Ig Program Updates - 2021

July 2021 Update

Key issue summary

Vaccine-Induced Thrombotic Thrombocytopenia (VITT). In April, the NBA temporarily added vaccine-induced immune thrombotic thrombocytopenia (VITT) - also known as thrombosis with thrombocytopenia syndrome (TTS) or vaccine-induced prothrombotic immune thrombocytopenia (VIPIT) - as a condition to Version 3 of the *Criteria for the Clinical Use of Immunoglobulin in Australia* (Criteria).

This addition ensures that intravenous immunoglobulin (IVIg) is available under national blood arrangements for the treatment of VITT, removing the need for clinicians to reply on access under Jurisdictional Direct Order arrangements, and ensuring nationally-consistent, timely access to treatment.

The change, which supports the continued rollout of the COVID-19 vaccine in Australia, was made following advice from the Commonwealth Chief Medical Officer, Professor Paul Kelly, the Secretary of the Department of Health, Dr Brendan Murphy, a number of jurisdictional representatives and, critically, the NBA's Haematology Specialist Working Group (SWG).

Work in this area is ongoing, with the latest version of VITT being reviewed by the NBA's Haematology Specialist Working Group to ensure the qualifying criteria and evidence items align with the available and developing information on diagnosing and treating VITT.

Details are available here: https://www.criteria.blood.gov.au/MedicalCondition/View/2669, with access through BloodSTAR, in line with usual procedures.

Prioritisation framework. Work is ongoing to develop a prioritisation framework for Ig in times of product shortage. Preliminary analysis has been undertaken and the NBA is exploring the option of engaging a consultant to assist with its further development. Once complete, this is will operate alongside – and eventually become part of - the National Blood Supply Contingency Plan. There is currently no threat to supply in Australia.

Ig authorisation management through BloodSTAR. BloodSTAR is regularly updated to improve its functionality and usability, with updates informed by feedback from BloodSTAR users.

The most recent update, implemented on 18 July with the release of BloodSTAR version 3.6, includes:

- new validation checks to ensure that the date required for continuing authorisations, dose change requests and additional dose requests does not overlap with previous authorisation periods
- new information messages displayed on all authorisation requests where a product has been automatically allocated to the patient based on NBA's product supply rules
- new validation checks to ensure that any product on the patient's "do not prescribe" list does not get allocated as the default product on an authorisation request.

Statistics on BloodSTAR activity are available here .

Usage data, statistics and evaluation. Data collection and analysis is an important part of the NBA Ig Governance Program, and the NBA's performance improvement strategy. Activities under this strategy are focussed on ensuring that precious Ig product is used for those who gain the most benefit from it.

Recent data on Ig usage is revealing an encouraging trend: the last two years' statistics show that Ig usage is currently increasing at a rate of approximately 7% per annum. This is a substantial decrease in Ig's rate of growth over the preceding decade and more; until 2018-19, Ig use had been rising at a rate of 10-12% per year.

To better understand the drivers of growth in Ig usage, including quantifying the contribution of individual elements of the Ig Governance Program to the change in usage, the NBA commissioned PriceWaterHouseCoopers Consulting (PwC) to conduct an evaluation. A number of key stakeholders were consulted as part of the process. The evaluation is currently being finalised.

See the latest Ig use statistics here. NBA's annual reports on the issue and use of immunoglobulin are available here. For more information on the Ig Governance Program's performance improvement initiatives see: National Immunoglobulin Governance Program Performance Improvement Strategy, 2019-2022.

Ig health technology assessment (HTA) reviews by the Medical Services Advisory Committee (MSAC). In 2018, the NBA and Department of Health commenced a pilot HTA review of Ig use currently funded under the National Blood Agreement. Of six medical conditions prioritised, five reviews are complete and have public summary documents (PSDs) available on the MSAC website: Acquired hypogammaglobulinaemia secondary to haematological malignancies, or post-haemopoietic stem cell transplantation (AHG); Myasthenia gravis (MG); Multifocal motor neuropathy (MMN); Primary immunodeficiency disease (PID), and; Secondary hypogammaglobulinaemia (SHG) unrelated to haematological malignancies or haemopoeitic stem cell transplantation. The review for Chronic inflammatory demyelinating polyneuropathy (CIDP) continues and this PSD will be published when available. The NBA is considering the PSDs for completed reviews, in consultation with NIGAC and relevant SWGs.

Education and training resources. BloodSafe eLearning Australia (BEA) has been working in collaboration with the NBA over a two year period to develop a series of five Immunoglobulin eLearning courses for health care staff involved in the prescription, administration and reporting of Ig product use. The fifth and final course was released in late June and covers:

- the appropriate selection and prescription of immunoglobulin
- considerations for selecting the dose and administration route of immunoglobulin
- the appropriate use of effective treatments other than immunoglobulin, and
- the need for accurate and ongoing patient assessment and follow-up.

This complements earlier courses that provide Australian-specific information on Ig products and their role in treatment, governance arrangements, use and administration.

Access to all the courses is free, but users must register. For further information, see Ig Resources.

Value in Prescribing (ViP) Immunoglobulin Program . The NBA has also been working in partnership with the Department of Health (DoH) and NPS Medicinewise to deliver the ViP Immunoglobulin Program. Funded through a DoH grant, this three-year initiative will deliver a range of educational resources for both medical professionals and consumers, supporting the NBA's Ig governance work with the key objective of ensuring that Australia can provide Ig treatment equitably and affordably to those who need it most. A number of resources have already been released, with many more expected within the next quarter.

More information is available at the NPS MedicineWise website. Links are also included on the NBA Ig Resources page.

Committee and stakeholder meetings

National Immunoglobulin Governance Advisory Committee (NIGAC). The NIGAC met late March and is scheduled to meet again in early August. Discussions are expected to include: the progressing outcomes of the immunoglobulin health technology assessment (HTA) reviews by the Medical Services Advisory Committee (MSAC)*; educational resource development work progressing through the Value in Prescribing Immunoglobulin Program and Bloodsafe e-learning Australia (BEA)*; updates on the use of intravenous immunoglobulin for treatment of COVID-19 patients and for treating blood clots associated with the vaccine; and progressive changes to the Criteria (further information about the Criteria update process).

*See key issues summary for further information.

Immunoglobulin Specialist Working Groups (SWGs). All four SWGs – Immunology, Haematology, Neurology and Transplant – met in May 2021. Key issues discussed at that time, and progressed out-of-session, include: Ig for the treatment of VITT*; HTA reviews by MSAC* on Multifocal Motor Neuropathy (MMN) and Therapeutic plasma exchange as well as the analysis of MSAC Ig reviews advice; potential changes to the Criteria; development of SWG work plans; feedback on the NBA's Ig usage data and reporting and how this can be used to better inform the work of the SWGs.

The Neurology chair also presented a paper on FcRn inhibitors for Myasthenia Gravis (MG) and the Haematology Group presented their group work reports on new treatments and cessation.

*See key issues summary for further information.

Jurisdictional Immunoglobulin Performance Improvement (JIPI) Group. The JIPI Group members have continued to work individually with the NBA to understand their subcutaneous Ig (SCIg) dispense patterns, with a view to ensuring that dispense and usage is in accordance with the National Policy: Access to Government Funded Immunoglobulin Products in Australia. Other topics progressing with this group include looking at Ideal Body Weight Dosing (IBWD) practice and variation in Ig use.

April 2021 Update

Committee and stakeholder meetings

National Immunoglobulin Governance Advisory Committee (NIGAC). The NIGAC held its first meeting of 2021 on 30 March. Issues discussed included: the progressing outcomes of the immunoglobulin health technology assessment (HTA) reviews by the Medical Services Advisory Committee (MSAC)*; educational resource development work progressing through the Value in Prescribing Immunoglobulin Program and Bloodsafe e-learning Australia (BEA)*; advances in research investigating the use of intravenous immunoglobulin for treatment of COVID-19 patients; and progressive changes to the Criteria (further information about the Criteria update process).

*See key issues summary for further information.

Immunoglobulin Specialist Working Groups (SWGs). Three of the four SWGs - Immunology, Haematology and Neurology - met in late 2020. The fourth – the Transplant SWG – received papers out of session. Key issues discussed at that time, and progressed out-of-session, include: whether any new research, treatment recommendations, or COVID-related treatment options should trigger consideration of any changes to the Criteria for the Clinical Use of Immunoglobulin in Australia; progress in developing a prioritisation framework for Ig in times of shortage*; educational material*; and the cost-benefit of attempting to collect more data for evaluation and research purposes, and subsequently educational use, through BloodSTAR.

All the SWGs are due to meet again in late April.

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Jurisdictional Immunoglobulin Performance Improvement (JIPI) Group. The JIPI Group members have been working individually with the NBA to understand their subcutaneous Ig (SCIg) dispense patterns, with a view to ensuring that dispense and usage is in accordance with the National Policy: Access to Government Funded Immunoglobulin Products in Australia. Other topics progressing with this group include looking at Jurisdictional Direct Orders (JDO), Ideal Body Weight Dosing (IBWD) practice and variation in Ig use.

Key issue summary

Prioritisation framework. Work is ongoing to develop a prioritisation framework for Ig in times of product shortage. Preliminary analysis has been undertaken and the NBA is exploring the option of engaging a consultant to assist with its further development. Once complete, this is will operate alongside – and eventually become part of - the National Blood Supply Contingency Plan. There is currently no threat to supply in Australia.

Ig authorisation management through BloodSTAR. BloodSTAR is regularly updated to improve its functionality and usability, with updates informed by feedback from BloodSTAR users. BloodSTAR v3.5 was released on March 28. The release includes improvements to authorisation request validations and the management of provisional medical officer access requests.

Click here for statistics on BloodSTAR activity.

BloodNet was also updated on March 28, with enhancements to the authorisations module to make it clearer which authorisations have been approved or declined.

Usage data, statistics and evaluation. Data collection and analysis is an important part of the NBA Ig Governance Program, and the NBA's performance improvement strategy. Activities under this strategy are focussed on ensuring that precious Ig product is used for those who gain the most benefit from it.

Recent data on Ig usage is revealing an encouraging trend: the last two years' statistics show that Ig usage is currently increasing at a rate of approximately 7% per annum. This is a substantial decrease in Ig's rate of growth over the preceding decade and more; until 2018-19, Ig use had been rising at a rate of 10-12% per year.

To better understand the drivers of growth in Ig usage, including quantifying the contribution of individual elements of the Ig Governance Program to the change in usage,

the NBA has commissioned PriceWaterHouseCoopers Consulting (PwC) to conduct an evaluation. Work commenced in mid-February and a number of key stakeholders have been consulted as part of the process. Evaluation is currently underway.

See the latest Ig use statistics here. Our annual reports on the issue and use of immunoglobulin are available here. For more information on the Ig Governance Program's performance improvement initiatives see: National Immunoglobulin Governance Program Performance Improvement Strategy, 2019-2022.

Ig health technology assessment (HTA) reviews by the Medical Services Advisory Committee (MSAC). In 2018, the NBA and Department of Health commenced a pilot HTA review of Ig use currently funded under the National Blood Agreement. Of six medical conditions prioritised, three reviews are complete and have outcomes available in public summary documents (PSDs) on the MSAC website: Acquired hypogammaglobulinaemia secondary to haematological malignancies, or post-haemopoietic stem cell transplantation (AHG); Myasthenia gravis (MG); and Multifocal motor neuropathy (MMN). The reviews for Chronic inflammatory demyelinating polyneuropathy (CIDP), Primary immunodeficiency disease (PID) and Secondary hypogammaglobulinaemia (SHG) unrelated to Haematological malignancies or haemopoeitic stem cell transplantation continue and these PSDs will be published as they become available.

The NBA is working closely with SWGs and the Commonwealth Department of Health to progress the outcomes of the Ig reviews and will act as coordinator of actions arising from MSAC advice. Many of these actions will help inform, confirm and prioritise work already underway. Other actions may lead to new projects for the NBA. A Sector Action Plan will be developed in consultation with NIGAC and the SWGs to manage and prioritise work arising.

Education and training resources. BloodSafe eLearning Australia (BEA) is developing a series of five Immunoglobulin eLearning courses for health care staff involved with the prescription, administration and reporting of Ig product use. These courses provide an overview of Ig therapy in Australia including general information on Ig products, their role in treatment, governance arrangements and usage and administration. Four of the five courses have now been released. Access is free, but users must register. For further information, see Ig Resources.

The NBA is also working with the Department of Health and NPS Medicinewise to deliver the Value in Prescribing (ViP) Program, which aims to develop improvement in the prescription and use of Ig through education and training initiatives. The first initiatives released as part

of this program were released in late October and a number of additional resources, including consumer videos, have been released this year, with many more to follow. More information is available at the NPS MedicineWise website, and on the NBA Ig Resources page.

New Immunoglobulin Product supply arrangements. New imported immunoglobulin supply arrangements have been agreed and imported immunoglobulin products CUVITRU (SCIg) and Octagam (IVIg) will be through BloodSTAR from 12 April 2021. AHPs will be able to order these products from Lifeblood from that date. For further information, see: https://www.blood.gov.au/new-imported-immunoglobulin-ig-supply-contracts.