Structured Administration and Supply Arrangement (SASA)

|  |  |
| --- | --- |
| **TITLE:** | **Administration of monoclonal antibody for Respiratory Syncytial Virus (RSV) for protection against RSV by Aboriginal Health Practitioners** |

1. **Authority:**

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

1. **Scope:**

This authorises Aboriginal Health Practitioners trained in RSV immunisation, to administer monoclonal antibody for RSV at suitably equipped and staffed places or premises in Western Australia (WA).

1. **Criteria:**

This SASA authorises the actions specified in the table below.

|  |  |
| --- | --- |
| Practitioner: | Aboriginal Health Practitioners who have completed approved training in accordance with Appendix 1. |
| Practice setting: | When employed by, or contracted to provide services to, WA Health, Local Government, Department of Justice, or a Health Service that is a member of the Aboriginal Health Council of WA. |
| Approved activity: | Administration. |
| Approved medicines: | Medicines listed in Appendix 2. |
| Medical conditions: | Prevention of RSV infection in infants in accordance with WA Immunisation Schedule. |

1. **Conditions:**

The administration of approved medicines under this SASA is subject to the following conditions:

* 1. The Aboriginal Health Practitioners must have successfully completed an immunisation training course meeting the requirements of Appendix 1. The training must relate to the medicines being administered, as detailed in Appendix 2.
  2. Sites where immunisation is being conducted must be appropriately equipped to treat patients in the event of an anaphylactic reaction.

* 1. Medicine selection, administration and follow-up care should be in accordance with the latest version of the WA Health Immunisation Schedule.
  2. Written or documented verbal consent must be obtained from the person, parent or guardian, before each instance of immunisation.
  3. All medicines administered must be recorded on the Australian Immunisation Register.
  4. All medicines administered must be recorded in the relevant clinical software.
  5. All adverse events occurring following immunisation must be notified to the   
     Western Australian Vaccine Safety Surveillance system.
  6. The medicines are procured by an authorised person or an appropriate Medicines and Poisons Permit holder.
  7. Procurement, storage and administration is in accordance with Part 9 of the Medicines and Poisons Regulations 2016.
  8. Record keeping is in accordance with Part 12 of the Medicines and Poisons Regulations 2016.
  9. Storage and transport of the medicines is in accordance with the *National Vaccine Storage Guidelines: Strive for 5.*

1. **References:**
2. *Beyfortus nirsevimab Therapeutic Goods Administration (TGA) product information* <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent=&id=CP-2023-PI-02637-1&d=20240305172310101>
3. *National Vaccine Storage Guidelines 2013: Strive For 5*, 3rd ed. Canberra: Australian Government, Department of Health and Ageing. Available at: <https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5>
4. *Western Australian Vaccine Safety Surveillance.* Western Australian Department of Health, 2016. Available at: <http://ww2.health.wa.gov.au/Articles/U_Z/Western-Australian-Vaccine-Safety-Surveillance-WAVSS>
5. *Western Australian Immunisation Schedule.* Western Australian Department of Health, 2024. Available at : [www.health.wa.gov.au/Articles/F\_I/Immunisation-schedule-and-catch-up-vaccines](http://www.health.wa.gov.au/Articles/F_I/Immunisation-schedule-and-catch-up-vaccines)
6. **Issued by:**

|  |  |
| --- | --- |
| **Name:** | Dr Clare Huppatz |
| **Position:** | A/Chief Health Officer, CEO delegate |
| **Date:** | 26 March 2024 |

|  |  |  |  |
| --- | --- | --- | --- |
| Enquiries to: | Medicines and Poisons Regulation Branch | Number: | 039/1-2024 |
|  | [MPRB@health.wa.gov.au](mailto:MPRB@health.wa.gov.au) | Date: | 26/3/2024 |

**APPENDIX 1**

|  |
| --- |
| **Approved Training** |

All Aboriginal Health Practitioners administering a medicine in accordance with this SASA must have successfully completed:

1. A general immunisation course that is:
   * 1. approved by the CEO of Health; or
     2. accredited by Health Education Services Australia; or
     3. delivered by a Registered Training Organisation or University.

**and**

1. RSV online training module, developed by the Communicable Disease Control Directorate, Department of Health (WA).

All Aboriginal Health Practitioenrs must maintain their immunisation competency through yearly updates.

All general immunisation courses must require participants to demonstrate satisfactory knowledge, understanding and minimum competencies in the following areas:

1. storage, transport and handling of vaccines (cold chain management);
2. obtaining informed consent for immunisation;
3. indications and contraindications for vaccines, including live attenuated vaccines;
4. administration of vaccines as per National Health and Medical Research Council Immunisation Guidelines, including subcutaneous and intramuscular injection techniques;
5. cardiopulmonary resuscitation (CPR);
6. diagnosis and management of anaphylaxis; and
7. documentation of vaccination and critical incidents.

**APPENDIX 2**

|  |
| --- |
| **Approved medicines** |

|  |
| --- |
| Aboriginal Health Practitioners may only administer the following medicines in accordance with this SASA and in accordance with the latest TGA approved product information: |
| 1. Beyfortus nirsevimab 50mg in 0.5mL solution for injection prefilled syringe (for infants <5kg bodyweight) 2. Beyfortus nirsevimab 100mg in 1mL solution for injection prefilled syringe (for infants ≥5kg bodyweight). |