Northern Territory of Australia

*Medicines, Poisons and Therapeutic Goods Act 2012*

**Nirsevimab for Maternity Services SSTP Approval**

I, Christine Maree Connors, Chief Health Officer:

(a) under section 254(1) of the Act, approve each Scheduled substance treatment protocol specified in Schedule A;

(b) under section 254(3) of the Act, state that each Schedule substance treatment protocol specified in Schedule A remains in effect for a period of 2 years on and from the date of this instrument.

Dated 31 October 2024

Chief Health Officer

# Nirsevimab for prevention of Respiratory Syncytial Virus (RSV) Scheduled Substance Treatment Protocol



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| **Areas Applicable** | Maternity services within NT Health hospitals |
| **Health Professionals authorised by this SSTP** | Nurses, Midwives, and Aboriginal and Torres Strait Islander Health Practitioners providing maternity services within a NT Health Hospital Setting |
| **Scheduled Substance(s)** | Nirsevimab |
| **Indication** | Prevention of severe Respiratory Syncytial Virus (RSV) disease in infants in accordance with the *Nirsevimab for Prevention of Severe Respiratory Syncytial Virus (RSV) Disease in Infants* guideline published by NT Health. The following children are eligible<br>• All First Nations infants under 6 months of age.<br>• All infants aged less than 6 months (chronological, uncorrected for prematurity) with at least **one identified risk factors**. |
| **Contraindications and/or Exclusions*** | This protocol cannot be used for:<br>• Persons older than 6 months<br>• Newborns with a gestation of less than 37 weeks<br>• Infants with an increased risk for excessive bleeding such as thrombocytopenia<br>Nirsevimab is contraindicated in individuals with a history of severe allergic reactions (e.g. anaphylaxis) to the active substance or to any of the excipients of the product |
| **Dose and Route** | Nirsevimab is recommended to be given by intramuscular injection as a single |

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| | dose according to weight as below:<br>• 50 mg in 0.5 mL if weight is <5 kg (prefilled syringe, purple plunger rod)<br>• 100 mg in 1 mL if weight is ≥5 kg (prefilled syringe, light blue plunger rod) |
| **Administration** | As per product information<br>Nirsevimab can be co-administered on the same day as other routine childhood vaccines.<br>Only the supplied syringe may be used and not mixed with any other product. |
| **Dose Frequency** | Single dose<br>• All First Nations neonates born with gestation equal or greater than 37 weeks, nirsevimab may be given as soon as possible after birth (or before discharge from maternity or hospital)- ALL YEAR ROUND<br>• For neonates born outside of hospital service, nirsevimab may be given as soon as possible when attending hospital maternity/ postnatal health facilities. Ideally within 1 week of age with other newborn care (e.g. vitamin K, or birth doses of hepatitis B vaccine) |
| **Drug Interactions** | Nil known |
| **Monitoring requirements** | Infants should be monitored by the provider for 15 minutes after administration of nirsevimab.<br>Appropriate equipment (as per the Australian Immunisation Handbook – Preparing an anaphylaxis response kit) – must be available to initiate treatment for adverse events if required.<br>Report any adverse event during or post administration via Adverse event following immunisation (AEFI) online<br>If consent to be monitored is withdrawn, ensure withdrawn consent is documented in the person's clinical record. |
| **Health Professional Accreditation Requirements** | Health professionals using this guideline must meet the requirements outlined by the NT Chief Health Officer:<br>***Nurses and Midwives***:<br>• Be registered with the Nursing and Midwifery Board of Australia with no conditions, undertakings or notations which may limit delivery of clinical services directly to patients<br>***Aboriginal Health Practitioners:***<br>• Be registered with the Aboriginal and Torres Strait Islander Health |

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| | Practice Board of Australia with no conditions or undertakings which may limit delivery of clinical services directly to patients<br><br>**All health professionals following this protocol must:**<br><br>• Maintain continuing professional development related to skills and competencies required for the delivery of medicines and vaccines including management of anaphylaxis<br><br>• Hold a current Cardiopulmonary Resuscitation (CPR) certificate<br><br>**All health professionals administering vaccines from this protocol must have completed and hold a current qualification in:**<br><br>• A program of study accredited by Health Education Services Australia (HESA) or the Australian Pharmacy Council **or**;<br><br>• A program of study approved by the Chief Health Officer **or**;<br><br>• Completed the assessment of an immuniser program of study that meets the curriculum content requirements of the National Immunisation Education Framework for Health Professionals |
| **Documentation** *(including necessary information to the patient)* | Patient consent (written or verbal) for vaccination must be recorded. Records of this should be maintained by the clinical service.<br><br>The health professional must:<br><br>• Complete all clinical documentation requirements as outlined by the Health Service.<br><br>• Documented Nirsevimab and strength have been administered as per **Nirsevimab for prevention of RSV SSTP.** Enter the mandatory fields in the Australian Immunisation Register within 24 hours and no later than 10 days after administration. For many vaccine providers this involves entry into routine clinical information systems for automatic upload |
| **Related Documents** | • Immunisation program \| NT Health<br><br>• The Australian Immunisation Handbook (health.gov.au)<br><br>• Nirsevimab Product Information<br><br>• National vaccine storage guidelines - Strive for 5, 3rd edition (health.gov.au)<br><br>• ASCIA_HP_Guidelines_Acute_Management_Anaphylaxis_2023.pdf (allergy.org.au)<br><br>• Nirsevimab for Prevention of Severe Respiratory Syncytial Virus (RSV) Disease in Infants NT Health guideline |

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| | • Nirsevimab for Prevention of Severe RSV Disease in Infants Guideline.docx | | |
| **Chief Health Officer** | **Signature** | **Name** | **Date** |
| | **EDOC2024/309827** | Adj Prof Christine Connors | 30/10/2024 |
| **Period of effect** | This SSTP is inforce until 30/10/2026 unless revoked earlier | | |
| **References:**<br>* The drug information provided is to act as a guide to outline the limits of legal dealing with the named scheduled substances. Further information reference should be made to the full manufacturer's product info and other reliable sources of medicines information. If contraindications or interactions are present refer to medical officer before administration | | | |

**Schedule A**

| Title | Publication Date | Author |
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| Nirsevimab for prevention of Respiratory Syncytial Virus (RSV) Scheduled Substance Treatment Protocol | 29 October 2024 | Obstetrics and Gynaecology, Paediatrics, Northern Territory Government, Department of Health. |
| Nirsevimab for prevention of Respiratory Syncytial Virus (RSV) Scheduled Substance Treatment Protocol - ACCHO | 30 October 2024 | Centre for Disease Control, Northern Territory Government, Department of Health. |

Scheduled Substance Treatment Protocol

# Nirsevimab for prevention of Respiratory Syncytial Virus (RSV) Scheduled Substance Treatment Protocol - ACCHO



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| **Areas Applicable** | Services delivered at or through Aboriginal Community Controlled Health Organisations partnering with NT Centre for Disease Control |
| **Health Professionals authorised by this SSTP** | Nurses, Midwives, and Aboriginal and Torres Strait Islander Health Practitioners |
| **Scheduled Substance(s)** | Nirsevimab |
| **Indication** | Prevention of severe Respiratory Syncytial Virus (RSV) disease in infants in accordance with the *Nirsevimab for Prevention of Severe Respiratory Syncytial Virus (RSV) Disease in Infants* guideline published by NT Health. The following children are eligible<br>• All First Nations infants under 6 months of age.<br>• All infants aged less than 6 months (chronological, uncorrected for prematurity) with at least **one identified risk factors**. |
| **Contraindications and/or Exclusions*** | This protocol cannot be used for:<br>• Persons older than 6 months<br>• Newborns with a gestation of less than 37 weeks<br>• Infants with an increased risk for excessive bleeding such as thrombocytopenia<br>Nirsevimab is contraindicated in individuals with a history of severe allergic reactions (e.g. anaphylaxis) to the active substance or to any of the excipients of the product |

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| **Dose and Route** | Nirsevimab is recommended to be given by intramuscular injection as a single dose according to weight as below:<br>• 50 mg in 0.5 mL if weight is <5 kg (prefilled syringe, purple plunger rod)<br>• 100 mg in 1 mL if weight is ≥5 kg (prefilled syringe, light blue plunger rod) |
| **Administration** | As per product information<br>Nirsevimab can be co-administered on the same day as other routine childhood vaccines.<br>Only the supplied syringe may be used and not mixed with any other product. |
| **Dose Frequency** | Single dose<br>• All First Nations neonates born with gestation equal or greater than 37 weeks, nirsevimab may be given as soon as possible after birth (or before discharge from maternity or hospital)- ALL YEAR ROUND<br>• For neonates born outside of hospital service, nirsevimab may be given as soon as possible when attending hospital maternity/ postnatal health facilities. Ideally within 1 week of age with other newborn care (e.g. vitamin K, or birth doses of hepatitis B vaccine) |
| **Drug Interactions** | Nil known |
| **Monitoring requirements** | Infants should be monitored by the provider for 15 minutes after administration of nirsevimab.<br>Appropriate equipment (as per the Australian Immunisation Handbook – Preparing an anaphylaxis response kit) – must be available to initiate treatment for adverse events if required.<br>Report any adverse event during or post administration via Adverse event following immunisation (AEFI) online<br>If consent to be monitored is withdrawn, ensure withdrawn consent is documented in the person's clinical record. |
| **Health Professional Accreditation Requirements** | Health professionals using this guideline must meet the requirements outlined by the NT Chief Health Officer:<br>***Nurses and Midwives***:<br>• Be registered with the Nursing and Midwifery Board of Australia with no conditions, undertakings or notations which may limit delivery of clinical services directly to patients<br>***Aboriginal Health Practitioners:*** |

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| | • Be registered with the Aboriginal and Torres Strait Islander Health Practice Board of Australia with no conditions or undertakings which may limit delivery of clinical services directly to patients<br><br>**All health professionals following this protocol must:**<br><br>• Maintain continuing professional development related to skills and competencies required for the delivery of medicines and vaccines including management of anaphylaxis<br><br>• Hold a current Cardiopulmonary Resuscitation (CPR) certificate<br><br>**All health professionals administering vaccines from this protocol must have completed and hold a current qualification in:**<br><br>• A program of study accredited by Health Education Services Australia (HESA) or the Australian Pharmacy Council **or**;<br><br>• A program of study approved by the Chief Health Officer **or**;<br><br>• Completed the assessment of an immuniser program of study that meets the curriculum content requirements of the National Immunisation Education Framework for Health Professionals |
| **Documentation** *(including necessary information to the patient)* | Patient consent (written or verbal) for vaccination must be recorded. Records of this should be maintained by the clinical service.<br><br>The health professional must:<br><br>• Complete all clinical documentation requirements as outlined by the Health Service.<br><br>• Documented Nirsevimab and strength have been administered as per **Nirsevimab for prevention of RSV SSTP.** Enter the mandatory fields in the Australian Immunisation Register within 24 hours and no later than 10 days after administration. For many vaccine providers this involves entry into routine clinical information systems for automatic upload |
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| | • Nirsevimab for Prevention of Severe RSV Disease in Infants Guideline.docx | | |
| **Chief Health Officer** | **Signature** | **Name** | **Date** |
| | EDOC2024/309828 | Adj Prof Christine Connors | 30/10/2024 |
| **Period of effect** | This SSTP is inforce until 30/10/2026 unless revoked earlier | | |
| **References:**<br>* The drug information provided is to act as a guide to outline the limits of legal dealing with the named scheduled substances. Further information reference should be made to the full manufacturer's product info and other reliable sources of medicines information. If contraindications or interactions are present refer to medical officer before administration | | | |