NATIONAL BLOOD AUTHORITY
AUSTRALIA

NATIONAL IMMUNOGLOBULIN GOVERNANCE ADVISORY COMMITTEE

Terms of Reference

October 2019

Role

Purpose

The National Immunoglobulin Governance Advisory Committee (NIGAC) is established by the National Blood Authority (NBA) Chief Executive under section 38 of the *National Blood Authority Act 2003* (the NBA Act) to assist with the performance of the NBA's functions in relation to the National Immunoglobulin (Ig) Governance Program (the Program).

As the peak committee within the immunoglobulin governance national network of committees, NIGAC is established to fulfil the following roles and responsibilities:

a. provide advice and make recommendations to the NBA to support the Program;
b. provide advice and make recommendations to support cost effective and clinically appropriate governance, management and use of Ig products, including advice and recommendations in relation to each of the performance areas within the Program; and
c. when requested by the NBA, provide advice or assistance to other parties on matters concerning the availability, governance, management or use of Ig products.

Background

The Program is established to achieve governments' objectives for immunoglobulin products funded and supplied under the national blood arrangements, namely to:

- ensure immunoglobulin product use and management reflects appropriate clinical practice and represents efficient, effective and ethical expenditure of government funds, in accordance with relevant national safety and quality standards for health care;
- ensure that access to immunoglobulin products is consistent with the criteria for access determined by governments; and
- improve the capture of information on the need for, use of, and outcomes of treatment (including adverse events) with immunoglobulin products to inform future changes to the criteria.

The Program is established and funded by the Commonwealth, State and Territory governments, through the NBA.

The NBA is responsible to the Commonwealth, State and Territory governments for ensuring that the Program meets the objectives for which it was established.

An overview of the Program is attached at **Appendix A**.

Operations of the Committee

Chair

The Chair of the NIGAC will be appointed at the discretion of the NBA Chief Executive. The NBA Chief Executive may nominate an alternative person to be a temporary Chair when the Chair is unable to attend a meeting or is otherwise unable to perform the role of Chair.

The position of Chair will usually undergo a review process every three years, or at the discretion of the NBA Chief Executive. Where possible, the former Chair will continue as a member of the NIGAC to maintain continuity.

The Chair's main role is to provide leadership to the NIGAC. The Chair will promote and advocate consistency in key messages and ensure the NIGAC carries out its functions effectively and efficiently. The Chair will also provide advice and guidance direct to the NBA Chief Executive or their delegate on issues that might arise outside the NIGAC processes.

Members

NIGAC members are appointed by the NBA Chief Executive. The NIGAC is a group comprising members with expertise and qualifications to consider the clinical appropriateness, safety and cost effectiveness of Ig, including comparative outcomes of different therapies. Members will also have qualifications and experience that allow them to provide high quality advice and assistance in the areas of nursing, health economics, epidemiology, quality and safety, and consumer issues. This group will enable a focussed approach to considering matters concerning the availability, governance, management or use of Ig products.

Membership should consist of nominees from key stakeholders with balanced representation from different clinical disciplines, organisations, and jurisdictions. Medical specialists in the disciplines of neurology, immunology, haematology, and transplantation on the NIGAC serve as Chair of the relevant Specialist Working Group and represent the activities of that Specialist Working Group to the NIGAC. A membership list for the NIGAC is at **Appendix B**.

Membership will undergo a rolling review process with a 'half-spill' usually every three years or otherwise at the discretion of the NBA Chief Executive. There will be a maximum term of membership not exceeding eight years. Members are responsible for obtaining all approvals necessary from their current employer or organisation as appropriate to accept appointment as a member and undertake the role of member.

NBA Support

The NBA Deputy Chief Executive or other delegate will be responsible for the day-to-day dealings with the NIGAC.

The NBA will provide funding, project management, secretariat services and administrative support for the NIGAC.

The secretariat will service and support the NIGAC and in particular, will:

- Support the Chair;
- Schedule meetings;
- Coordinate papers for meetings;
- Draft meeting minutes and action items;
- Monitor and report on actions from meetings; and
- Prepare formal correspondence on behalf of the Committee.

Meetings

The timing, agenda and mode of meetings will be determined by the NBA and the Chair, after any necessary consultation with members. Meetings of no more than two hours will usually be held via teleconference, dependent on the agenda. It is intended that the NIGAC will hold a minimum of three meetings annually with at least one being face-to-face.

A quorum shall comprise at least seven members, consisting of the Chair, three Specialist Working Group representatives, one NBA representative, and two members who are not representing a Specialist Working Group.

Proxies for Specialist Working Group representatives will be identified through the nomination and selection process. For other positions, NIGAC members can nominate proxies where they are unable to attend, and must advise the NIGAC Secretariat of the relevant details.

If the Chair is unable to attend a meeting then the meeting will be rescheduled.

Reporting

NIGAC shall provide a written annual report to the NBA Chief Executive summarising its outcomes for the year. The report should include:

a. a summary of the work NIGAC performed to fully discharge its responsibilities during the preceding year; and
b. details of meetings, including the number of meetings held during the relevant period, and the number of meetings each member attended.

Out of session activities

NIGAC may, in accordance with a process determined by the Chair, undertake activities to give advice or assistance to the NBA out of session, in a manner consistent, as far as possible, with the application of these procedures to meetings of NIGAC.

Members may be called upon for ad-hoc advice via email between meetings.

Members should not undertake out of session activities in their capacity as NIGAC without the prior approval of the Chair.

Expert advisers and working groups

Additional expert advice will be sought on an ad hoc basis from experts on specific issues as required and cleared by the Chair. This could include, but is not limited to nominees from BloodSafe eLearning Australia, the Australian Commission on Safety and Quality in Health Care, and the National Prescribing Service.

There may be times when small working groups are required to deliver specific programs to the NIGAC. These working groups can consist of NIGAC members and/or expert advisors. The working groups may contribute to national Ig Governance activities including, but not limited to Criteria development and

promulgation, tools and resource development and implementation, research and development, data analysis, education and training, and promotion and communication in order to identify opportunities for improvement and contribute to performance measures if required.

The working groups will provide advice to the NIGAC and NBA as required.

Remuneration and allowances

NIGAC members are to be paid the remuneration and allowances as determined by the Remuneration Tribunal in accordance with the NBA Act and the *Remuneration Tribunal Act 1973*.

Conflict of Interest

NIGAC members and observers must declare any actual or potential, real or perceived conflicts of interest to the NBA Chief Executive. NIGAC members and observers may be required to complete undertakings and comply with the terms of those undertakings in relation to any conflicts of interest, confidentiality, document control and intellectual property.

NIGAC members must declare any conflicts of interest at the start of each meeting or before discussion of the relevant agenda item or topic. Details of any conflicts should be appropriately minuted.

Members will use a form of declaration notified by the NBA.

Conduct

Members of NIGAC hold a public office and accordingly are expected to carry out their role as members in accordance with the highest ethical standards. A NIGAC member should:

a. act honestly and in good faith;
b. use due care and diligence;
c. only use their office for a proper purpose;
d. not make improper use of information acquired as a NIGAC member, both during and after the term of appointment;
e. be fair, honest and courteous in interactions with other members, NBA and stakeholders;
f. contribute to NBA activities in a co-operative, impartial and productive way; and
g. not engage in conduct likely to bring discredit upon the NBA or the Program.

A member must not express any opinion, make any commitment, or otherwise purport to represent or act on behalf of the NBA, unless specifically requested by the Chair or the NBA Chief Executive to do so.

Reviews

The Chair, in consultation with the NBA Chief Executive, will initiate a review of the performance of NIGAC annually. The review will be conducted on a self-assessment basis (unless otherwise determined by the Chief Executive).

At least once a year NIGAC will review this Terms of Reference document. This review will include consultation with the NBA Chief Executive.

Substantive changes to the Terms of Reference may be recommended by NIGAC for consideration by the NBA Chief Executive as per section 38(3) of the NBA Act.

NIGAC may be discontinued by a further administrative decision of the NBA Chief Executive under Section 38 of the NBA Act.

Appendix A – Overview of National Immunoglobulin Governance Program

Objectives

The National Immunoglobulin (Ig) Governance Program was established to achieve governments' objectives for immunoglobulin products funded and supplied under the national blood arrangements, namely to:

- ensure immunoglobulin product use and management reflects appropriate clinical practice and represents efficient, effective and ethical expenditure of government funds, in accordance with relevant national safety and quality standards for health care;
- ensure that access to immunoglobulin products is consistent with the criteria for access determined by governments; and
- improve the capture of information on the need for, use of, and outcomes of treatment (including adverse events) with immunoglobulin products to inform future changes to the criteria.

Description

The Program is delivered through a package of measures which implements an integrated national framework for governance and management of immunoglobulin products.

The integrated national framework provides the following benefits for the governance and management of immunoglobulin products under the national blood arrangements:

- greater clarity in the roles, responsibilities, authority and accountability of those involved in authorising, supplying, managing and using the products throughout the supply chain and within health services;
- integration of specialist clinical expertise with policy, analysis and health economist perspectives to support and improve the governance and management;
- the consistent and efficient collection of authorisation, supply, use and outcomes data through a national system;
- progressive updating of governments' criteria for access to the products under the national blood arrangements, based on improvements in data, knowledge and practice;
- agreed indicators and processes to report on, evaluate and improve both clinical practice and outcomes in relation to the products, and the performance of the arrangements for governance and management of the products;
- coordinated processes to define, prioritise and deliver an improved knowledge base in relation to the products through well-directed research, education and training; and
- the potential to consider and, if approved, implement efficiency improvements in the processes for management of the products, including:
    - an appropriate level of automated authorisation of access to the products through the national system, within appropriate safeguards
    - streamlined product distribution.

Implementation

Implementation of the Program was managed and coordinated through the NBA, under the policy oversight of governments through the Jurisdictional Blood Committee, and working in conjunction with the range of participants involved in the governance and management of immunoglobulin products including health consumers, clinicians, health services, jurisdictional health departments, and product suppliers, distributors and authorisers.

The specific implementation arrangements may vary according to the circumstances of different jurisdictions or health services, within the objective of ensuring nationally consistent governance and management outcomes.

Program measures

The specific National Ig Governance Program measures are:

Development and maintenance of policies and procedures for access to Ig products - A defined set of policies and associated procedures have been developed and are regularly reviewed, describing the roles and responsibilities of key participants in the governance and management framework for immunoglobulin products.

Establishment and support of a national network of committees - An integrated network of committees has been established, including the National Immunoglobulin Governance Advisory Committee and specialist working groups. These committees have been integrated with a network of existing local governance committees and Ig user groups. The advice and recommendations of this committee network fundamentally inform the development, implementation and ongoing operation of the other governance program measures.

Evolving the criteria for access - The Criteria for the clinical use of immunoglobulin in Australia (Criteria) were issued in 2007 and updated in 2012 and 2018, and have been successful in defining the eligibility for access to product funded under the national blood arrangements. The Criteria is evolved through the improved governance framework, in particular through the role of the national committee network, improved data collection and analysis, and clinical practice development and targeted research. Considerations for the evolution of the Criteria will include appropriate clinical practice, alternative therapies and health economic aspects.

Development and implementation of a national ordering and outcomes database - A national Ig ordering and outcomes database (BloodSTAR) has been developed to support and contribute to the effectiveness of the program. The database supports the Criteria, policies and processes for access to immunoglobulin products, and generates clinical and management information to support improved patient care and efficient and effective product management and usage. Improved national data enhances the ability to further develop the Criteria, and provide an improved evidence base for practice improvement and research.

Development and implementation of a performance improvement program - Under the guidance of the national committee network, and utilising the Criteria and governance policies,the outcomes and ordering database, and other sources which may provide relevant information, a program has been developed to monitor, assess and improve the performance of the governance system and identify improvements to systems and processes. This includes the development of indicators, reports and benchmarking processes, and an appropriate framework for auditing.

Facilitate knowledge development - A knowledge development program identifies priorities for the development of better knowledge to support more informed decision making both at the clinician and system-wide management levels. In particular it identifies areas of need and evaluates the value of

investment in research and in education and training to improve clinical practice, governance and management.

Potential efficiency improvements - In light of the other elements of the improved governance and management framework, consideration will be given to:

- automated authorisation of access to products through the national system, within appropriate safeguards, for conditions where use is sufficiently established and indications robust enough to ensure that automated approval is feasible and appropriate
- improved efficiency through streamlined product distribution.

Appendix B – Membership

Member	Attributes
• **Chair**	Person who is impartial, understands the objectives of the NBA and can lead discussion.
• **Specialist Working Group representatives:** ○ **Neurology** ○ **Haematology** ○ **Immunology** ○ **Transplant Medicine**	Persons with clinical expertise to consider the clinical appropriateness, safety and cost effectiveness of Ig, including comparative outcomes of therapies. These members Chair the Specialist Working Groups for their relevant speciality.
• **Consumer representatives (two positions)**	Persons who provide a patient, carer and community perspective.
• **Nurse representatives (two positions)**	Persons with expertise in Ig product administration.
• **Dispenser**	Person with expertise in Ig product dispensing and product management.
• **Health Economist** • **Epidemiologist**	Person with 10 or more years of relevant experience and are able to evaluate the comparative outcomes of therapy and consider the clinical effectiveness, safety and cost effectiveness of Ig compared to other therapies
• **Commonwealth representative** • **State/territory representatives** ○ **Large jurisdiction (QLD, NSW or VIC)** ○ **Small jurisdiction (TAS, ACT, WA, SA or NT)**	Person representing the government department by which they are employed
• **Subject Matter Advisor**	The NBA Chief Executive may appoint to the Committee any person with the appropriate skills, knowledge and attributes who may be able to assist the Committee with its work.
• **NBA representatives (Chief Executive and Deputy Chief Executive)**	
Observer	**Attributes**
• **National Authoriser representative**	Person who represents national authorisers.