Policy Title:	Synagis (palivizumab)		
		Department:	PHA
Effective Date:	08/25/2010		
Review Date:	8/25/10, 11/19/2013, 9/16/2014, 9/1/15, 8/22/2016, 8/23/2019, 10/9/2019, 9/2020, 9/2021, 9/2022, 11/2022, 8/2023, 12/2023, 01/2024, 08/2024		

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

Annually, Neighborhood's Pharmacy and Therapeutics Committee reviews the American Academy of Pediatrics' Red Book Guidelines to establish medical necessity criteria for Neighborhood eligible members.

Description

Palivizumab is a humanized monoclonal antibody for IM injection that inhibits respiratory syncytial virus (RSV) replication. It is supplied as lyophilized powder in single use vials of 50mg and 100mg.

Synagis is used for the prevention of severe lower respiratory tract diseases caused by RSV in pediatric patients at high risk of developing RSV disease. Safety and efficacy of palivizumab have been established in infants with chronic lung disease, formerly known as bronchopulmonary dysplasia (BPD), infants with a history of prematurity (<35 weeks gestational age at birth), and children with hemodynamically significant congenital heart disease (CHD). Palivizumab is not indicated for treatment of reactive airway disease/asthma. Palivizumab is not approved for use in adults.

Typically, in the Northern Hemisphere RSV season lasts from November to April. If the season changes, the dose start, and end times may be adjusted. The 2023/2024 Synagis season is from November to April. Based on pharmacokinetic data available, the necessary trough concentration of 30mcg/mL will be maintained for a full month after repeated doses when given on this schedule. The American Academy of Pediatrics policy issued in 2014 recommends that in most regions of the Northern Hemisphere, the first dose of palivizumab should be administered at the start of RSV season and the last dose at the beginning of March to provide protection into April.

MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Summary of Evidence

Synagis is a respiratory syncytial virus (RSV) F protein inhibitor monoclonal antibody indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients. Synagis (palivizumab) has undergone extensive clinical trials to evaluate its efficacy and safety in preventing serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in high-risk pediatric populations. These trials have consistently demonstrated the effectiveness of Synagis in reducing the incidence and severity of RSV infections in vulnerable infants, particularly premature infants born at ≤ 35 weeks' gestational age and infants with chronic lung disease or congenital heart disease. Common adverse reactions reported include fever and rash.

Prior Authorization Criteria

- Synagis is approvable for a patient who meets at least **ONE** of the following:
    - Patient was born before 29 weeks *0 days* gestation and will be less than 12 months old at the beginning of the RSV season may receive Synagis; **OR**
    - Patient is less than 12 months old and has chronic lung disease of prematurity. Chronic lung disease of prematurity is defined as gestational age less than 32 week 0 days and received greater than 21% supplemental oxygen for at least the first 28 days following birth; **OR**
    - Patient is 12 months or younger with hemodynamically significant congenital heart disease defined as: acynanotic heart disease requiring medication to control CHF and will require cardiac surgical procedure or infants with moderate to severe pulmonary hypertension; **OR**
    - Patient is 12 months or younger with cyanotic heart disease (particularly those with congestive heart failure) and pediatric cardiologist has been consulted and recommended treatment with Synagis **OR**
    - Patient is 12-24 months old at the start of the RSV season, has chronic lung disease of prematurity (chronic lung disease of prematurity is defined as gestational age less than 32 week 0 days and received greater than 21% supplemental oxygen for at least the first 28 days following birth) and requires medical treatment including supplemental oxygen, corticosteroids, or diuretic therapy during the six months preceding the second RSV season; **OR**
    - Patient is less than 24 months old and will be undergoing a cardiac transplant during RSV season; OR
    - Patient is less than 12 months with neuromuscular disease (i.e. cerebral palsy) or anatomic pulmonary abnormalities that impair ability to clear secretions from upper airways due to ineffective Cough; **OR**
    - Patient is less than 24 months and profoundly immunocompromised (such as children who undergo solid organ transplantation or hematopoietic stem cell transplantation, children receiving chemotherapy or who are immunocompromised because of other conditions) during RSV season; **AND**
- Patient has a documented contraindication to treatment with Beyfortus (nirsevimab) * *

**Administration Guidelines

- If Synagis (palivizumab) was administered initially for the RSV season and less than 5 doses were administered, one dose of Beyfortus (nirsevimab) may be administered. No further doses of Synagis (palivizumab) should be administered.
- Based on guidance from the American Academy of pediatrics (AAP), if Beyfortus (nirsevimab) is not available to administer, high risk infants who are recommended to receive Synagis (palivizumab) in the first or second year of life should receive Synagis (palivizumab) until Beyfortus (nirsevimab) becomes available.
- Beyfortus (nirsevimab) may be administered prior to or during the second RSV season in children 8-19 months old who are eligible for Beyfortus (nirsevimab) and who received Synagis (palivizumab) in their first RSV season.
- Per the FDA label, children who have received Beyfortus (nirsevimab) should not receive Synagis (palivizumab) for the same RSV season.

Approval Duration:

- Approved for 5 months and will be adjusted for therapy start date (qualifying infants born during the RSV season will require fewer than 5 doses).

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

Policy Rationale:
Synagis was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Synagis according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

Dosing Allowance:

Synagis is available only in 50mg and 100mg vials. Due to the potential for significant waste, the following table should be utilized to determine permitted dose (within 10% of calculated dose due to vial overfill) and vials to dispense.

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Weight-based Dose	Range Vial Quantity Recommendation
≤ 52.49 mg	1 vial of 50 mg/0.5 mL
52.5 mg – 104.99 mg	1 vial of 100 mg/1 mL
105 mg – 157.49 mg	1 vial of 50 mg/0.5 mL and 1 vial of 100 mg/1 mL
157.5 mg – 209.99 mg	2 vials of 100 mg/1 mL
210 mg – 262.49 mg	1 vial of 50 mg/0.5 mL and 2 vials of 100 mg/1 mL
262.5 mg – 314.99 mg	3 vials of 100 mg/1 mL

Patients who are to discontinue Synagis for the remainder of the season include:

1. Patients receiving Synagis and have experienced at least one hospitalization due to break through infection.

Patients who are not candidates for Synagis include:

1. Patients who are at 24 months or greater at the beginning of the RSV season.
2. Patient diagnosed with the at least one of the following: a) hemodynamically insignificant heart disease such as ASD, small VSD, pulmonic stenosis, and uncomplicated aortic stenosis, mild coarctation of the aorta, patent ductus arteriosus; or b) children whose cardiac lesions have been corrected by surgery and no longer require medications; or c) children with mild cardiomyopathy not requiring medical therapy; or
3. Patients less than 12 months of age who are otherwise healthy infants born at 29 weeks 0 days gestation or later; or
4. Patients with Down syndrome who do not have other qualifying medical conditions.

Disclaimer:

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's coverage plan; a member's coverage plan will supersede the provisions of this medical policy. For information on member-specific benefits, call member services. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. Neighborhood reserves the right to review and revise this policy for any reason and at any time, with or without notice.

References:

American Academy of Pediatrics News**:** RSV recommendations unchanged after review of new data. 2017 URL: http://www.aappublications.org/news/2017/10/19/RSV101917. Available from internet. Accessed 2018 August 17.
American Academy of Pediatrics: Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection; PEDIATRICS Vol. 134 No. 2 August 2014, pp 415-420.
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