

2017 (v3.0) Proposed changes to v2.1 of the Criteria for the clinical use of intravenous immunoglobulin in Australia

CONDITION NAME IN v2.1	Myocarditis in children
PROPOSED APPROACH: To move Myocarditis in children from <i>Exceptional circumstances only to Not supported</i>.	SUMMARY OF RATIONALE: The recommended changes are supported by factors including that: <ul style="list-style-type: none"> - While Ig therapy was once routinely prescribed for children with acute myocarditis, a recent update of a Cochrane review (Robinson 2005, updated May 2015) found only one randomised trial of 62 adults demonstrating no benefit. A second trial evaluating 83 children was biased because the children included in the study had the relative rare combination of both myocarditis and encephalitis. This review concluded that ‘more study is required before IVIg can be routinely recommended for adults or children with myocarditis’. - IVIg usage data indicates that 15 to 30 patients have been treated annually with Ig therapy for this condition over the last five years. There may also be some cross over for patients with congenital heart block. Ig therapy will continue to be funded for congenital heart block. - Myocarditis in Children is not listed in the UK NHS immunoglobulin Guidelines (UK Department of Health, 2011), or the national Canadian IVIg Utilisation Management Guidelines (Ontario Regional Blood Coordinating Network, 2016).
Role of Ig therapy, if appropriate: Not applicable	
Access Information in v2.1	
Condition Category	Condition for which Ig use is in exceptional circumstances only (Chapter 7)
Level of Evidence	Insufficient data (Category 4a)
Description	
Qualifying Criteria	There is some evidence that intravenous immunoglobulin (IVIg) improves cardiac function in children with proven or likely viral myocarditis.
References (most recent update: February 2016)	

Drucker NA, Colan SD, Lewis AB, Beiser AS, Wessel DL, Takahashi M, et al (1994). Gamma-globulin treatment of acute myocarditis in the pediatric population. *Circulation*, 89:252–7.

<https://www.ncbi.nlm.nih.gov/pubmed/8281654>

Ontario Regional Blood Coordinating Network (2016). Ontario Intravenous Immune Globulin (IVIg) Utilization Management Guidelines, Version 3.0. [online]. Available at: <http://transfusionontario.org/en/download/ontario-intravenous-immune-globulin-IVIg-utilization-management-guidelines-2/>.

Robinson J, Hartling L, Vandermeer B and Klassen TP (2005). Intravenous immunoglobulin for presumed viral myocarditis in children and adults (Cochrane Review). *Cochrane Database of Systematic Reviews 2005*, Issue 1. (Updated May 2015)

http://www.cochrane.org/CD004370/VASC_intravenous-immunoglobulin-for-presumed-viral-myocarditis-in-children-and-adults

UK Department of Health (2011) Clinical Guidelines for Immunoglobulin Use: Second Edition Update. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216671/dh_131107.pdf

UK Department of Health (2011) Clinical Guidelines for Immunoglobulin Use: Second Edition Update: Summary Poster. Available at: https://www.igd.nhs.uk/wp-content/uploads/2016/04/DemandManagementPoster_v4_February2016.pdf

POTENTIAL OPERATIONAL IMPACT						
<p>Prescribers will need to be advised that Ig therapy will not be available for this condition to enable them to be prepared to manage patients without Ig therapy. Following public consultation and the subsequent endorsement by governments, specific communication with relevant prescribers is planned. As Ig treatment for this condition has historically been short term therapy, it is anticipated that a very small number of patients is likely to be being treated at the time of implementation of this change. To support doctors to provide optimal patient management, advice will be provided to prescribers well prior to the date of implementation of this change.</p>						
POTENTIAL IMPACT ON PATIENTS, DEMAND AND EXPENDITURE						
Potential impact on patients:		<p>It is recommended that this condition no longer be supported for funding under the national blood arrangements because alternative therapies have been demonstrated to be effective in managing the condition, are available and are being used in Australia. There is very little evidence to support any beneficial effect from Ig therapy and recent scientific reviews have suggested that Ig therapy should not be used as routine treatment in children or adults with this condition. It is inappropriate to treat patients with medication that has no demonstrable benefit and in addition, there are small but not insignificant risks of harm from Ig therapy, as well as a high cost.</p> <p>Given the very low level of use over the last few years for myocarditis, it is clear that where patients have received Ig therapy, it has been for very short periods of treatment only. It is therefore unlikely that there would be any impact to ongoing patient care at the time of transition. It is possible that some of the patients treated under this condition may have been eligible under Autoimmune congenital heart block, noting that access in that condition is ongoing.</p>				
Impact on demand		<p>Given that this condition will no longer be supported, there would be a reduction in use, however, it is possible that some patients should have been treated under Autoimmune congenital heart block, in which case, the demand for that condition would increase. The overall impact is expected to be a small reduction in use.</p>				
	2011-12	2012-13	2013-14	2014-15	2015-16	The Specialist Working Group estimated magnitude of effect: Marginal: <\$500K reduction against projected demand
Patient number	16	31	15	28	29	
Total Grams issued	627	795	525	778	1,055	
% Total Grams issued	0.02%	0.02%	0.01%	0.02%	0.02%	
Specialist Working Group knowledge development opportunities and recommendations						

None identified at this stage

END OF PUBLIC CONSULTATION DOCUMENT

Next review: Two years from BloodSTAR v3.0 implementation