Structured Administration and Supply Arrangement (SASA)

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| **TITLE:** | **Supply of subcutaneous immunoglobulin by laboratory staff from accredited pathology services** |

1. **Authority:**

Issued by the Chief Executive Officer of Health under Part 6 of the *Medicines and Poisons Regulations 2016*.

1. **Scope:**

This SASA authorises medical scientists and laboratory technicians in National Association of Testing Authorities, Australia (NATA) accredited pathology services to supply subcutaneous immunoglobulin products in Schedule 4 to patients.

1. **Criteria:**

This SASA authorises the actions specified in the table below:

| **Practitioner:** | Medical scientists and laboratory technicians employed within the practice setting detailed below, who are eligible for professional membership with the Australian Institute of Medical and Clinical Scientists (AIMS). |
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| **Practice setting:** | NATA accredited pathology services in Western Australia, with   1. Scope of accreditation which includes immunohaematology – storage and distribution of blood and blood components and 2. A current Permit under the *Medicines and Poisons Act 2014* to allow purchase and use of Schedule 4 medicines. |
| **Approved activity:** | Supply |
| **Approved medicines:** | National Blood Authority (NBA) funded subcutaneous immunoglobulin products in Schedule 4. |
| **Medical conditions:** | Medical conditions listed in the current version of the Criteria for the clinical use of immunoglobulin in Australia. |

1. **Conditions:**

4.1 Supply must only be made where all the following requirements are met:

* 1. A medical practitioner, approved to participate in the National Subcutaneous Immunoglobulin Program, has submitted a Patient Authorisation Request for subcutaneous immunoglobulin via BloodSTAR (Blood System for Tracking Authorisations and Reviews)
  2. The Patient Authorisation Request has been approved for supply in BloodSTAR,
  3. The medical practitioner has given a direction to supply subcutaneous immunoglobulin consistent with the BloodSTAR authorisation
  4. The date of supply is prior to the next mandatory clinical review date for the patient as recorded in BloodSTAR
  5. Each supply is made in accordance with the BloodSTAR authorisation for the patient with regards to product, supply quantity and supply interval.

4.2 The supply of medicines under this SASA is subject to the conditions that on each occasion of supply:

1. The product is packaged and labelled in accordance with Part 9 of the Medicines and Poisons Regulations 2016 and
2. A record of supply is made in accordance with Part 12 of the Medicines and Poisons Regulations 2016
3. A record of supply is made directly in BloodNet or via a BloodNet Laboratory Information System interface.

4.3 If a patient related adverse event is reported to a practitioner who supplies subcutaneous immunoglobulin, the practitioner must advise the patient’s medical practitioner as soon as practicable.

4.4 All supply of subcutaneous immunoglobulin products must be in accordance with the access arrangements of the Immunoglobulin Governance National Policy: Access to Government Funded Immunoglobulin Products in Australia.

1. **References:**

National Blood Authority, Information on access to Immunoglobulins via Blood portal. Available at <https://www.blood.gov.au/Ig>

Criteria for clinical use of immunoglobulin in Australia: available via BloodSTAR or at <https://www.criteria.blood.gov.au/>

National Blood Authority. Immunoglobulin Governance National Policy: Access to Government Funded Immunoglobulin Products in Australia. Third Edition, July 2019. Available at: <https://www.blood.gov.au/system/files/documents/2019-immunoglobulin-governance-national-policy-V8FINAL.pdf>

1. **Issued by:**

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| **Name:** | Dr Andrew Robertson |
| **Position:** | Chief Health Officer |
| **Date:** | 12 January 2021 |

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