

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	HIV in children
PROPOSED APPROACH: To move HIV in children from <i>Exceptional circumstances only to Not supported.</i>	SUMMARY OF RATIONALE: <p>The recommended changes are supported by factors including that:</p> <ul style="list-style-type: none"> - Consultation with the Australian Society for Infectious Diseases has confirmed that Ig therapy is not indicated for this condition because preferable superior alternative treatments are available. - IVIg usage data confirms that no Ig therapy has been prescribed for this condition over the last five years - The condition is allocated to 'black' indicating that Ig therapy is not funded in the UK NHS NHS immunoglobulin Guidelines (UK Department of Health, 2011), and is not included in the national Canadian IVIg Utilisation Management Guidelines (Ontario Regional Blood Coordinating Network, 2016).
Role of Ig therapy: Not applicable	
Access Information in v2.1	
Condition Category	Condition for which Ig use is in exceptional circumstances only (Chapter 7)
Level of Evidence	Evidence of probable benefit – more research needed (Category 2a)
Description	(Blank)
Qualifying Criteria	The need for intravenous immunoglobulin (IVIg) in paediatric HIV has been substantially reduced with the advent of highly active antiretroviral therapy (HAART). A trial of therapy may, however, be considered in children with significant recurrent bacterial infections despite HAART.
References (most recent update: August 2016)	

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	<p>Orange JS, Hossny EM, Weiler CR, Ballow M, Berger M, Bonilla FA, et al (2006) Use of intravenous immunoglobulin in human disease: a review of evidence by members of the Primary Immunodeficiency Committee of the American Academy of Allergy, Asthma and Immunology. <i>Journal of Allergy and Clinical Immunology</i>, 117(4): S525–53.</p> <p>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/. https://www.ncbi.nlm.nih.gov/pubmed/16580469</p> <p>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</p> <p>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</p>

POTENTIAL OPERATIONAL IMPACT						
There is not anticipated to be any operational impact as a result of this change as Ig therapy is not prescribed for these patients.						
POTENTIAL IMPACT ON PATIENTS, DEMAND AND EXPENDITURE						
Potential impact on patients		The recommendation to no longer support this condition for access under the national blood arrangements has been made in consultation with the Australian Society for Infectious Diseases. The Society has confirmed that Ig therapy is not indicated or used in the treatment of HIV in children because preferable superior alternative treatments are available. It is inappropriate to treat patients with conditions for which specific medications have no demonstrable benefit and in addition, there are small but not insignificant risks of harm from Ig therapy, as well as a high cost. The recommendation is supported by the fact that there have been no requests for use to treat HIV in children over at least the last five years and therefore there is unlikely to be any impact on the clinical treatment of patients as a result of this change.				
Impact on demand		No impact on demand as no usage over the last 5 years				
	2011-12	2012-13	2013-14	2014-15	2015-16	Estimated number of patients that will be affected. ZERO. The Specialist Working Group estimated magnitude of effect: No impact against projected demand
Patient number	0	0	0	0	0	
Total Grams issued	0	0	0	0	0	
% Total Grams issued	0%	0%	0%	0%	0%	
Specialist Working Group knowledge development opportunities and recommendations						
None identified at this stage						

END OF PUBLIC CONSULTATION DOCUMENT

Next review: Two years after BloodSTAR v3.0 implemented