Australian Government

Department of Health

General Guidance for Providing Feedback to the Contracted Assessment

Immunoglobulin Review

MSAC Referral 1591

Review of immunoglobulin use for secondary hypogammaglobulinaemia unrelated to haematological malignancies, or post-haemopoietic stem cell transplantation (HSCT)

Public consultation closes 9.00 am 10 September 2020

COVER SHEET FOR ALL FEEDBACK SUBMISSIONS

This cover sheet must be included with your feedback (submission). If completing by hand, please ensure your writing is clear and legible.

Details	
Individual name/group name/organisation name[1]	Dr Theresa Cole, ASCIA Immunodeficiency committee chair
Please delete categories that do not apply	Medical Officer/NGO

CONTACT DETAILS	
We would like to collect your contact details should further information or clarification be required on your submission. If you agree, contents of your submission may be included in subsequent documents accessed by the Department of Health, MSAC and any documents published during the review process (refer to permissions to publish below). Please provide at least one contact address. If you are making a submission for a group or organisation, please provide contact information for one member of your group or organisation. If you would like to remain anonymous, please leave this section blank.	
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INTERNET PUBLICATION	
Please tick this box if you wish for your submission to remain confidential and **do not consent** to having information from your submission published on the internet or as part of the MSAC public summary document.	
If you wish for only parts of your submission to remain **confidential** and not be published, please outline the confidential sections clearly (above and below the confidential content). If you wish for only parts of your submission to be treated as confidential, it would be appreciated if you could provide the confidential and non-confidential parts of your submission as separate documents.	

ANONYMITY	
Please tick this box if you want your submission to be treated as anonymous and you **do not consent** to having your name, or the name of your organisation, published on the internet or as part of the MSAC public summary document.	

THIRD PARTY PERSONAL INFORMATION	
Please tick this box if your submission contains **personal information of third party individuals.**	

EVIDENCE OF CONSENT	
You should not include personal information about a third party unless you are able to provide evidence of written consent. Please tick this box if you have **attached evidence of written consent**.	

[1] Please leave blank if you would like to remain anonymous. A pseudonym may be provided if preferred.

N.B. Feedback will be accepted up to a maximum of 4 pages using font no smaller than size 11 Calibri.

GENERAL INSTRUCTIONS (ALL RESPONDENTS)

The purpose of the consultation is to obtain feedback on the draft Contracted Assessment on Immunoglobulin for Secondary Hypogammaglobulinaemia unrelated to haematological malignancies or post-haemopoietic stem cell transplantation.

The information collected will be used to inform the Medical Services Advisory Committee (MSAC) process to ensure that the use of government-funded immunoglobulin in Australia, is patient focused and seeks to achieve best value.

You are invited to provide feedback on the following questions:

1. The context for the Contracted Assessment is outlined in the executive summary on pages 14-16, and the body of the report on pages 28-37. Do you agree or have any comments on this section?

   The review combines data on patients with solid organ transplant and post B cell depleting therapy. These are two very different groups in terms of their immunology. The literature reviewed is focussed primarily on solid organ transplant and may not be applicable to other situations. Patients with solid organ transplants will be on immunosuppressive agents that impact on their infection risk in a different way to those who have received B cell depleting therapies alone.

   The data is too limited and heterogeneous to draw conclusions across the spectrum of secondary hypogammaglobulinaemia diagnoses.

2. The benefits (effectiveness) of immunoglobulin therapy are provided in the executive summary on pages 19-23, and the main body of the report on pages 55-66. Is this a reasonable interpretation of the evidence?
   Efficacy data appears only to reflect solid organ transplant patients. This cannot be extrapolated to other situations.

3. Are there other benefits not captured in the report?
   There is limited discussion of subcutaneous immunoglobulin (SCIg) use which may be provided to some secondary hypogammaglobulinaemia patients. This is better tolerated, with fewer side effects than intravenous immunoglobulin (IVIg) and does not require travel to hospital as frequently.
   The ability to return to work or school and productivity increases because of IRT is also not captured in the report.

4. The safety or side effects associated with immunoglobulin therapy are provided in the executive summary on page 19, and the body of the report on pages 51-53. Are there other adverse effects that are not captured in the report?
   No.

5. Overall, has all the relevant evidence been taken into account?
   Side effects are primarily focussed on IVIg, not SCIg, which is often better tolerated

6. An economic evaluation was not conducted for this assessment due to the paucity of evidence to support development of a model (executive summary page 24, and body of the report pages 75-85). Do you agree with this decision?
   Yes I agree. However, development of a national model of care for SCIg funding should be considered. Initial costs for nursing resources and equipment are often the main reasons why SCIg has been poorly taken up for IRT in Australia. Patients require nurses (not technicians) for successful home management of SCIg. A national model of care for SCIg should ensure that patients are appropriately supported and that governance of the product is secured with home based IRT.

7. Do you have any comments on the assumptions and estimates of the overall financial costs for governments in the Contracted Assessment (executive summary pages 24-25, and body of the report pages 86-96)?
   I agree that there is inadequate relevant data to support proper analysis.

ADDITIONAL QUESTIONS FOR PATIENTS, CARERS AND CONSUMER ORGANISATIONS
Patients, carers and consumer organisations are invited to provide feedback **on all areas** of the draft Contracted Assessment as outlined above. In particular, feedback on the following areas are considered of value from a patient and carer perspective: 1. The evidence presented in the assessment report suggests that immunoglobulin (Ig) therapy has poorer safety (more adverse effects) and uncertain effectiveness compared to no Ig therapy. Based on your knowledge and experience do you agree with this? What are the benefits of Ig therapy and do they outweigh any adverse effects you may have experienced? 2. Where do you receive your immunoglobulin infusions (e.g. public hospital, private hospital, or home)? Do you have any issues accessing this therapy? 3. What out-of-pocket costs are there for patients when receiving Ig therapy (e.g. specialist fees, tests required for review not fully covered by Medicare or health insurance)? 4. Do you receive antimicrobial prophylaxis (e.g. ongoing treatment with antibiotics to prevent infections) in addition to Ig therapy? 5. Do you have any other comments you would like to make in relation to this review? If you require any further guidance, please contact the MSAC IG secretariat.

Privacy

Unless otherwise requested, all submissions on the draft contracted assessment to MSAC Ig Referral 1591 will be provided to the Evaluation Sub-Committee of MSAC and the MSAC.

Responsibility for copyright in submissions resides with the author(s), not with the Department of Health.

Your submission and contact details will be stored in accordance with the Australian Privacy Principles from Schedule 1 of the *Privacy Amendment (Enhancing Privacy Principles) Act 2012* and the *Archives Act 2012*. Should you have any concerns about the storage of your submission, or if you wish to gain access to make a correction, please contact the MSAC Ig Review Secretariat. A copy of the Department's privacy policy is available on request. If you wish to make a complaint about the handling of your private information, you may contact the Department of Health Privacy Contact Officer on 02 6289 5773 and, if unsatisfied with the response, you may submit a complaint to the Office of the Australian Information Commissioner.