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	**Acute leukaemia in children**
PROPOSED APPROACH: **To remove Acute leukaemia in children as a stand-alone condition in *Exceptional circumstances only* and allow access for eligible patients under Secondary hypogammaglobulinaemia related to haematological malignancy and post haemopoietic stem cell transplantation (HSCT) (*Established therapeutic use*).**	**SUMMARY OF RATIONALE:** The recommended changes are supported by factors including that: - Ig therapy is currently provided for children with Acute leukaemia under 'Acquired hypogammaglobulinemia secondary to haematological malignancies' which is consistent with international practice and published treatment protocols. - Treatment under Acute leukaemia as a standalone condition (category of *Exceptional circumstances only)* supports access for children with neutropenic sepsis with life threatening infection without hypogammaglobulinaemia necessarily being proven. There is insufficient evidence to continue to support this practice and alternative therapies are likely to be more effective. - Up to thirteen patients have been treated under this condition annually over the last 5 years and levels of use suggests predominantly one-off treatment with a more recent trend to further dosing. Usage has been confined predominantly to Victoria for the past three years where numbers are increasing. - An additional specific condition has been added to 'Secondary hypogammaglobuliaemia related to haematological malignancy and post haemopoetic stem cell transplant' so that the data will become available to distinguish the number of patients with Acute leukaemia being treated. - This condition is not recommended for Ig therapy in the Canadian (Ontario Regional Blood Coordinating Network, 2016) or UK guidelines (UK Department of Health, 2011) for IVIg use. 'Sepsis in the intensive care unit not related to specific toxins or C.difficle' is specifically not funded in the UK Guidelines.
Role of Ig therapy, if appropriate: Children with Acute leukaemia are routinely screened and given maintenance Ig therapy if both recurrent infections and hypogammaglobulinemia are confirmed, consistent with the current access criteria for Acquired hypogammaglobulinaemia (level of evidence 2a). This practice aligns with international treatment protocols, published guidelines and is also informed by children not receiving Ig to develop chronic bronchiectasis in the past. Children are monitored and once they are well, Ig therapy is trialled off. There is insufficient evidence to demonstrate clinical benefit for Ig treatment of neutropenic sepsis in the absence of hypogammaglobulinaemia given that alternative therapies are considered more effective.	

Access Information in v2.1	
Condition Category	Condition for which Ig use in is exceptional circumstances only (Chapter 7)
Level of Evidence	Evidence of probable benefit – more research needed (Category 2a)
Description	(Includes acute lymphoblastic or lymphoid leukaemia [ALL] and acute myeloblastic leukaemia [AML]).
Qualifying Criteria	Intravenous immunoglobulin (IVIg) may be considered in cases of ALL or AML with neutropenic sepsis in patients aged ≤15 years in whom conventional antimicrobial therapy has been ineffective and who have life-threatening infection.

References

(most recent update: February 2016)

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/.

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

The potential operational impact of this change is considered to be minor given the low number of patients and short term treatment being provided. There will be an appropriate communication plan including consultation with appropriate specialist societies and colleges such that clinicians should be aware of how to access Ig therapy for eligible children with Acute leukaemia, if they are not already accessing under Acquired Hypogammaglobulinaemia.

POTENTIAL IMPACT ON PATIENTS, DEMAND AND EXPENDITURE

Description of impact on patients:	Patients with Acute leukaemia and other blood cancers can have low levels of IgG which can make them susceptible to severe infections, especially while they are being treated for their cancer. When patients have low Ig G levels, they can be treated under a different condition (i.e. Secondary hypogammaglobulinaemia related to haematological malignancies and post haemopoetic stem cell transplantation) where they will receive monthly infusions for as long as required. However, Ig therapy will no longer be available for patients with Acute leukaemia who have normal IgG levels, even if they suffer severe infections. This is because alternative treatments have been proven to be more effective than Ig therapy in treating the infections. Therefore access under this condition will no longer be made available. Given that treatment is by single dose, there is not anticipated to be any impact for patients as a result of this change. Specific communications will be provided to doctors to make sure that they are aware of these changes and the appropriate way for patients to access Ig therapy when it is required.
Impact on demand:	There is likely to be no impact on demand, given that a very small number of patients are receiving predominantly one-off treatment and if ongoing therapy is prescribed, the children may be eligible under Secondary hypogammaglobulinaemia related to haematological malignancy.

	2011-12	2012-13	2013-14	2014-15	2015-16	The Specialist Working Group estimated magnitude of effect:
Patient number	**7**	**5**	**5**	**5**	**13**	No impact against projected demand
Total Grams issued	**135**	**63**	**213**	**291**	**975**	
% Total Grams issued	**0.004%**	**0.002%**	**0.005%**	**0.007%**	**0.02%**	

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