Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Effective Date: 10/12/2023

Synagis® (palivizumab)

HCPCS: 90378

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. Criteria follow the recommendations of the American Academy of Pediatrics (AAP) policy statement Modified Recommendations for Use of Palivizumab for Prevention of Respiratory Syncytial Virus (RSV) Infections. - This statement is consistent with the 2009 *Red Book* recommendations (See table 1). Table 1 has been modified to reflect 2014 guidance which were reaffirmed in February 2019.
   b. Not to be used in combination with Beyfortus™

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Initiation is at the onset of the RSV season for at least 60 days and should continue until the maximum doses have been completed for that particular set of risk factors.
   b. Quantity Limits: No more than 5 doses for given risk factors (see table 1). However, requests for an extra dose of Synagis may be considered on an individual basis only under rare circumstances and in the event of an extended RSV season for the geographic area of residence OR in the event of a cardiopulmonary bypass, where an extra dose is to be administered directly following the procedure.
      i. Infants born during RSV season will only be approved for 1 dose per month until the end of the RSV season for the geographic area of residence (maximum of 5 doses).
      ii. The Midwest region's general RSV season is considered to be from November 1st until March 31st and requests outside this timeframe will be reviewed on a case by case basis. All other geographic regions will be reviewed on a case by case basis.

C. Synagis is considered investigational when used for all other conditions, including but not limited to:
   a. Infants and children with insignificant heart disease (secundum atrial septal defect, pulmonary stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus).
   b. Infants with lesions that have been corrected by surgery (UNLESS they continue to require medication for CHF).
   c. Infants with mild cardiomyopathy who are NOT receiving medical therapy for the condition.
   d. The treatment of RSV infections.

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- RSV is a single-stranded, negative-sense ribonucleic acid (RNA) virus and a member of the Pneumoviridae family that causes seasonal outbreaks throughout the world causing acute respiratory tract illness in persons of all ages. Almost all children are infected by two years of age, and reinfection is common.

- RSV is the most common cause of lower respiratory tract infections (LRTI) and the leading viral cause of severe lower respiratory tract disease in infants and young children worldwide. In the United States, RSV is the leading cause of hospitalization of infants and, globally, is second only to malaria as a cause of death in children under 1 year of age. There are currently approximately 18 million children in the United States between 6 months and 5 years of age. In the United States, RSV is responsible for approximately 57,000 hospitalizations of children under 5 years of age annually, the vast majority of which occur in infants less than 1 year of age, and especially those under 6 months of age.

- AAP guidelines have been updated to address the initiation and termination of prophylaxis doses for all geographical locations. This reflects the current CDC descriptions of RSV seasons in different geographic locations of the US. The 5-dose maximum is recommended for all geographical locations and should be initiated at the onset of the season for that area. In the continental US; a total of 5 doses for qualifying infants and young children will provide an optimal balance of benefit and cost even with variation in the season's onset. This rationale is based on:

    - The national median duration of the RSV season is 17 weeks or less

    - Serum Synagis trough concentrations are well above the protective concentration for most infants greater than 30 days after the 5th dose. This is giving approximately 20 weeks of protection for most infants

    - Despite varied onsets, the duration of the RSV season is the same in the different regions of the state of Florida

    - Administration during the 5 months after the onset of the season should provide coverage during the peak of the season which is when prophylaxis is most effective

- AAP recommendations for immunoprophylaxis have been updated in an effort to ensure optimal balance of benefit and cost with this drug. Even though prophylaxis treatment has not been evaluated in randomized trial for immunocompromised children, severely immunodeficient infants and young children (severe combined immunodeficiency and advanced AIDS) may benefit from prophylaxis.

References:

1. Modified Recommendations for Use of Palivizumab for Prevention of Respiratory Syncytial Virus Infections Committee on Infectious Diseases *Pediatrics* 2009;124;1694; originally published online September 7, 2009;DOI: 10.1542/peds.2009-23451
2. © 2010 Regence Rx Medication policy Manual Synagis® , palivizumab, Respiratory Syncytial virus (RSV) immune prophylaxis
3. Synagis [prescribing information]. Waltham, MA; Sobi Inc. November 2021.
4. American Academy of Pediatrics. Respiratory syncytial virus. In: Pickering LK, Baker CJ, Kimberlin DW, Long SS, eds. Red Book: 2012 Report of the Committee on Infectious Diseases. Elk Grove Village, IL: American Academy of Pediatrics; 2012: 609-618.
5. Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. *Pediatrics* 2014; 134;415; originally published online July 28, 2014.
6. Pediatrics Aug 2019, 144 (2) e20191767; DOI: 10.1542/peds.2019-1767 https://pediatrics.aappublications.org/content/144/2/e20191767
7. Novavax. Our Pipeline. https://novavax.com/our-pipeline [accessed July 2020]

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>2.4</td><td>Effective Date: 10/12/2023</td><td>Update to not allow combination use with Beyfortus</td></tr>
<tr><td>2.3</td><td>Effective Date: 04/06/2023</td><td>Update to clarify that authorization will be for at least 60 days to comply with new legislation</td></tr>
<tr><td>2.2</td><td>Effective Date: 08/04/2022</td><td>Annual Review of Medical Policy. No changes to the criteria were made at this time</td></tr>
<tr><td>2.1</td><td>Effective Date: 08/12/2021</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>2.0</td><td>Effective Date: 08/13/2020</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.9</td><td>Effective Date: 08/15/2019</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.8</td><td>Effective Date: 08/09/2018</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.7</td><td>Effective Date: 08/10/2017</td><td>Updated criteria for prophylaxis recommendations in children who experience a breakthrough RSV hospitalization while on Synagis therapy
Also added quantity limit and RSV season information</td></tr>
<tr><td>1.6</td><td>Effective Date: 05/04/2017</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.5</td><td>Effective Date: 07/01/2016</td><td>UM medical management system update for BCN
<table>
<tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr>
<tr><td>BCBS</td><td>Yes</td></tr>
<tr><td>BCN</td><td>Yes</td></tr>
<tr><td>MAPPO</td><td>No</td></tr>
<tr><td>BCNA</td><td>No</td></tr>
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<tr><td>1.4</td><td>Effective Date: 05/05/2016</td><td>Update</td></tr>
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<tr><td></td><td></td><td>• Clarified criteria for preterm infants, infants with CHD and children with cystic fibrosis</td></tr>
<tr><td>1.3</td><td>Effective Date: 10/30/2014</td><td>Update
• New guidelines were updated from AAP which made the recommendations much narrower</td></tr>
<tr><td>1.2</td><td>Effective Date: 10/01/2014</td><td>UM medical management system update for BCBS
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
<tr><td>1.1</td><td>Effective Date: 08/14/2014</td><td>Update
• Updated criteria to enforce more strict age limit for all indications that is stated in guidelines
• Deleted sentence that no Quantity Limits recommended since it should be limited to 5 doses per season
• Please see ad hoc meeting minutes from July 3, 2014 email: Quantity Limit was changed from allowing 6 doses per season to no more than 3 or 5 doses per season with the allowance of an extra dose for reasons stated within this policy</td></tr>
<tr><td>1.0</td><td>Effective Date: 11/10/2011</td><td>New Policy
Policy History:
• Custom/Clinical Formulary: n/a
• Custom formulary chapter: n/a
• Part D: Part D
• Part D formulary: Immunology and Hematology: Immunoglobulins
• Recommended criteria and QL
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
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** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*

TABLE 1: Eligibility Criteria for Prophylaxis of Infants and Young Children at High Risk			
When Gestational age is not a consideration	Action	Maximum dose	Duration
• **Younger than 12 months** of age with a diagnosis of hemodynamically significant cyanotic or acyanotic CHD (such as CHF, moderate to severe pulmonary hypertension, cyanotic heart disease) AND require treatment for these CHD*	Eligible	5	At the start of the RSV season and continue through the 5 doses
• **Younger than 24 months** of age and immunocompromised with severe combined immunodeficiency or advanced AIDS	Eligible	5	At the start of the RSV season and continue through the 5 doses
• **Younger than 12 months** of age with significant congenital abnormalities of the airway or neuromuscular disease that compromises the handling of respiratory tractsecretions	Eligible	5	5 doses during the 1st year of life
• **Younger than 12 Months** of age with cystic fibrosis with clinical evidence of CLD and/or nutritional compromise in the first year of life may be considered for prophylaxis.	Eligible	5	Continued use of palivizumab prophylaxis in the second year may be considered for infants 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 weight for length less than the 10th percentile.
When Gestational age is a consideration:			
• Infants born 29 weeks, 0 days gestation or less and are less than 12 months of age at the start of RSV season.	Eligible	5	Once an infant qualifies for initiation of prophylaxis at the start of the RSV season, administration should continue throughout the season and not stop when the infant reaches either 6 or 12 months of age
• Infants born <32 weeks, 0 days who have CLD and a requirement for >21% oxygen for at least the first 28 days after birth AND are less than 1 year. • Exceptions may be made for children less than2 years old who fulfill the definition of CLD of prematurity and continue to require medical support during the 6-month period before the start of the second RSV season	Eligible	5	Will qualify up to the second year of life, who fulfill the definition of CLD of prematurity and continue to require medical support during the 6-month period before the start of the second RSV season

*The following groups of infants with CHD are not at increased risk of RSV infection and generally should not receive immunoprophylaxis:

1. Infants and children with hemodynamically insignificant heart disease (eg, secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus).
2. Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure.
3. Infants with mild cardiomyopathy who are not receiving medical therapy for the condition.
4. Children in the second year of life.

Blue Cross Blue Shield/Blue Care Network of Michigan
Medication Authorization Request Form
Synagis® (palivizumab) Procedure Code: 90378

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This form is to be used by participating physicians to obtain coverage for Synagis. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	**Name**
ID Number	**Specialty**
D.O.B. ☐Male ☐Female	**Address**
Diagnosis	**City /State/Zip**
Drug Name	**Phone/Fax: P**: ( ) - **F**: ( ) -
Dose and Quantity	**NPI**
Directions	**Contact Person**
Date of Service(s)	**Contact Person Phone / Ext.**

STEP 1: DISEASE STATE INFORMATION

1. Has the patient been treated with Synagis before? ☐ Yes ☐ No ***Dates of treatment:*** _____
2. Please provide the NPI number for the place of administration: _____
3. Has the patient already received doses for this RSV Season? ☐ Yes ☐ No ***Doses:*** _____ ***Dates:*** _____
4. What is the age in months at the start of RSV season? _____ months
5. What is the patient's weight in kg? _____ kg Date weight taken: _____
6. How many weeks gestation was the patient at birth? _____ weeks
7. Does the patient have significant congenital abnormalities of the airway or neuromuscular disease that compromise the handling of respiratory tract secretions? ☐ Yes ☐ No
8. Does the patient have hemodynamically significant cyanotic or acyanotic congenital heart disease (CHD) AND require treatment for CHD? ☐ Yes ☐ No
9. Does the patient have cystic fibrosis with clinical evidence of chronic lung disease (CLD) and/or nutritional compromise? ☐ Yes ☐ No
10. Does the patient have a disease state such as severe combined immunodeficiency or advanced AIDS that is causing them to be immunocompromised? ☐ Yes ☐ No Disease state: _____
11. Does the patient have CLD and a requirement for > 21% oxygen for at least the first 28 days after birth and are less than 1 year? ☐ Yes ☐ No
12. Does the patient have CLD of prematurity and continue to require medical support (i.e. supplemental oxygen, chronic corticosteroid therapy) during the 6 month period before the start of the second RSV season? ☐ Yes Medical support required: _____ ☐ No
13. Please attach any chart notes or additional documentation and submit to plan. ***(Required)***

Please add any other supporting medical information that may be useful in the decision-making process:

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name **Physician Signature** **Date**

Step 2: Checklist	☐ Form Completely Filled Out ☐ Attached Chart Notes	☐ Concurrent Medical Problems ☐ Concurrent Therapies
Step 3: Submit	**By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979**	**By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320**

9/22/2015; 11/20/2015; 5/9/2016; 2/2/2018;10/11/2018

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