 hours of Ig therapy in line with ITP International Working Party (ITPIWP). Definition. Maintenance therapy is only supported for 3 indications – ongoing refractory ITP, pregnant Ig responders and chronic ITP (history of diagnosis now 12 rather than 6 months in line with ITPIWP).</p>

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		<p>The objective of therapy is to maintain a safe platelet count while other treatment options are explored.</p> <p>ITP with life-threatening haemorrhage or the potential for life-threatening haemorrhage.</p> <p>Review Is not mandated for this indication however the following criteria may be useful in assessing the effectiveness of therapy.</p> <p>Outcome data to be measured</p> <ul style="list-style-type: none"> • maximum platelet count achieved within 72 hours of Ig treatment of greater than $30 \times 10^9/L$ and at least double the pre-treatment count • prevention of or reduction in bleeding risk or bleeding, if prior bleeding. <p>Initial therapy for ITP in pregnancy.</p> <p>Review Is not mandated for this indication.</p> <p>Ongoing treatment for ITP responders during pregnancy and the postpartum period.</p> <p>Review is not mandated for this indication however the following criteria may be useful in assessing the effectiveness of therapy.</p> <p>Maximum length of authorisation is 12 months.</p>	

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		<p>Outcome data to be measured Review criteria for assessing the effectiveness of IVIg use include:</p> <ul style="list-style-type: none"> • maximum platelet count within 72 hours of Ig treatment of greater than $30 \times 10^9/L$ and at least double the pre-treatment count • prevention of or reduction in bleeding, if prior bleeding. <p>ITP and inadequate platelet count for planned surgery.</p> <p>Review Is not mandated for this indication however the following criteria may be useful in assessing the effectiveness of therapy.</p> <p>Outcome data can be measured</p> <ul style="list-style-type: none"> • maximum platelet count within 72 hours of Ig treatment of greater than $30 \times 10^9/L$ and at least double the pre-treatment count • prevention of or reduction in bleeding, if prior bleeding. <p>Severe ITP.</p> <p>Review is not mandated for this indication however the following criteria may be useful in assessing the effectiveness of therapy.</p> <p>Outcome data to be measured Review criteria for assessing the effectiveness of IVIg use include:</p>	

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		<ul style="list-style-type: none"> • maximum platelet count within 72 hours of Ig treatment of greater than $30 \times 10^9/L$ and at least double the pre-treatment count • prevention of or reduction in bleeding, if prior bleeding. <p>Chronic ITP. Review must be undertaken six monthly by Haematologist.</p> <p>Patients qualify for continuing doses when splenectomy has failed or is contraindicated AND where therapy with at least one second-line agent has been unsuccessful in maintaining a platelet count of $>30 \times 10^9/L$.</p> <p>With ongoing therapy, IVIg may be administered to achieve a platelet count of $>30 \times 10^9/L$.</p> <p>On review of an initial authorisation period</p> <ul style="list-style-type: none"> • Current Platelet count $<30 \times 10^9/L$. <p>AND</p> <ul style="list-style-type: none"> • Response was demonstrated by maximum platelet count (at least $30 \times 10^9/L$ and at least double the qualifying platelet count) achieved within 72 hours after Ig treatment and prevention of or reduction in bleeding, if prior bleeding. <p>AND</p>	<p>SWG advised that a maintenance platelet count of $> 30 \times 10^9/L$ was required in Chronic ITP rather than the response defined for other conditions.</p>

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		<ul style="list-style-type: none"> • Patient remains unresponsive to all available therapies or other therapies are contraindicated. <p>Patients with chronic ITP may be considered for long-term therapy with IVIg, subject to regular review by a Haematologist.</p> <p>HIV-associated ITP.</p> <p>Review Is not mandated for this indication however the following criteria may be useful in assessing the effectiveness of therapy.</p> <p>Outcome data to be measured</p> <ul style="list-style-type: none"> • maximum platelet count within 72 hours of Ig treatment of greater than $30 \times 10^9/L$ and at least double the pre-treatment count • prevention of reduction in bleeding, if prior bleeding. 	
Dose	<p>Initial therapy: 1–2 g/kg as a single or divided dose.</p> <p>Ongoing therapy: When indicated, 1–2 g/kg in</p>	<p>Refractory acute ITP — initial therapy.</p> <p>Induction Dose: 1–2 g/kg as a single dose or divided dose.</p>	<p>SWG observed that approach to dosing is variable amongst clinicians. Use of 1g/Kg as a single dose is more common than 0.4 g/Kg for 5 days (total dose 2g/Kg). When the patient is regionally based - 5 days of treatment will be approved,</p>

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	<p>single or divided dose at 4 to 6 weekly intervals titrated to symptoms and platelet count.</p> <p>Dosing above 1 g/kg per day is contraindicated for some IVIg products.</p> <p>Refer to the current product information sheet for further information.</p> <p>The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient.</p>	<p>The objective of IVIg therapy in ITP is to maintain a safe platelet count while other therapeutic options are explored.</p> <p>The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient.</p> <p>Dosing above 1g/kg per day is contraindicated for some IVIg products.</p> <p>Refer to the current product information sheet for further information.</p> <p>Refractory acute ITP — splenectomy failed or contraindicated and second-line agent unsuccessful.</p> <p>Maintenance Dose: When indicated, 0.4–2 g/kg in single or divided dose at 4- to 6-weekly intervals titrated to symptoms and platelet count. A maximum dose of 2 g per month might be divided in lower doses more frequently.</p> <p>The objective of IVIg therapy in ITP is to maintain a safe platelet count while other therapeutic options are explored.</p> <p>The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient.</p> <p>Dosing above 1 g/kg per day is contraindicated for some IVIg products.</p> <p>Refer to the current product information sheet for further information.</p>	<p>whereas in metro centres where imprest stock is available, 3 days at 0.4g/kg is approved. If patients have the first 3 days and have not responded then the Blood Service will approve the last 2 days.</p> <p>It was noted that there have been a couple of studies using 1g/kg however dosing with 1-2g/L is in line with published international guidelines and consensus statements for ITP.</p> <p>SWG discussion noted that the lower limit should be set to 0.4g/L for all conditions. The SWG noted that if a prescriber tried to dose below the recommended minimum, an alert should advise that they are dosing below because prescribing should be at or above the minimum in this condition.</p>

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		<p>ITP with life-threatening haemorrhage or the potential for life-threatening haemorrhage.</p> <p>Induction Dose: 1–2g /kg as a single dose or divided dose.</p> <p>The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient.</p> <p>Dosing above 1 g/kg per day is contraindicated for some IVIg products.</p> <p>Refer to the current product information sheet for further information.</p> <p>Initial therapy for ITP in pregnancy.</p> <p>Induction Dose: 1–2 g/kg as a single dose or divided dose. During pregnancy, further doses titrated to maintain a platelet count $>30 \times 10^9/L$ may be administered every three to four weeks throughout pregnancy. For impending delivery, IVIg therapy may be used to achieve a platelet count considered safe for delivery ($80\text{--}100 \times 10^9/L$).</p> <p>The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient.</p> <p>Dosing above 1 g/kg per day is contraindicated for some IVIg products.</p> <p>Refer to the current product information sheet for further information.</p> <p>Ongoing treatment for ITP responders during pregnancy and the postpartum period.</p> <p>Maintenance Dose: When indicated, 0.4–2 g/kg in single or divided dose at 4- to 6-weekly intervals titrated to symptoms and platelet count. A maximum dose of 2 g per month might be divided in lower doses more frequently.</p>	

ITEM	CRITERIA FOR THE CLINICAL USE OF INTRAVENOUS IMMUNOGLOBULIN IN AUSTRALIA, SECOND EDITION (CRITERIA)	PROPOSED REVISIONS TO THE CRITERIA	SWG RATIONALE FOR PROPOSED CHANGE (A) Administrative) (B) Progressive (C) Programmed
		<p>The objective of IVIg therapy in ITP is to maintain a safe platelet count while other therapeutic options are explored.</p> <p>The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient.</p> <p>Dosing above 1 g/kg per day is contraindicated for some IVIg products.</p> <p>Refer to the current product information sheet for further information.</p> <p>ITP and inadequate platelet count for planned surgery.</p> <p>Induction Dose: 1–2 g/kg as a single or divided dose.</p> <p>IVIg may be used to achieve a platelet count considered safe for surgery.</p> <p>The safe threshold will vary with the nature of the surgery.</p> <p>The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient.</p> <p>Dosing above 1 g/kg per day is contraindicated for some IVIg products.</p> <p>Refer to the current product information sheet for further information.</p> <p>Severe ITP.</p> <p>Induction Dose: 1–2 g/kg as a single dose or divided dose.</p>	

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		<p>The objective of IVIg therapy in ITP is to maintain a safe platelet count while other therapeutic options are explored.</p> <p>The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient.</p> <p>Dosing above 1 g/kg per day is contraindicated for some IVIg products.</p> <p>Refer to the current product information sheet for further information.</p> <p>Chronic ITP.</p> <p>Maintenance Dose: When indicated, 1–2 g/kg in single or divided dose at 4- to 6-weekly intervals titrated to symptoms and platelet count. A maximum dose of 2 g per month might be divided in lower doses more frequently.</p> <p>The objective of IVIg therapy in ITP is to maintain a safe platelet count while other therapeutic options are explored.</p> <p>The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient.</p> <p>Dosing above 1 g/kg per day is contraindicated for some IVIg products.</p> <p>Refer to the current product information sheet for further information.</p> <p>HIV-associated ITP.</p> <p>Induction Dose: 1–2 g/kg as a single dose or divided dose.</p>	

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		<p>The objective of IVIg therapy in ITP is to maintain a safe platelet count while other therapeutic options are explored.</p> <p>The aim should be to use the lowest dose possible that achieves the appropriate clinical outcome for each patient.</p> <p>Dosing above 1 g/kg per day is contraindicated for some IVIg products.</p> <p>Refer to the current product information sheet for further information.</p>	

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