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The Ig Criteria have changed.

Criteria for clinical use of immunoglobulin in Australia (the Criteria)

Haematology Conditions - Summary of Criteria Changes

The *Criteria for clinical use of immunoglobulin in Australia* (Criteria) is under a continuous review cycle following release of Version 3 on 22 October 2018. The table below summarises subsequent changes made by medical condition and indication to the Criteria following the publication of Version 3. Changes will be applied immediately to new authorisations and to existing authorisations at the next continuing treatment request, unless otherwise stated. This table will be updated when any change is made.

Medical condition	Indication/s	Summary of changes	Date changed	Version number
Acquired hypogammaglobulinaemia secondary to haematological malignancies, or post-haemopoietic stem cell transplantation (HSCT)	<ul style="list-style-type: none"> Prevention of recurrent bacterial infections due to hypogammaglobulinemia associated with haematological malignancies or post haemopoietic stem cell transplant 	<ul style="list-style-type: none"> The date of test is now only required for the first immunoglobulin level, where more than one Immunoglobulin is tested on the same day The interpretation of results values for all Ig levels now include recording of results that are above normal range Data entry error has been corrected to remove mandatory field for pre-treatment IgA and IgM levels in Qualifying Criteria The Qualifying Postscript and Review Preamble have been updated to allow any specialist to diagnose and review patients with this medical condition 	March 2020	3.3

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Medical condition	Indication/s	Summary of changes	Date changed	Version number
		<ul style="list-style-type: none"> The trial cessation criterion wording in Review Criteria has been updated to ensure medical officers know it needs to be completed The Exclusion Criteria has been updated for Transplantation related immunomodulatory therapy in the absence of hypogammaglobulinaemia and the link to Solid organ transplantation has been removed 		
		<ul style="list-style-type: none"> An additional one off dose is now available during the course of the authorisation in the form of intravenous immunoglobulin or subcutaneous immunoglobulin The maintenance dose has been amended to allow 0.4 – 0.6g/kg every four weeks or more frequently Separate doses are now available for intravenous and subcutaneous immunoglobulin administration. 	October 2019	3.1
Fetal and neonatal alloimmune thrombocytopenia (FNAIT)	<ul style="list-style-type: none"> Description and Diagnostic Criteria 	<ul style="list-style-type: none"> Diagnostic criteria have been updated to replace the term 'Blood Service' with 'Lifeblood'. 	November 2023	3.1
Haemolytic disease of the fetus (HDF)	<ul style="list-style-type: none"> Haemolytic disease of the fetus with high risk of early fetal hydrops or death 	<ul style="list-style-type: none"> The Description and Diagnostic Criteria has been updated to align with Patient Blood Management Guidelines (PBM) Module 6 - Paediatric and Neonatal 	March 2020	3.1
Haemophagocytic lymphohistiocytosis (HLH)	<ul style="list-style-type: none"> Management of severe haemophagocytic lymphohistiocytosis not responding to other treatments 	<ul style="list-style-type: none"> Correcting a typographical error – “Platelets <100 ...” replaces “Platelets <10 ...” 	February 2024	3.2
Heparin induced thrombocytopenia (HIT)	<ul style="list-style-type: none"> Spontaneous aHIT – no antecedent heparin exposure Persistent aHIT – ongoing thrombocytopenia after 1 week of heparin discontinuation 	<ul style="list-style-type: none"> New condition included in the Criteria 	February 2024	3.0

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Medical condition	Indication/s	Summary of changes	Date changed	Version number
	<ul style="list-style-type: none"> Refractory HIT – progression of thrombocytopenia and/or thrombosis despite heparin discontinuation and commencement of non-heparin anticoagulant Immediate need to correct thrombocytopenia in HIT- either for active bleeding or in preparation for life/limb saving surgery Prevention of rapid-onset HIT – unavoidable heparin re-exposure (where non-heparin alternatives are not locally available e.g. cardiac bypass). 			
Immune thrombocytopenic purpura (ITP)	<ul style="list-style-type: none"> Newly diagnosed or persistent ITP – subsequent therapy (diagnosis < 12 months) 	<ul style="list-style-type: none"> Comment section added to Qualifying criteria 4 for evidence item 'There is a risk of clinically significant bleeding' 	November 2023	3.2
Immune thrombocytopenic purpura (ITP) - Children	<ul style="list-style-type: none"> Treatment of moderate to severe bleeding in chronic ITP in responsive patients with platelet count less than $30 \times 10^9/L$ where other therapeutic options have failed or are contraindicated 	<ul style="list-style-type: none"> The Multiplication symbol (X) has been added to the unit of measure in qualifying Criteria 3. 	November 2023	3.2
Neonatal haemochromatosis (NH)	<ul style="list-style-type: none"> Pregnant women who have had a previous pregnancy affected by neonatal haemochromatosis 	<ul style="list-style-type: none"> The dosing controls have been updated to allow divisions. 	March 2020	3.1
Post-transfusion purpura (PTP)	<ul style="list-style-type: none"> Description and Diagnostic Criteria 	<ul style="list-style-type: none"> Diagnostic criteria have been updated to replace the term 'Blood Service' with 'Lifeblood'. 	November 2023	3.1
Vaccine induced immune thrombotic	<ul style="list-style-type: none"> Treatment of vaccine induced immune thrombotic thrombocytopenia (VITT) 	<ul style="list-style-type: none"> The NBA has temporarily added VITT as a new condition in the Criteria to enable supply of intravenous immunoglobulin under 	April 2021	3.0

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Medical condition	Indication/s	Summary of changes	Date changed	Version number
thrombocytopenia (VITT)/ Vaccine induced prothrombotic immune thrombocytopenia (VIPIT)		the national blood arrangements. This is based on advice received from the NBA's Haematology Specialist Working Group as well as jurisdictions, including the Commonwealth. • VITT will continue to be included in the Criteria on a continuing basis, with its initial temporary status being removed.	February 2024	3.0