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Palivizumab Indication

Adjudication Guideline

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Abstract

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.

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.

Approved by:
Daman

Responsible:
Medical Standards & Research

Related Adjudication Guidelines: None

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Scope

This adjudication rule specifies the coverage details for medically necessary indications for the immuno-prophylaxis 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 benefit from the injection treatments as per the policy terms and conditions of each health insurance plan administered by Daman.

Adjudication Policy

Eligibility / Coverage Criteria

Criteria	Age with RSV season
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.
<i>*Receiving medical therapy for CLD (Chronic Lung disease) within 6 months</i>	

Eligible clinician specialities

Paediatrician
Neonatologist
Cardiologist
Pulmonologist

Quantity Limits Dosage and Administration ^{12,3}:

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⁻³

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

Dosing Calculation as per Weight ^{12,13,18}:

Weight	Dosage Calculation in mL	Dosage Calculation in Mg	Palivizumab 100 Mg / Per Encounter with quantity	Palivizumab 50 Mg / Per Encounter with quantity
2 KG	0.30 mL	30 MG	-	1 vial
3 KG	0.45 mL	45 MG	-	1 vial
4 KG	0.60 mL	60 MG	1 vial	2 vials
5 KG	0.75 mL	75 MG	1 vial	2 vials
6 KG	0.90 mL	90 MG	1 vial	2 vials
7 KG	1.05 mL	105 MG	1 vial	3 vials
8 KG	1.20 mL	120 MG	1 vial	3 vials
9 KG	1.35 mL	135 MG	1 vial	3 vials
10 KG	1.50 mL	150 MG	1 vial	3 vials
11 KG	1.65 mL	165 MG	2 vials	4 vials
12 KG	1.80 mL	180 MG	2 vials	4 vials
13 KG	1.95 mL	195 MG	2 vials	4 vials
14 KG	2.10 mL	210 MG	2 vials	5 vials
15 KG	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.*

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).

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).
9. Not covered for clinician speciality other than the specified speciality mentioned in eligibility /coverage criteria.

Plan	Coverage
Visitor plan	Not covered
Basic plan	Covered as per medical Criteria
Enhanced plan	Covered as per medical Criteria
Thiqa	Covered as per medical Criteria

Payment and Coding Rules

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

Denial codes

Regulator denial codes with description are elaborated for reference. These are specialized codes directed by regulator, that explains the reason of rejection of the service by DAMAN to the providers.

Code description
Service is not clinically indicated based on good clinical practice
Service is not clinically indicated based on good clinical practice, without additional supporting diagnoses/activities
Service /supply may be appropriate, but too frequent
Service(s) is (are) not covered
Activity /diagnosis is inconsistent with the patient's age/gender
Activity / diagnosis is inconsistent with clinician speciality
Prior approval is required and was not obtained.

Additional Information

JAWDA clinical quality KPI: Not applicable

Appendices

A. References

1. <https://www.isahd.ae/content/docs/DSC%20RSV.pdf>
2. Clinical Guidelines (Nursing): Palivizumab for at-risk patients (rch.org.au)
3. https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/103770s5185lbl.pdf

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6. <https://doh.gov.ae/-/media/1BAE995557FE42789AC2CDDA5262E2BB.ashx>
7. <https://www.isahd.ae/content/docs/DSC%20RSV.pdf>
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B. Revision History

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13 th May 2022	Release of V1.0