

D.5 Prescription Drugs, Medications, Biologicals

Palivizumab Approval Criteria

I. Purpose:

To ensure that corporate authorization processes are consistent.

II. Description:

Generic Name: Palivizumab
Brand Name: Synagis
Medication Class: Monoclonal antibody. Immunoprophylaxis for RSV

FDA Approved Uses: Respiratory syncytial virus (RSV): For the prevention of serious lower respiratory tract disease caused by RSV in pediatric patients at high risk of RSV disease.

III. Criteria:

1. Children younger than 2 years of age at the start of RSV season with chronic lung disease (CLD) requiring medical therapy for CLD within the past 6 months
2. Children 2 years of age and younger at the start of RSV season with any of the following:
 - o hemodynamically significant cyanotic and acyanotic congenital heart disease;
 - o moderate –to-severe pulmonary hypertension;
 - o receiving medications to control congestive heart failure;
3. Infants 12 months and younger at the start of RSV season and \leq 28 weeks gestation
4. Infants up to 6 months of age at the start of RSV season and 29 – 32 weeks gestation (\leq 31 weeks 6 days)
5. Infants younger up to 3 months of age at the start of RSV season and 32 weeks 0 days through 34 weeks 6 days gestation with 1 risk factor from the following:
 - a. Child care attendance (ie. Day care)
 - b. 1 or more siblings younger than 5 years of age living permanently in the child’s household.
6. Infants younger than 3 months of age at the start of RSV season and 32 weeks 0 days through 34 weeks 6 days gestation with genital abnormalities of the airway or neuromuscular disease
7. In the Northern Hemisphere, the first dose should be administered at the beginning of November, and the last dose should be administered at the beginning of March.

D.5 Prescription Drugs, Medications, Biologicals

Palivizumab Approval Criteria

8. Approved Prior authorization requests will effective no earlier than November 1st, and will not continue beyond March 31st.

Required Medical Information:

1. Appropriate documentation to support above, chart notes, statement of medical necessity

Contraindications:

1. Patients with a history of a severe reaction to palivizumab or other components of the product (histidine & glycine)

Not Approved if:

1. Patient does not meet Criteria for Use above
2. 6th dose, if requested
3. Patient has hemodynamically insignificant heart disease (eg. Secundum atrial septal defect, small ventricular septal defect, pullmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
4. Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
5. Infants with mild cardiomyopathy who are not receiving medical therapy for the condition.

Authorization:

1. Pediatrician or Family Practice physician

Dosing:

1. 15mg/kg/dose IM once monthly
2. Table A identifies the maximum number of palivizumab doses to be approved for infants without a diagnosis of CLD.

D.5 Prescription Drugs, Medications, Biologicals

Palivizumab Approval Criteria

TABLE A Maximum Number of Doses Authorized

Month of Birth	Maximum number of doses for season beginning Nov 1		
	≤28 wk 6 d Gestation and < 12 mo age at Start of Season	29 wk 0 d through 31 wk 6 d gestation and < 6 mo of age at start of season	32 wk 0 d through 34 we 6 d and WITH RISK FACTOR
Nov 1 – Mar 31 of previous RSV season	5	0	0
Apr	5	0	0
May	5	5	0
Jun	5	5	0
Jul	5	5	0
Aug	5	5	1
Sep	5	5	2
Oct	5	5	3
Nov	5	5	3
Dec	4	4	3
Jan	3	3	3
Feb	2	2	2
Mar	1	1	1

Criteria for continuation of therapy:

1. Refer to Criteria for Use above

IV. References:

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D.5 Prescription Drugs, Medications, Biologicals

Palivizumab Approval Criteria

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D.5 Prescription Drugs, Medications, Biologicals

Palivizumab Approval Criteria

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D.5 Prescription Drugs, Medications, Biologicals

Palivizumab Approval Criteria

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D.5 Prescription Drugs, Medications, Biologicals

Palivizumab Approval Criteria

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D.5 Prescription Drugs, Medications, Biologicals

Palivizumab Approval Criteria

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D.5 Prescription Drugs, Medications, Biologicals

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D.5 Prescription Drugs, Medications, Biologicals

Palivizumab Approval Criteria

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D.5 Prescription Drugs, Medications, Biologicals

Palivizumab Approval Criteria

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Approved by: _____
Medical Director

Date: _____

Review and Approved by Physician Advisory Committee

Date: _____

Review and Approved by Utilization Management Committee

Date: _____

Initial PAC Approval:	4/24/2009;
Updated PAC :	
Yearly PAC Review:	4/24/2009;
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Retire Date:	