



AmeriHealth.

Policy Title Palivizumab (Synagis®)

Policy Number FS.CLIN.91

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This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy

Palivizumab (Synagis) is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV disease.

The use of Palivizumab (Synagis) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

Policy description

Palivizumab (Synagis) is a monoclonal antibody that exhibits neutralizing and fusion-inhibitory activity against RSV. These activities inhibit RSV replication.

Policy guideline inclusion

Palivizumab (Synagis) is approved for the prophylaxis of respiratory syncytial virus (RSV) when one of the following inclusion criteria is met:

- Infants and children with chronic lung disease (CLD) such as bronchopulmonary dysplasia (BPD)
 - For use in infants and children younger than 24 months of age with CLD who require medical therapy for CLD within the six months before the start of the RSV season. A second season of palivizumab (Synagis) may be indicated for children with severe CLD who continue to require medical therapy for respiratory or cardiac dysfunction. Medical therapy includes any of the following:
 - A requirement for supplemental oxygen
 - Use of bronchodilators, diuretics, or corticosteroids
- Infants born prematurely
 - Infants born at 28 weeks gestation or earlier (up to and including 28 weeks, 6 days) may benefit from immune prophylaxis if they are 12 months of age or younger at the start of the RSV season.

- Infants born at 29 to 32 weeks gestation (29 weeks, 0 days through 31 weeks, 6 days) may benefit from immune prophylaxis if they are 6 months of age or younger at the start of the RSV season.
- Infants with risk factors
 - Infants born at 32 weeks to less than 35 weeks gestation (32 weeks, 0 days through 34 weeks, 6 days) may benefit from immune prophylaxis if they are younger than 3 months of age at the start of or during the RSV season, and at least one of the following risk factors is present (infants in this category will not be eligible for immune prophylaxis after reaching the chronological age of 3 months):
 - Child care attendance (home or facility where child care is provided for any number of infants or young toddlers)
 - Sibling younger than 5 years of age
- Infants born at less than 35 weeks gestation may benefit from immune prophylaxis if they are 12 months of age or younger at the start of the RSV season with either of the following indications:
 - Congenital abnormalities of the airway
 - Neuromuscular disease that compromises mobilization of respiratory secretions
- Infants and children younger than 24 months of age at the start of the RSV season with congenital heart disease (CHD) with any of the following indications:
 - Hemodynamically significant cyanotic or acyanotic CHD
 - Diagnosis of moderate-to-severe pulmonary hypertension
 - Concurrent use of medication to control congestive heart failure

An additional postoperative dose of palivizumab (Synagis) is considered medically necessary and, therefore, covered for infants or children who have undergone surgical procedures that use cardiopulmonary bypass, are medically stable, and meet the above criteria for immune prophylaxis.

- Infants eligible for up to a maximum of five monthly doses of palivizumab (Synagis) for RSV:
- Infants younger than 24 months of age who require medical therapy for chronic lung disease (CLD)
- Preterm infants born at 31 weeks, 6 days of gestation or less
- Certain infants with congenital abnormalities of the airway or neuromuscular disease that compromises mobilization of respiratory secretions
- Infants younger than 24 months of age who require medical therapy for congenital heart disease (CHD)

Infants eligible for up to a maximum of three monthly doses of palivizumab (Synagis) for RSV:

Infants born at 32 weeks to less than 35 weeks gestation (32 weeks, 0 days through 34 weeks, 6 days) with at least one risk factor and younger than 3 months of age at the start of or during the RSV season.

Policy guideline exclusion

Palivizumab (Synagis) is denied for the prophylaxis of respiratory syncytial virus (RSV) when all of the following exclusion criteria are present:

- No documentation of Infants and children with chronic lung disease (CLD) such as bronchopulmonary dysplasia (BPD)
 - For use in infants and children younger than 24 months of age with CLD who require medical therapy for CLD within the six months before the start of the RSV season. A second season of palivizumab (Synagis) may be indicated for children with severe CLD who continue to require medical therapy for respiratory or cardiac dysfunction. Medical therapy includes any of the following:

- A requirement for supplemental oxygen
 - Use of bronchodilators, diuretics, or corticosteroids
- No documentaion of Infants born prematurely
 - Infants born at 28 weeks gestation or earlier (up to and including 28 weeks, 6 days) may benefit from immune prophylaxis if they are 12 months of age or younger at the start of the RSV season.
 - Infants born at 29 to 32 weeks gestation (29 weeks, 0 days through 31 weeks, 6 days) may benefit from immune prophylaxis if they are 6 months of age or younger at the start of the RSV season.
- No documentaion of Infants with risk factors
 - Infants born at 32 weeks to less than 35 weeks gestation (32 weeks, 0 days through 34 weeks, 6 days) may benefit from immune prophylaxis if they are younger than 3 months of age at the start of or during the RSV season, and at least one of the following risk factors is present (infants in this category will not be eligible for immune prophylaxis after reaching the chronological age of 3 months):
 - Child care attendance (home or facility where child care is provided for any number of infants or young toddlers)
 - Sibling younger than 5 years of age
- No documentation of the following-Infants born at less than 35 weeks gestation may benefit from immune prophylaxis if they are 12 months of age or younger at the start of the RSV season with either of the following indications:
 - Congenital abnormalities of the airway
 - Neuromuscular disease that compromises mobilization of respiratory secretions
- No documentation of Infants and children younger than 24 months of age at the start of the RSV season with congenital heart disease (CHD) with any of the following indications:
 - Hemodynamically significant cyanotic or acyanotic CHD
 - Diagnosis of moderate-to-severe pulmonary hypertension
 - Concurrent use of medication to control congestive heart failure
- No documentation of the following-An additional postoperative dose of palivizumab (Synagis) is considered medically necessary and, therefore, covered for infants or children who have undergone surgical procedures that use cardiopulmonary bypass, are medically stable, and meet the above criteria for immune prophylaxis.
- No documentation of the following- Infants eligible for up to a maximum of five monthly doses of palivizumab (Synagis) for RSV:
 - Infants younger than 24 months of age who require medical therapy for chronic lung disease (CLD)
 - Preterm infants born at 31 weeks, 6 days of gestation or less
 - Certain infants with congenital abnormalities of the airway or neuromuscular disease that compromises mobilization of respiratory secretions
- Infants younger than 24 months of age who require medical therapy for congenital heart disease (CHD)
- No documentenation of the following- Infants eligible for up to a maximum of three monthly doses of palivizumab (Synagis) for RSV:

Infants born at 32 weeks to less than 35 weeks gestation (32 weeks, 0 days through 34 weeks, 6 days) with at least one risk factor and younger than 3 months of age at the start of or during the RSV season.

Policy List of Applicable Drugs

Brand Name	Generic Name
Synagis	Palivizumab

Dosing and administration

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

Policy references	<p>American Academy of Pediatrics (AAP). <i>Red Book: 2009 Report of the Committee on Infectious Diseases</i>. 28 ed. Elk Grove Village, IL: AAP; 2009: 560-569.</p> <p>American Academy of Pediatrics (AAP) Subcommittee on Diagnosis and Management of Bronchiolitis. Clinical practice guideline: Diagnosis and management of bronchiolitis. <i>Pediatrics</i>. 2006;118(4):1774-1793. Also available on the AAP Web site at: http://aappolicy.aappublications.org/cgi/content/full/pediatrics;118/4/1774. Accessed September 9, 2011.</p> <p>Centers for Disease Control and Prevention (CDC). The National Respiratory and Enteric Virus Surveillance System (NREVSS). Respiratory syncytial virus (RSV) surveillance. [CDC Web site]. 08/20/08. Available at: http://www.cdc.gov/surveillance/nrevss/rsv/default.html. Accessed September 9, 2011.</p> <p>Centers for Disease Control and Prevention (CDC). Respiratory syncytial virus infection (RSV). [CDC Web site]. 10/23/08. Available at: http://www.cdc.gov/rsv/. Accessed September 9, 2011.</p> <p>Meissner HC, Anderson LJ, Pickering LK. Annual variation in respiratory syncytial virus season and decisions regarding immunoprophylaxis with palivizumab. <i>Pediatrics</i>. 2004;114(4):1082-1084.</p> <p>Meissner HC, Bocchini JA Jr. Reducing RSV hospitalizations. [American Academy of Pediatrics (AAP) News Web site]. 06/04/09. Available at: http://aapnews.aappublications.org/cgi/content/full/aapnews.20090604-1v1. [link no longer active]</p> <p>Meissner HC, Long SS, American Academy of Pediatrics (AAP) Committee on Infectious Diseases and Committee on Fetus and Newborn. Technical report: Revised indications for the use of palivizumab and respiratory syncytial virus immune globin intravenous for the prevention of respiratory syncytial virus infections. <i>Pediatrics</i>. 2003;112(6 Pt 1):1447-1452. Also available on the AAP Web site at: http://aappolicy.aappublications.org/cgi/content/full/pediatrics;112/6/1447. Accessed September 9, 2011.</p> <p>Palivizumab (Synagis®) [prescribing information]. Gaithersburg, MD: MedImmune, Inc; 2002.</p> <p>US Food and Drug Administration (FDA). Information for patients and their caregivers: Palivizumab (Synagis®). [FDA Web site]. March 2009. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/103770s5116lbl.pdf. Accessed September 9, 2011.</p> <p>US Food and Drug Administration (FDA). Department of Health and Human Services. Synagis® (Palivizumab). Product approval letter. [FDA Web site]. 03/23/09. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/103770s5116ltr.pdf. Accessed Septmeber 9, 2011.</p>
Policy link to related policies	
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