



Please don't Ignore this.

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 dayThe interpretation of results values for all Ig levels now include recording of results that are above normal rangeData entry error has been corrected to remove mandatory field for pre-treatment IgA and IgM levels in Qualifying CriteriaThe 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

		<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	3.2
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
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
Vaccine induced immune thrombotic thrombocytopenia (VITT)/ Vaccine induced prothrombotic immune thrombocytopenia (VIPIT)	<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 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. 	April 2021	3.0