Pharmacy Policy Bulletin

Title: Palivizumab (Synagis®)
Policy #: Rx.01.70

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

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. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. 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.

Intent:
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 (i.e. clinical pharmacist and/or Medical Director review).

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

Black Box Warning:
None

Policy:
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)
1) 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. A requirement for supplemental oxygen
   b. Use of bronchodilators, diuretics, or corticosteroids

Infants born prematurely
1) 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.

2) 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

1) 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):
   a. Child care attendance (home or facility where child care is provided for any number of infants or young toddlers)
   b. 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:

1) Congenital abnormalities of the airway

2) 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:

1) Hemodynamically significant cyanotic or acyanotic CHD

2) Diagnosis of moderate-to-severe pulmonary hypertension

3) 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:

1) Infants younger than 24 months of age who require medical therapy for chronic lung disease (CLD)

2) Preterm infants born at 31 weeks, 6 days of gestation or less

3) Certain infants with congenital abnormalities of the airway or neuromuscular disease that compromises mobilization of respiratory secretions

4) 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:

1. 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.
Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

**BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company’s products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

**References:**


Palivizumab (*Synagis®*) [prescribing information]. Gaithersburg, MD: MedImmune, Inc; 2002.


**Applicable Drugs:**

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tr>
<td>Synagis</td>
<td>Palivizumab</td>
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**Cross References:**

Policy Version Number: 1.00
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