Pharmacy Medical Policy
RSV Immunoprophylaxis

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Policy Number: 422
BCBSA Reference Number: 5.01.10

Related Policies
None

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Note: All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department at (800)366-7778 to request a prior authorization/formulary exception verbally. Physicians may also submit requests for retail pharmacy exceptions via the web using Express PAth which can be found on the BCBSMA provider website or directly on the web at https://provider.express-path.com. Patients must have pharmacy benefits under their subscriber certificates.

BCBSMA covers Palivizumab (Synagis™) in accordance with the American Academy of Pediatrics Guidelines, injections are given once a month during the RSV season. The 2014 American Academy of Pediatrics guidelines noted that the first dose should be administered at the beginning of November and the last dose should be administered at the beginning of March, which provides protection into April. Unless otherwise specified below, one course of treatment will be defined as five monthly doses typically given from November through March. Qualifying infants born during the RSV season may require fewer doses.

First Course of Treatment

Prematurity: We cover one course of prophylaxis with palivizumab for infants and children who were born prematurely, as follows:

- Infants born at 28 weeks 6 days of gestation or earlier may benefit if they are less than 12 months of age at start of the RSV season

Reduced lung reserve: We cover prophylaxis with palivizumab for infants who are 12 months or younger at the start of the RSV season and develop chronic lung disease (CLD) of prematurity defined as:

- Gestational age < 32 weeks, 0 days
- Requirement for > 21% oxygen for at least first 28 days after birth
Anatomic pulmonary abnormalities/Neuromuscular diseases: We cover prophylaxis with palivizumab for children with neuromuscular diseases that affect respiratory mechanics if they are 12 months or younger at the start of the RSV season.

Congenital heart defects: We cover prophylaxis with palivizumab for infants with hemodynamically significant congenital heart defects in the following circumstances if they are 12 months or younger at the start of the RSV season:
- Infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures
- Infants with moderate to severe pulmonary hypertension
- Infants with cyanotic heart disease at the recommendation of a pediatric cardiologist

Surgical procedures: For infants/children who are receiving prophylaxis and who continue to require prophylaxis after cardiopulmonary bypass, a postoperative dose of palivizumab (15 mg/kg) should be considered after surgery or at the conclusion of extracorporeal membrane oxygenation for infants and children younger than 24 months.

Cardiac transplantation: We cover palivizumab prophylaxis for infants/children younger than 2 years who undergo cardiac transplantation during the RSV season.

Immunocompromised children: We cover prophylaxis with palivizumab for infants/children younger than 24 months of age who are profoundly immunocompromised during the RSV season.

Cystic Fibrosis: We cover prophylaxis with palivizumab for infants with cystic fibrosis with clinical evidence of CLD and/or nutritional compromise in the first year of life.

Second Course of Treatment
- Infants who meet the chronic lung disease of prematurity definition above may benefit from RSV immunoprophylaxis for a second RSV season if they continue to require medical support (chronic corticosteroid therapy, diuretic therapy or supplemental oxygen) during the six month period before the start of the second RSV season.
- Infants/children younger than 24 months of age who are profoundly immunocompromised during the RSV season may benefit from a second season of prophylaxis.
- Infants with cystic fibrosis may benefit from palivizumab prophylaxis for a second RSV season who have 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.

We do not cover experimental uses not approved by the FDA, because there is not enough published scientific information about health outcomes for other uses. For example, we do not cover palivizumab for adults.

We do not cover this drug for infants/children receiving palivizumab prophylaxis who experience a breakthrough RSV hospitalization. Monthly prophylaxis should be discontinued because of the extremely low likelihood of a second RSV hospitalization in the same season.

We do not cover this drug for infants born at > 29 weeks 0 days gestation, except for those indicated above.

The following groups of infants are not at increased risk of RSV and generally should not receive immunoprophylaxis:
- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with mild cardiomyopathy who are not receiving medical therapy for the condition
We do not cover this drug for infants with Down syndrome unless qualifying heart disease, CLD, airway clearance issues, or prematurity (< 29 weeks, 0 days' gestation) is present.

We do not cover this drug for infants/children with cystic fibrosis unless above criteria are met.

We do not cover this drug for prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing.

**Individual Consideration**

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:

Blue Cross Blue Shield of Massachusetts
Clinical Pharmacy Department
One Enterprise Drive
Quincy, MA 02171
Tel: 1-800-366-7778
Fax: 1-800-583-6289

**Managed Care Authorization Instructions**

- Prior authorization is required for all out patient sites of service
- For retail pharmacy requests, physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients.
  - Pharmacy Operations: (800)366-7778
- For all outpatient sites of service, physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients.
- For all outpatient sites of service, physicians may also submit requests for retail pharmacy exceptions via the web using Express PAth which can be found on the BCBSMA provider website or directly on the web at https://provider.express-path.com

**PPO and Indemnity Authorization Instructions**

- Prior authorization is required when these medications are processed under the retail pharmacy benefit and home infusion therapy benefit.
- Prior authorization is not required when these drugs are purchased by the physician and administered in the office in accordance with this medical policy.
- For retail pharmacy requests, physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients.
  - Pharmacy Operations: (800)366-7778
- Physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients.
- Physicians may also submit requests for retail pharmacy exceptions via the web using Express PAth which can be found on the BCBSMA provider website or directly on the web at https://provider.express-path.com

**CPT Codes / HCPCS Codes / ICD-9 Codes**

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member. A draft of future ICD-10 Coding related to this document, as it might look today, is included below for your reference.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.
PALIVIZUMAB (SYNAGIS™) when administered in the office:

Option #1
- The pediatrician will request the dose required from the contracted Specialty Retail Pharmacy or HIT provider below:

<table>
<thead>
<tr>
<th>Vendor:</th>
<th>Contact Information:</th>
</tr>
</thead>
<tbody>
<tr>
<td>AcariaHealth (Specialty Only)</td>
<td>Telephone: 1-866-892-1202</td>
</tr>
<tr>
<td></td>
<td>Fax: 1-866-892-3223</td>
</tr>
<tr>
<td></td>
<td>Website: <a href="http://www.acariahealth.com">www.acariahealth.com</a></td>
</tr>
<tr>
<td>CVS Caremark, LLC (Specialty and HIT)</td>
<td>Telephone: 1-800-237-2767</td>
</tr>
<tr>
<td></td>
<td>Fax: 1-800-323-2445</td>
</tr>
<tr>
<td></td>
<td>Website: <a href="http://www.caremark.com">www.caremark.com</a></td>
</tr>
</tbody>
</table>

- The Specialty Retail Pharmacy or HIT provider will ship the Synagis™ directly to the physician’s office.
- The Specialty Retail Pharmacy or HIT provider will bill BCBSMA directly for the reimbursement of the drug sent to the physician according to the appropriate benefit.
- Coverage for the drug will be applied to the members Specialty Retail Pharmacy or HIT benefit. (The pediatrician has no out of pocket expense for the drug up front.) and applicable co-pays/coinsurance will apply.
  
  Note: The above arrangement is only for the reimbursement for Synagis™ and no other immunizations.

Option #2
- Use CPT code 90378 to report respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each
- If the physician has purchased Synagis™ from his/her regular drug vendor, bill for the cost of the drug using CPT code 90378.
- The physician may bill for the administration of Synagis™ using CPT code 96372. Home Infusion Therapy Providers: Use CPT code 90378.

CPT Codes

<table>
<thead>
<tr>
<th>CPT codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>90378</td>
<td>Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each</td>
</tr>
<tr>
<td>96372</td>
<td>Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular</td>
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</tbody>
</table>

Diagnosis coding

<table>
<thead>
<tr>
<th>ICD-9-CM diagnosis codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>079.6</td>
<td>Respiratory syncytial virus (RSV)</td>
</tr>
<tr>
<td>466.11</td>
<td>Acute bronchiolitis due to respiratory syncytial virus (RSV)</td>
</tr>
<tr>
<td>480.1</td>
<td>Pneumonia due to respiratory syncytial virus</td>
</tr>
<tr>
<td>V04.82</td>
<td>Need for prophylactic vaccination and inoculation against respiratory syncytial virus (RSV)</td>
</tr>
</tbody>
</table>

ICD-10 Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10-CM Diagnosis codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>B97.4</td>
<td>Respiratory syncytial virus as the cause of diseases classified elsewhere</td>
</tr>
<tr>
<td>J12.1</td>
<td>Respiratory syncytial virus pneumonia</td>
</tr>
<tr>
<td>J20.5</td>
<td>Acute bronchitis due to respiratory syncytial virus</td>
</tr>
<tr>
<td>J21.0</td>
<td>Acute bronchiolitis due to respiratory syncytial virus</td>
</tr>
</tbody>
</table>
**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>8/2014</td>
<td>Update to include 2014 AAP practice guidelines</td>
</tr>
<tr>
<td>7/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
</tr>
<tr>
<td>9/2013</td>
<td>Updated to include 2013-14 vendor information</td>
</tr>
<tr>
<td>9/2012</td>
<td>Updated: 9/2012 to update 2012 AAP guidelines and update HIT and Specialty Retail Pharmacy Network contact information.</td>
</tr>
<tr>
<td>9/2011</td>
<td>Updated to include update HIT and Specialty Retail Pharmacy Network contact information.</td>
</tr>
<tr>
<td>10/2010</td>
<td>Updated to include preferred vendor information for 2010-2011 RSV season.</td>
</tr>
<tr>
<td>10/2009</td>
<td>Updated to include new 2009 AAP practice guidelines and UM requirements.</td>
</tr>
<tr>
<td>9/2007</td>
<td>Updated to include additional references for 2006 American Academy of Pediatric Guidelines.</td>
</tr>
</tbody>
</table>

**References**

1. FDA labeling, based upon data submitted to the Food and Drug Administration
2. Prophylactic administration of RSV immune globulin to high-risk infants and young children by Groothuis JR 1993 NEJM 329:1524-30. Also see the FDA’s response by Ellenberg SS, 1994 NEJM 331:203-4, regarding the randomization and other procedures used in the above trial, which might have introduced bias to results.
4. See the FDA labeling from Palivizumab (Synagis™), approved by the FDA on June 19, 1998:
7. See [http://www.cdc.gov/mmwr](http://www.cdc.gov/mmwr).
8. The AAP Policy Statement
9. Note that asthma or reactive airway disease treated intermittently does not meet the definition of chronic lung disease for purposes of this medical policy.
13. AMERICAN ACADEMY OF PEDIATRICS: Revised Indications for the Use of Palivizumab and Respiratory Syncytial Virus Immune Globulin Intravenous for the Prevention of Respiratory Syncytial Virus Infections Committee on Infectious Diseases and Committee on Fetus and Newborn Pediatrics 2003; 112:6 1442-1446
Updates to guidelines include:
Clarification for risk factor of siblings under the age of 5 living in the infant’s household does not include multiple births younger than 1 year of age under this criteria.

14. Pediatrics 2014;134;415; originally published online July 28, 2014; GUIDELINES COMMITTEE COMMITTEE ON INFECTIOUS DISEASES AND BRONCHIOLITIS Infection Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Updated Guidance for Palivizumab Prophylaxis Among Infants and YounG. Available at: http://pediatrics.aappublications.org/content/134/2/415.full.html
To ensure that we can confirm your request (required by NCQA), please be sure to include your fax number.

We cannot process requests unless they contain **all** of the information requested below:

### Patient Information (REQUIRED)
- **Name**
- **BCBSMA ID number**
- **Is the patient a BCBSMA employee?**
  - [ ] Yes
  - [x] No
- **Date of Birth**
- **Patient's Diagnosis**

### Physician Information (REQUIRED)
- **Name**
- **Medical Specialty/NPI #**
- **BCBSMA Provider number**
- **Telephone Number**
- **Fax Number**
- **Is this fax number ‘secure’ for PHI receipt/transmission per HIPAA requirements?**
  - [ ] Yes
  - [x] No
- **Contact Name (if different from physician)**

Please select **one** of the three following sections to complete, depending on the nature of your request for the above-named patient.

#### Formulary Exception Request
- **Name of non-covered drug you want to prescribe**
- **Reason for Individual Consideration Request (please check one):**
  - [ ] Treatment failure with the following covered drugs in class
  - [ ] Documented adverse reaction to the following covered drugs
  - [ ] Other clinical reason (please specify) _____________________________________________

#### Quality Care Dosing Override Request
- **Drug name, strength and quantity requested:**
- **Clinical reason for override (please specify)**

#### Outpatient Retail Pharmacy Prior Authorization Request
- **Drug name:**
- **Start/End date (must be one year or less):**
- **Associated Co-morbid diagnosis:**
- **MD Signature:**
- **Date:**
Home Infusion Therapy
Prior Authorization Form

Please complete and fax with the physician's prescription to: (888) 641-5355. If the patient is a BCBSMA employee, please fax the form to: (617)246-4013

FOR TPN THERAPY, USE MEDICAL POLICY #296 REQUEST FORM

<table>
<thead>
<tr>
<th>Company name:</th>
<th>Contact Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone #:</td>
<td>Provider #:</td>
</tr>
</tbody>
</table>

Fax# 

Is this fax number ‘secure’ for PHI receipt/transmission per HIPAA requirements? (circle one)
Yes No

Patient name: 

Address: 

Patient ID#: 

DOB: / / 

Diagnosis: 

Prescribing Physician/addr: 

Telephone: 

PCP name/address: 

Telephone: 

Place of Service  Home  SNF  MD office  other (specify) 

Primary Therapy

Primary drug name: 

Approximate duration: to 

Dose: 

Frequency: 

Route of Administration: pump: Y N

Other Therapy

Other drug name: 

Approximate duration: to 

Dose: 

Frequency: 

Route of Administration: pump: Y N

☐ If this is a “drug only” authorization request, indicate other services the nursing agency is providing:

Nursing provided by: Contact: 

Phone: Fax: 

Request for 7 Day Coverage: Date of occurrence: request dates: 

Occurrence type: Hospitalization  Death  Change of Therapy

Physician signature: Date: 

OR Copy of prescription REQUIRED with this request
Outpatient Medical Prior Authorization Form
Please complete and fax to: (888) 641-5355
Please contact Pharmacy Operations with questions at (800) 366-7778
If the patient is a BCBSMA employee, please fax the form to: (617) 246-4013

<table>
<thead>
<tr>
<th>Servicing Provider</th>
<th>Name:</th>
<th>NPI Number:</th>
<th>Requesting Provider</th>
<th>Name:</th>
<th>NPI Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone#</td>
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<td>Fax#</td>
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</tbody>
</table>

Is this fax number ‘secure’ for PHI receipt/transmission per HIPAA requirements? (circle one)
Yes  No

Contact Person:

Patient Name:  DOB ___/___/___  Diagnosis:

Patient BCBSMA ID#

Drug/Therapy:
Drug Name: ___________________________ Dates of Service: ___/___/___ to ___/___/___

Dose: __________________________________________

Frequency: ______________________________________

Additional Clinical (including previous treatment failure):

Physician signature: ___________________________ Date: ___________________________