

Palivizumab

Adjudication Guideline

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1. Abstract

1.1 For Members

Palivizumab injection is used to prevent serious lung infection in children and babies caused by respiratory syncytial virus (RSV). It belongs to a group of medicines known as immunizing agents. This medicine works by giving your body antibodies to protect it against RSV infection.

1.2 For Medical Professionals

Palivizumab is a man-made antibody to a respiratory syncytial virus (RSV)F protein inhibitor monoclonal antibody that neutralises and inhibits fusion of respiratory syncytial virus (RSV) with the host cell, preventing its replication.

Is the only drug approved by the U.S Food and Drug Administration (FDA) for Prevention of RSV (Respiratory Syncytial Virus) for lower respiratory tract disease in preterm infants and in children with congenital heart disease or Chronic lung disease of prematurity.

Its work best in children who are 24month old or younger at the beginning of RSV season (6 month or younger for premature infants). Its intramuscular use and single-use-vial.

2. Scope

This adjudication rule specifies the coverage details for medically necessary indications for the immunoprophylaxis with drug Palivizumab injection to reduce the risk of severe respiratory syncytial virus (RSV) infection in high-risk infants and to prevent RSV infection in hospitalization among high-risk infants who are likely to benefits from the injection treatments as per the policy terms and conditions of each health insurance plan administered by Daman.

3. Adjudication Policy

3.1 Eligibility / Coverage Criteria

Criteria	Age with RSV reason
Premature, No CLD (Chronic Lung disease), NO CHD (congenital heart disease).	<28week Gestational Age, Palivizumab if <12-month-old at start of RSV season.
	29-32week Gestational Age, Palivizumab if <6month old at start of RSV season
	Infants born between 32-35 weeks of gestation (35 weeks and 6 days or less), are less than 3 months old at the start of the RSV season and with at least one of factor i.e. attending day-care or have siblings less than 5 years old at home. In such cases, infants must be offered a prophylaxis dose until they reach 3 months chronological age (a maximum of 3 doses).
Hemodynamically Significant Congenital Heart disease (CHD)	Palivizumab if <1years old at Start of RSV season
Chronic Lung Disease * (CLD) who still require medical therapy (diuretics, steroid or oxygen)	Palivizumab if <2 years old at start of RSV season.
*Receiving medical therapy for CLD (Chronic Lung disease) within 6 months	

Eligible clinician specialities
Paediatrician
Neonatologist
Cardiologist
Pulmonologist

Quantity Limits Dosage and Administration:

Palivizumab 50 mg/0.5ml, 100 mg vial 15 mg/kg once a month for up to 5 doses per RSV season

*One additional dose may be approved for individuals undergoing cardiopulmonary bypass for a surgical procedure as noted in clinical criteria:

Generic name	Strength	Dosage form with Package size
Palivizumab	100 mg/ml	Solution for Intramuscular Injection 1 Glass Vial
Palivizumab	50 mg/0.5ml	Solution for Intramuscular Injection 1 Glass Vial

Dosing Calculation as per Weight:

Weight	Dose calculation in mL	Dosage calculation in Mg	Palivizumab 100 Mg / Per Encounter with quantity	Palivizumab 50 Mg / Per Encounter with quantity
2KG	0.30 mL	30 MG	-	1 vial
3KG	0.45 mL	45 MG	-	1 vial
4KG	0.60 ML	60 MG	1 vial	2 vials
5KG	0.75 ML	75 MG	1 vial	2 vials
6KG	0.90 mL	90 MG	1 vial	2 vials
7KG	1.05 mL	105 MG	1 vial	3 vials
8KG	1.20 mL	120 MG	1 vial	3 vials
9KG	1.35 mL	135 MG	1 vial	3 vials
10KG	1.50 mL	150 MG	1 vial	3 vials
11KG	1.65 mL	165 MG	2 vials	4 vials
12KG	1.80 mL	180 MG	2 vials	4 vials
13KG	1.95 mL	195 MG	2 vials	4 vials
14KG	2.10 mL	210 MG	2 vials	5 vials
15KG	2.25 mL	225 MG	2 vials	5 vials
15.8KG	2.37 mL	237 MG	2 vials	5 Vials
*The recommended dose of Palivizumab is 15ml/kg of body weight given monthly by IM injection: patient weight (Kg) *15mg/kg ÷ 100 mg/ml.				
*Notes: Palivizumab can be taken 100mg or 50mg vial as per recommended dosage calculation ml/mg				

3.2 Requirements for Coverage

1. Cost of administration of RSV prophylaxis, including consultation, vaccine cost and other supplies, shall be covered under insurance plans (Basic, Enhanced and Thiqa) for the eligible members as any other medical condition.
2. Coverage under health insurance ends at age of 24 months (last day of child's birthday month).

3.3 Non-Coverage

1. Non-FDA approved indications.
2. Children older than 2 years of age.
3. More than 5 injections.
4. Hemodynamically insignificant heart disease i.e. Secundum atrial septal defect (ASD), Small Ventricular septal Defects (VSD), Pulmonic Stenosis, Aortic Stenosis, Mild coarctation of the aorta and Patent Ductus arteriosus (PDA).
5. Infants with corrected surgical lesions unless they continue to require medication for Congestive heart failure (CHF).
6. Infants with mild cardiomyopathy who are not receiving medical therapy.
7. Use in children with Down syndrome without other risk factor
8. Use in children with Cystic Fibrosis (CF).

Plan	Coverage
Visitor plan	Not covered.
Basic plan	Covered as per medical Criteria and member SOB
Enhanced plan	Covered as per medical Criteria and member SOB
Thiqa	Covered as per medical Criteria and member SOB

3.4 Payment and Coding Rules

Please apply regulator payment rules and regulations and relevant coding manuals for ICD, CPT.

4. Denial Codes

Code	Code Description
MNEC-004	Service is not clinically indicated based on good clinical practice
CODE-010	Activity/diagnosis inconsistent with clinician specialty
MNEC-005	Service/supply may be appropriate, but too frequent
CODE-014	Activity/diagnosis is inconsistent with the patient's age/gender

5. Appendices

5.1 References

<https://www.isahd.ae/content/docs/DSC%20RSV.pdf>
[Clinical Guidelines \(Nursing\) : Palivizumab for at-risk patients \(rch.org.au\)](https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/103770s5185lbl.pdf)
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[Synagis, INN-palivizumab; \(europa.eu\)](https://www.efcni.org/wp-content/uploads/2021/04/2021_RSV_Positionpapier.pdf)
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[Letter - Respiratory Syncytial Virus prophylaxis \(Gateway ref. 14848\) \(publishing.service.gov.uk\)](https://www.med.umich.edu/asp/pdf/pediatric_guidelines/Palivizumab_PEDS.pdf)
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[Preventing RSV \(Respiratory Syncytial Virus\) | CDC](https://www.med.umich.edu/asp/pdf/pediatric_guidelines/Palivizumab_PEDS.pdf)
[Green Book Chapter 27a Respiratory syncytial virus \(publishing.service.gov.uk\)](https://www.med.umich.edu/asp/pdf/pediatric_guidelines/Palivizumab_PEDS.pdf)
[palivizumab | Michigan Medicine \(uofmhealth.org\)](https://www.med.umich.edu/asp/pdf/pediatric_guidelines/Palivizumab_PEDS.pdf)
[SYNAGIS \(palivizumab\) Dose Calculator & RSV Infection Rates \(synagishcp.com\)](https://www.med.umich.edu/asp/pdf/pediatric_guidelines/Palivizumab_PEDS.pdf)

5.2 Revision History

Date	Version No.	Change(s)
13/05/2022	V1.0	Release of V1.0
16/08/2024	V2.0	AR Review
30/10/2024	V3.0	No changes/ Release of V2.0

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