Pharmacy Management Drug Policy

SUBJECT: Respiratory Syncytial Virus (RSV) Prophylaxis
POLICY NUMBER: PHARMACY-51
EFFECTIVE DATE: 08/2008
LAST REVIEW DATE: 12/19/2024

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☒ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☒ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☒ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Respiratory syncytial virus (RSV) is the leading cause of lower respiratory illness in children. The risk of serious RSV illness is highest among children with prematurity, chronic lung disease, congenital heart disease, multiple congenital anomalies and certain immunodeficiencies. In the United States, RSV infection accounts for more than 90,000 pediatric hospitalizations and 4,500 deaths annually.

Prophylaxis to prevent RSV infection in infants and children at increased risk for severe disease is available using Synagis (palivizumab) and Beyfortus (Nirsevimab):

Synagis is an intramuscularly administered monoclonal antibody preparation. It is administered in a dose of 15 mg/kg once a month during the RSV season (usually considered beginning around November and terminating around the beginning of April). Number of doses varies based on risk factors, gestational age, and age at the start of season.

In recent years, the national median duration of RSV season has been 17 weeks or less. For most children in the appropriate high-risk categories, five monthly doses of Synagis will result in substantially more than 20 weeks of protective serum antibody concentrations for most of the RSV season, even with variation in season onset and conclusion.

Beyfortus is an intramuscularly administered monoclonal antibody preparation, recommended to be given to patients younger than 8 months old born during or entering their first RSV season, and for infants 8 months through 24 months entering their second RSV season who remain at high risk of severe RSV disease. A single dose of Beyfortus given prior to the start of or during the RSV season provides a duration of protection of at least 5 months, enough to cover the length of the typical RSV season. **Please note: Beyfortus is covered without prior authorization.**

Start and Duration of RSV prophylaxis therapy *varies by regional and seasonal rates of infection. CDC reporting of percent positive PCR testing for specific regions will be monitored throughout the season. Typically, a 3% PCR positivity rate is considered epidemic*

Current levels can be found at Respiratory Virus Activity Levels (cdc.gov) except where noted otherwise

SYNAGIS DRUG SPECIFIC POLICY CRITERIA:

All requests for Synagis for RSV Prophylaxis will be required to use Beyfortus unless there is a medical reason Beyfortus cannot be used.

Based upon our criteria and review of the peer-reviewed literature, RSV prophylaxis using Synagis administered in accordance with FDA and American Academy of Pediatrics (AAP) guidelines, has been medically proven to be effective and therefore, **medically appropriate** for the following indications. *Prevention of RSV disease for the duration of one RSV season with maximum of 5 monthly doses of Synagis is recommended in those who meet one of the following criteria:*

1. **Infants born prematurely:**

   Infants with a gestational age of 28 weeks 6 days or less who are less than twelve months old at the start of RSV season
   a. The number of doses approved will be based on start date of the initial dose. Doses for months outside of the Synagis season will not be approved.
   b. For infants born during the RSV season, fewer than 5 monthly doses will be needed.

OR

2. **Infants with immunodeficiencies:**

   Children less than 2 years of age at the start of RSV season with severe immunodeficiencies, such as, severe combined immunodeficiency or advanced acquired immunodeficiency syndrome (AIDS), and children less than 2 years of age, who have undergone lung transplant or hematopoietic stem cell transplant (BMT, peripheral blood, placental or cord blood).

OR

3. **Infants with pulmonary abnormalities or a neuromuscular disorder:**

   Children less than 12 months of age at the start of RSV season, with significant congenital abnormalities of the airway or severe neuromuscular disease which compromises handling of respiratory secretions. (such as, cerebral palsy, muscular dystrophy, neurological disease of the brain & spinal cord, i.e., Tay Sachs, spinal muscle atrophy)
   (Please note insufficient data exist to determine the effectiveness of Synagis in infants with Down syndrome and currently no recommendation exists for routine prophylaxis in these patients. Please see exclusion list. Patients with active chronic lung disease or BPD please see #4)

OR

4. **Infants with Chronic Lung Disease (CLD)**

   During the first year of life for Infants and children less than 12 months old at the start of RSV season with a clinical diagnosis of chronic lung disease of prematurity or formerly designated as bronchopulmonary dysplasia (BPD). CLD of prematurity is defined as gestational age <32 weeks, 0 days, and a requirement for >21% oxygen for at least the first 28 days after birth.

   Second year of life:
   Pavilizumab prophylaxis will only be approved during the second year of life for infants (≤ 24 months at the start of the season) who meet the definition of CLD of prematurity and continue to require medical treatment for their CLD within 6 months of RSV season.
   Medical Treatment is defined as at least one of the following:

- Supplemental oxygen
- Chronic Systemic Corticosteroid therapy
- Diuretics to treat pulmonary disease

OR

5. Infants with congenital heart disease (CHD)

Infants and children less than 12 months old at the start of RSV season considered by a cardiologist to have hemodynamically significant CHD (acyanotic [e.g., ventricular septal defect, etc.] or cyanotic [right to left shunt]). Including:

- Infants with acyanotic heart disease who are receiving medication to control congestive heart failure (CHF) and will require cardiac surgical procedures
- Infants with "moderate to severe" pulmonary hypertension
- Infants with cyanotic heart disease in consultation with a pediatric cardiologist

The following conditions were noted to be considered hemodynamically *insignificant* in the 2012 AAP Red Book update, and would not typically be considered approvable CHD diagnoses:

- Hemodynamically insignificant heart disease (secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus.
- infants with lesion adequately corrected by surgery unless they continue to require medication for congestive heart failure
- infants with mild cardiomyopathy who are not receiving medical therapy.
- Children in the second year of life

Note: For infants and children younger than 24 months who are receiving prophylaxis and continue to require prophylaxis after a surgical procedure, a post-operative dose of palivizumab should be considered after cardiac bypass or at the conclusion of extracorporeal membrane oxygenation

Children younger than 2 years who undergo cardiac transplantation during the RSV season may be considered for prophylaxis

OR

6. Cystic Fibrosis

During the first year of life for Infants and children less than 12 months old at the start of RSV season with a diagnosis of cystic fibrosis and clinical evidence of nutritional compromise **OR** a diagnosis of chronic lung disease of prematurity defined as gestational age <32 weeks, 0 days, and a requirement for >21% oxygen for at least the first 28 days after birth.

Second year of life:
Pavilizumab prophylaxis will only be approved during the second year of life for infants (≤ 24 months at the start of the season) in patients with cystic fibrosis with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) **OR** have a weight for length less than the 10th percentile.

POLICY EXCLUSIONS:

- Use in otherwise healthy infants born at or after 29 weeks 0 days (28 weeks, 6 days) gestation. Prophylaxis will only be approved for children who meet the above criteria.
- Use for prevention of RSV outside of the RSV season in the region in which the patient resides
- Use for the TREATMENT of RSV disease. (If a child develops breakthrough infection while on immunoprophylaxis therapy, therapy should be discontinued)[31]
- Use in adults for any diagnosis
- Use in children greater than 2 years old or in adults with congenital heart disease or immunodeficiencies
- Use in patients with Down Syndrome who do not otherwise meet the above criteria
- Health-care care associated RSV.

POLICY GUIDELINES:

1. Synagis will not be approved in the same RSV season for any patients that have already received Beyfortus. Per the FDA labeling for Beyfortus, Palivizumab should not be administered to infants who have already received Beyfortus in the same season.
2. Prior authorization is contract dependent.
3. Synagis is paid under the medical benefit.
4. All indications other than those listed in the policy section above are not covered.
5. Synagis Prophylaxis against RSV should be initiated at the onset of the RSV season and terminated at the end of the RSV season. In most seasons in the Northeast, the start of the season occurs mid-November, and ends mid-March to April 1. For those children meeting criteria for 5 monthly doses, the last dose should be administered at the beginning of March, which will provide protection through April.
6. The number of Synagis doses approved will be based on start date of the initial dose. Doses for months outside of the Synagis season will not be approved. For infants born during the RSV season, fewer than 5 monthly doses may be needed.
    a. For individuals who reside in states outside of New York, approval will be based upon RSV trends within that state.
7. Currently policy guidelines are based on available RSV trends and guidance from the American Academy of Pediatrics (AAP) guidelines. This information will be regularly reviewed and subject to change based on evolving evidence and guidance.
8. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
9. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.
10. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, imaging and other objective or subjective measures of benefit which support continued use of the requested product is medically necessary.

Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.

- Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition.

11. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
12.

Synagis Approval Time Periods:

Line of Business	Medical approval time-period
SafetyNet (Medicaid, HARP, CHP, Essential Plan)	Maximum of 5 doses through 3/31/2025
Commercial/Exchange	Maximum of 5 doses through 3/31/2025
Medicare	Maximum of 5 doses through 3/31/2025

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

HCPCS: 90378: Synagis

UPDATES:

Date	Revision
12/19/2024	Revised
11/21/2024	P&T Committee Review / Approval
09/13/2024	Revised
06/25/2024	Revised
06/20/2024	Revised
11/30/2023	P&T Committee Approval
11/09/2023	Reviewed
10/26/23	Revised
10/20/23	Revised
9/22/23	Revised
9/12/2023	Revised
08/10/2023	Revised

11/17/2022	P&T Committee Approval
11/2022	Revised
10/2022	Revised
1/2022	Revised
11/2021	Revised / P&T Committee Approval
8/2021	Revised
07/2021	Revised
06/30/2021	Revised
06/2021	Revised
05/2021	Revised
03/2021	Revised
11/2020	P&T Committee Approval
08/20	Reviewed
08/19	Revision
10/18	Revision
10/17	Reviewed
9/16	Revised
10/15	Revised
9/15	Revised
8/14	Revised
10/13	Reviewed
9/12	Revised
9/11	Reviewed
9/10	Reviewed
10/09	Revised
9/09	Revised
9/08	Revised

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