Palivizumab for neonates and infants

BRIEF ADMINISTRATION GUIDE

For detailed information refer to the Synagis® NZ data sheet or The Australasian Neonatal Medicines Formulary **palivizumab** guideline

⚠ Note: This guide has been developed in line with Medsafe approved use and PHARMAC approved funding for palivizumab in NZ. There are minor variations between this information and the ANMF guideline for this medicine which are indicated by the yellow shaded text

1. Medicine

1.1. Indications

Prophylaxis against RSV infection in at risk infants for PHARMAC approved eligibility criteria (and upon application for *Special Authority* by a Paediatrician) which are:

1. Infant was born in the last 2 years and has severe lung, airway, neurological or neuromuscular disease that requires community ventilation (CPAP or nasal high flow); or
2. Both:

2.1 Infant was born in the last 12 months; and
2.2 Any of the following:
2.2.1. Patient was born at less than 28 weeks gestation; or
2.2.2. Both:
2.2.2.1. Patient was born at less than 32 weeks gestation; and
2.2.2.2. Either:
2.2.2.2.1. Patient has chronic lung disease; or
2.2.2.2.2. Patient is Māori or any Pacific ethnicity; or
2.2.3. Both:
2.2.3.1. Patient has haemodynamically significant heart disease; and
2.2.3.2. Any of the following:
2.2.3.2.1. Patient has unoperated simple congenital heart disease with significant left to right shunt (see note a); or
2.2.3.2.2. Patient has unoperated or surgically palliated complex congenital heart disease; or
2.2.3.2.3. Patient has severe pulmonary hypertension (see note b); or
2.2.3.2.4. Patient has moderate or severe LV failure (see note c).

Note:
a) Patient requires/will require heart failure medication, and/or patient has significant pulmonary hypertension, and/or patient will require surgical palliation/definitive repair within the next 3 months
b) Mean pulmonary artery pressure more than 45 mmHg
c) LV Ejection Fraction less than 40%.

- Can be administered concurrently with other childhood immunisations
- No minimum age criteria – should be given prior to discharge from NICU for inpatients.
- A moderate to severe acute infection or febrile illness may warrant delaying the use of palivizumab, unless, in the opinion of the physician, withholding palivizumab entails a greater risk. A mild febrile illness, such as a mild upper respiratory infection, is not usually reason to defer administration of palivizumab.
- Chronic lung disease is defined as requiring oxygen or respiratory support at 36 weeks post menstrual age.
- Although the protection against RSV is not long lasting (over years), it is likely that short term protection happens after one episode of RSV and can prevent RSV being acquired in the same season so ongoing palivizumab is not needed after infection. Factors like additional medications and immunocompromise may be reasons to continue a seasonal course of palivizumab once recovery from RSV in the same RSV season.

1.2. Route and Presentation

Intramuscular

- Supplied as palivizumab 100 mg/mL vial

1.3. Dose

15 mg/kg once per month during periods of RSV risk.

Maximum of 5 doses over 5 months.

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Palivizumab should be prescribed in the "once only section" of the inpatient medication chart for inpatients and on a Day Stay medication chart for outpatients.

2. Preparation and Administration

2.1. Compatible fluids

Not required as palivizumab is administered undiluted

2.2. Administration Method

Patient co-ordination

- Eligible patients to be identified and parental consent obtained and documented in inpatient clinical notes and CWS or discharge summary. For outpatients, document in CWS or Outpatient progress note.
- Special authority applied for electronically by SMO for all patients
- Outpatients in Hamilton and surrounding areas to be booked into Waikids clinic at respective dates.
- Doses can be prescribed in advance using the most recent weight (up to a month prior) or on the day of administration and drug chart scanned to inpatient pharmacy for dispensing. If the advanced prescribed dose is 5mg or more difference from the dose calculation per the new weight, access the Waikids clinic doctor to adjust the prescription to the up to date weight accurate dose.
- Outpatients in Waikato rural areas such as Thames, Tokoroa, Te Kuiti, Taumarunui:
  1) Book appointment at local hospital / clinic
  2) Advance prescribe palivizumab if possible. If difficult to have prescribed use standing order and have prescription signed within 24 hours.
  3) Co-ordinator to pick up dispensed vials from Pharmacy packed in chiller pack for transport and take with them to rural clinics.
  4) Upon arrival at rural hospital /clinic record infant's current weight and administer palivizumab as per this guideline. If the prescribed dose is 5mg or more difference from the dose calculation per the new weight invoke the standing order to administer the up to date weight accurate dose.
- Inpatients receive dose(s) in NICU or paediatric ward (stock obtained from inpatient Pharmacy)

IM injection

- Draw up the required dose and administer undiluted into the vastus lateralis in the anterolateral thigh. Do not shake vial. If dose is > 1 mL give in divided doses.
- If administered concurrently with other childhood immunisations, injection sites need to be separated by 2 cm vertically

2.3. Monitoring

- Monitor for hypersensitivity reactions
- Observe injection site for induration and swelling
- Observations for adverse effects should continue for at least 15 minutes after receiving the palivizumab

2.4. Storage and Stability

- Store vials at 2 to 8 ^{o}C. Do not freeze.
- Multiple doses may be drawn up from one vial using strict aseptic technique if infants are due their dose at the same time. Discard unused portion of the vial if not using for another scheduled baby within that clinic/shift.
- Administer as soon as possible after withdrawal from the vial.

2.5. Competency for Administration

This procedure is carried out by, or under, the direct supervision of a registered nurse/registered midwife who holds current Te Whatu Ora Waikato Generic Medicine Management.

2.6. Guardrails

N/a

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3. Associated Documents

- Synagis® (palivizumab) patient information leaflet, accessed via https://www.medsafe.govt.nz/consumers/cmi/s/synagis.pdf
- Pharmac Application for subsidy by Special Authority, form SA2128 available from https://schedule.pharmac.govt.nz/2022/06/01/SA2128.pdf

4. References

- Australasian Neonatal Medicines Formulary (ANMF). Palivizumab 2020. Available from
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- NZ Data Sheet for Synagis® (palivizumab). AstraZeneca Ltd, October 2021. Available from https://medsafe.govt.nz/profs/Datasheet/s/synagisinj.pdf
- Truven Health Analytics Inc. Micromedex®. Palivizumab monograph. Available from: http://www.micromedexsolutions.com.
- Pharmac decision to fund palivizumab for infants and young children at high risk of respiratory syncytial virus during the COVID-19 pandemic 16 May 2022 https://pharmac.govt.nz/news-and-resources/consultations-and-decisions/decision-2022-05-16-palivizumab/
- Pharmac June 2022 HML https://schedule.pharmac.govt.nz/HMLOnline.php?osq=Palivizumab and Community Schedule https://schedule.pharmac.govt.nz/ScheduleOnline.php?osq=Palivizumab

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