



## MASSACHUSETTS

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# Pharmacy Medical Policy RSV Immunoprophylaxis

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## Policy Number: 422

BCBSA Reference Number: None

## Related Policies

None

## Prior Authorization Information

|  |   |   |   |
|--|---|---|---|
| Policy   | <input checked="" type="checkbox"/> Prior Authorization<br><input type="checkbox"/> Step Therapy<br><input type="checkbox"/> Quality Care Dosing<br><input type="checkbox"/> Administrative | Reviewing Department<br><br>Policy Effective Date   | <b>Pharmacy Operations:</b><br>Tel: 1-800-366-7778<br>Fax: 1-800-583-6289<br><br><b>11/1/2023</b> |
| Pharmacy (Rx) or Medical (MED) benefit coverage  | <input checked="" type="checkbox"/> Rx<br><input type="checkbox"/> MED  | <b>To request for coverage:</b> Physicians may call, fax, or mail the attached form ( <a href="#">Massachusetts Synagis Form for Medication Prior Authorization Requests</a> ) to the address below.  |   |
| <b>Policy applies to Commercial Members:</b> <ul style="list-style-type: none"> <li>• Managed Care (HMO and POS),</li> <li>• PPO and Indemnity</li> <li>• MEDEX with Rx plan</li> <li>• Managed Major Medical with Custom BCBSMA Formulary</li> <li>• Comprehensive Managed Major Medical with Custom BCBSMA Formulary</li> <li>• Managed Blue for Seniors with Custom BCBSMA Formulary</li> </ul> <b>Policy does NOT apply to:</b> <ul style="list-style-type: none"> <li>• Medicare Advantage</li> </ul> |   | <b>Blue Cross Blue Shield of Massachusetts Pharmacy Operations Department</b><br>25 Technology Place<br>Hingham, MA 02043<br>Tel: 1-800-366-7778<br>Fax: 1-800-583-6289<br><br><b>Individual Consideration:</b> Policy for requests that do not meet clinical criteria of this policy, see section labeled <a href="#">Individual Consideration</a> |   |

## Summary

Respiratory syncytial virus (RSV) is the most common cause of lower respiratory tract infections in children. Several factors that put certain children at a higher risk for contracting RSV have been identified: they are age (<2 years old), prematurity, chronic lung disease of prematurity (formerly known as bronchopulmonary dysplasia), congenital heart disease, immunodeficiencies, and multiple congenital anomalies. Immune prophylaxis against RSV is a preventive strategy to reduce the incidence of infection and its associated morbidity, including hospitalization, in high-risk infants

## Policy

|                              |   |
|------------------------------|---|
| <b>Length of Approval</b>    | Maximum of 5 doses or number of doses left until end of RSV season, OR as clinically indicated in the corresponding coverage criteria |
| <b>Benefit consideration</b> | Only <b>ONE</b> course of treatment is covered  |

Monthly administration of immune prophylaxis for respiratory syncytial virus (RSV) with palivizumab during the RSV season may be considered **MEDICALLY NECESSARY** when **ANY** of the following criteria are met in infants and children in accordance with guidelines-based recommendations:

### I. In first year of life – less than 12 months at start of RSV season

#### a. Prematurity

- i. Infants born before 29 weeks, 0 days of gestation; **AND**
- ii. ≤ 12 months at start of RSV season

#### b. Chronic Lung Disease of prematurity (Bronchopulmonary Dysplasia)

Preterm infants with chronic lung disease (CLD) of prematurity, defined as:

- i. Less than 32 weeks, 0 days of gestation at birth; **AND**
- ii. Requirement for > 21% oxygen for at least the first 28 days after birth; **AND**
- iii. ≤ 12 months at start of RSV season

#### c. Anatomic pulmonary abnormalities/neuromuscular diseases:

- i. Children with pulmonary abnormality\*

**\*Examples of pulmonary abnormality:** pulmonary malformations, tracheoesophageal fistula, upper airway conditions, or conditions requiring tracheostomy

**OR**

- ii. Neuromuscular disease that impairs ability to clear secretions from upper airways\*

**\*Examples of Neuromuscular disease:** ineffective cough, recurrent gastroesophageal tract reflux, pulmonary malformations, tracheoesophageal fistula, upper airway conditions, or conditions requiring tracheostomy

#### d. Congenital heart defects (CHD\*)

Infants and children with hemodynamically significant CHD such as:

- i. Infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures; **OR**
- ii. Infants with cyanotic heart disease in consultation with a pediatric cardiologist; **OR**
- iii. Infants with moderate-to-severe pulmonary hypertension; **OR**
- iv. Infants with lesions adequately corrected by surgery who continue to require medication for heart failure; **AND**
- v. ≤ 12 months at start of RSV season

**\* Examples of CHD** - Atrial or ventricular septal defect, Coarctation of aorta, Double-outlet right ventricle, D-Transposition of great arteries, Ebstein's anomaly, Hypoplastic left/right ventricle, Patent ductus arteriosus, Pulmonary or aortic valve stenosis, Pulmonary atresia, Single ventricle, Tetralogy of Fallot, Transposition of great arteries, Tricuspid atresia, Truncus arteriosus, Total anomalous pulmonary venous return

#### e. Cystic Fibrosis

Children with cystic fibrosis who ALSO have at least one of the following conditions:

- i. Clinical evidence of Chronic Lung Disease (i.e., < 32 weeks, 0 days of gestation at birth, requirement for > 21% oxygen for at least the first 28 days after birth); **AND/OR**
- i. Nutritional compromise; **AND**
- ii. < 12 months at start of RSV season

### II. In the second year of life – less than 24 months at the start of RSV Season

Prophylaxis based solely on the history of prematurity is not recommended in the second year of life.

Prophylaxis may be considered **MEDICALLY NECESSARY** during the RSV season in the second year of life for infants who meet the following criteria:

#### a. Chronic Lung Disease or Bronchopulmonary Dysplasia

Preterm infants with chronic lung disease (CLD) of prematurity, defined as:

- i. Less than 32 weeks, 0 days of gestation at birth; **AND**
- ii. Requirement for > 21% oxygen for at least the first 28 days after birth; **AND**
- iii. Continue to require supplemental oxygen, chronic corticosteroid, or diuretic therapy during the 6-month period before the start of the second RSV season; **AND**
- i. < 24 months at start of RSV season OR born during RSV season

#### b. Cystic Fibrosis

Children with cystic fibrosis who have either:

- i. Manifestations of severe lung disease such as previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persists when stable; **OR**
- ii. Weight for length less than the 10th percentile; **AND**
- iii. < 24 months at start of RSV season

### III. Infants in the first or second year of life

Prophylaxis may be considered **MEDICALLY NECESSARY** during the RSV season in the first or second year of life for infants who meet the following criteria

#### a. Surgical procedures

For children who still require prophylaxis, 1 postoperative dose of palivizumab may be considered **MEDICALLY NECESSARY** after:

- i. Procedures that use cardiopulmonary bypass; **OR**
- ii. At conclusion of extracorporeal membrane oxygenation for infants and children younger than 24 months.

#### b. Immunocompromised children

Children who will be profoundly immunocompromised e.g., will undergo solid organ transplantation **OR** hematopoietic cell transplantation **OR** receive chemotherapy during the RSV season.

## Non-Medical Necessity Determination

Immunoprophylaxis for respiratory syncytial virus is considered **NOT MEDICALLY NECESSARY** in:

- 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 heart failure;
- Infants with mild cardiomyopathy who are not receiving medical therapy for the condition; or
- Children with congenital heart disease in the second year of life.
- Primary asthma or asthma prevention to reduce subsequent episodes of wheezing; and
- Continued RSV prophylaxis children who experience breakthrough RSV hospitalization; and
- For treatment in children or infants with known RSV disease; and
- For all other indications not otherwise addressed as medically necessary, including, but not limited to, individuals with cystic fibrosis or Down syndrome who do not otherwise meet criteria above.

## Investigational Determination

Palivizumab for any other indication is considered **INVESTIGATIONAL** including, but not limited to:

- controlling outbreaks of healthcare-associated disease
- use in children with cystic fibrosis or Down syndrome without other risk factors
- Use in children over 2 years of age, unless criteria for medical necessity (outlined above) are satisfied

## Individual Consideration (for individuals with unique clinical circumstances)

Our medical policies are written for most people with a given condition. Each policy is based on peer reviewed clinical evidence. We also take into consideration the needs of atypical patient populations and diagnoses.

If the coverage criteria outlined is unlikely to be clinically effective for the prescribed purpose, the health care provider may request an exception to cover the requested medication based on an individual's unique clinical circumstances. This is also referred to as "individual consideration" or an "exception request."

Some reasons why you may need us to make an exception include: therapeutic contraindications; history of adverse effects; expected to be ineffective or likely to cause harm (physical, mental, or adverse reaction).

To facilitate a thorough and prompt review of an exception request, we encourage the provider to include additional supporting clinical documentation with their request. This may include:

- Clinical notes or supporting clinical statements;
- The name and strength of formulary alternatives tried and failed (if alternatives were tried) and specifics regarding the treatment failure, if applicable;
- Clinical literature from reputable peer reviewed journals;
- References from nationally recognized and approved drug compendia such as American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex or Drugdex®; and
- References from consensus documents and/or nationally sanctioned guidelines.

Providers may call, fax or mail relevant clinical information, including clinical references for individual patient consideration, to:

Blue Cross Blue Shield of Massachusetts  
Pharmacy Operations Department  
25 Technology Place  
Hingham, MA 02043

Phone: 1-800-366-7778

Fax: 1-800-583-6289

**We may also use prescription claims records to establish prior use of formulary alternatives or to show if step therapy criteria has been met. We will require the provider to share additional information when prescription claims data is either not available or the medication fill history fails to establish use of preferred formulary medications or that step therapy criteria has been met.**

### CPT Codes / HCPCS Codes / ICD Codes

*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.*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

*The following codes are included below for informational purposes only; this is not an all-inclusive list.*

**The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:**

### CPT Codes

| CPT codes: | Code Description   |
|------------|--|
| 90378      | Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each  |
| 96372      | <b>For the administration of Synagis™ by medical providers</b> - Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular |
| 90378      | <b>For administration of Synagis™ by Home Infusion Therapy providers</b> - Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each   |

### ICD-10 Diagnosis Codes

| ICD-10-CM codes: | Code Description  |
|------------------|---|
| I08.0-I08.9      | Multiple valve diseases code range  |
| I28.0-I28.9      | Other diseases of pulmonary vessels code range  |
| I34.0-I34.9      | Nonrheumatic mitral valve disorders code range  |
| I35.0-I35.9      | Nonrheumatic aortic valve disorders code range  |
| I36.0-I36.9      | Nonrheumatic tricuspid valve disorders code range   |
| I37.0-I37.9      | Nonrheumatic pulmonary valve disorders code range   |
| I42.0-I42.9      | Cardiomyopathy code range   |
| I43              | Cardiomyopathy in diseases classified elsewhere   |
| I50.1-I50.9      | Heart failure code range  |
| J41.0-J42        | Chronic bronchitis code range   |
| J44.0-J44.9      | Other chronic obstructive pulmonary disease code range  |
| P07.00-P07.32    | Disorders of newborn related to short gestation and low birth weight, not elsewhere classified code range   |
| P27.0-P27.9      | Chronic respiratory disease originating in the perinatal period (includes bronchopulmonary dysplasia P27.1) |
| P28.0-P28.9      | Other respiratory conditions originating in the perinatal period code range                                 |
| Q20.0-Q28.9      | Congenital malformations of the circulatory system code range   |
| Z29.11           | Encounter for prophylactic immunotherapy for respiratory syncytial virus (RSV)                              |

|         |   |
|---------|---|
|         | <b>ICD-10-PCS codes are only used for inpatient services</b>  |
| 3E0234Z | Administration, physiological systems and anatomical regions, introduction, muscle, percutaneous, serum, toxoid and vaccine           |
| 3E0334Z | Administration, physiological systems and anatomical regions, introduction, peripheral vein, percutaneous, serum, toxoid, and vaccine |

## 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:

| Vendor:   | Contact Information: |  |
|---|----------------------|--|
| AcariaHealth.(Specialty Only)                       | Telephone:           | 1-844-796-2447   |
|   | Fax:                 | 1-866-892-3223   |
|   | Website:             | <a href="http://www.acariahealth.com">www.acariahealth.com</a> |
| Accredo (Specialty Only)                            | Telephone:           | 1-877-482-5927, Option 3                                       |
|   | Fax:                 | 1-866-489-1907   |
|   | Website:             | <a href="http://www.accredo.com">www.accredo.com</a>           |
| CVS Specialty (Caremark, Inc.) (Specialty and HIT*) | Telephone:           | 1-800-237-2767   |
|   | Fax:                 | 1-800-323-2445   |
|   | Website:             | <a href="http://www.caremark.com">www.caremark.com</a>         |

\*Any Participating Home Infusion Provider can submit and bill under their Home Infusion agreement for Synagis

- 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. 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.

## Summary of Evidence

For individuals with high-risk indications for RSV in infancy who receive immune prophylaxis for RSV, the evidence includes several randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are overall survival (OS), symptoms, morbid events, and hospitalizations. Evidence from systematic reviews of RCTs has demonstrated that RSV prophylaxis with palivizumab is associated with reductions in RSV-related hospitalizations and length of intensive care unit stays. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with cystic fibrosis (CF) without other risk factors for RSV in infancy who receive immune prophylaxis for RSV, the evidence includes an RCT, several prospective and retrospective cohort studies, and systematic reviews. Relevant outcomes are OS, symptoms, morbid events, and hospitalizations. Although some studies have demonstrated reductions in hospitalizations in palivizumab-treated patients, studies that used contemporaneous controls did not. In the available RCT, rates of adverse events were high in both the palivizumab and placebo groups, making it difficult to draw conclusions about the net benefit of palivizumab. A more recent nonrandomized study using noncontemporaneous controls found fewer RSV infections in palivizumab-treated patients with CF. Additional studies are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with immunodeficiencies without other risk factors for RSV in infancy who receive immune prophylaxis for RSV, the evidence includes case series. Relevant outcomes are OS, symptoms, morbid events, and hospitalizations. Descriptive findings from a consensus panel and case reports of 2 infants with primary immunodeficiencies and 2 infants with acquired immunodeficiencies in whom palivizumab was used with good compliance and efficacy have been reported in the literature. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with Down syndrome without other risk factors for RSV in infancy who receive immune prophylaxis for RSV, the evidence includes a prospective cohort study. Relevant outcomes are OS, symptoms, morbid events, and hospitalizations. The available cohort study reported reduced rates of RSV-related hospitalization in treated patients but had methodologic limitations, including the use of a noncontemporaneous comparative cohort from a different country; such limitations introduce uncertainty into any conclusions that can be made. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## Policy Guidelines

### Dosing and Administration

Palivizumab is administered by intramuscular injection at a dose of 15 mg/kg of body weight per month. The anterolateral aspect of the thigh is the preferred injection site. Routine use of the gluteal muscle for the injection site can cause sciatic nerve damage.

Clinicians may administer up to a maximum of 5 monthly doses of palivizumab (15 mg/kg per dose) during the respiratory syncytial virus (RSV) season to infants who qualify for prophylaxis. Qualifying infants born during the RSV season will require fewer doses. For example, infants born in January would receive their last dose in March (see Initiation and Termination of Immunoprophylaxis subsection below).

Hospitalized infants who qualify for prophylaxis during the RSV season should receive the first dose of palivizumab 48 to 72 hours before discharge or promptly after discharge.

### Break Through Respiratory Syncytial Virus

Guidelines make the following recommendation on breakthrough RSV: "If any infant or young child receiving monthly palivizumab prophylaxis experiences a breakthrough RSV hospitalization, monthly prophylaxis should be discontinued because of the extremely low likelihood (<0.5%) of a second RSV hospitalization in the same season."

### Practice Guidelines

Table 1. Guidelines on Use of Palivizumab Prophylaxis for Infants (American Academy of Pediatrics)

| Recommendations for Using Palivizumab Prophylaxis  |
|--|
| <b><i>Prophylaxis recommended</i></b>  |
| <ul style="list-style-type: none"><li>• Infants born before 29 weeks, 0 days of gestation, during first year of life</li></ul> |

|   |
|---|
| <ul style="list-style-type: none"> <li>• Infants born before 32 weeks, 0 days of gestation with chronic lung disease of prematurity, during first year of life</li> </ul>   |
| <ul style="list-style-type: none"> <li>• Children in the second year of life who require 28 or more days of supplemental oxygen and continue to require medical intervention during respiratory syncytial virus season</li> </ul> |
| <b><i>Prophylaxis may be considered</i></b>   |
| <ul style="list-style-type: none"> <li>• Infants with hemodynamically significant heart failure, during first year of life</li> </ul>   |
| <ul style="list-style-type: none"> <li>• Infants with a pulmonary abnormality or neuromuscular disease that impairs ability to clear secretions from lower airways, during first year of life</li> </ul>                          |
| <ul style="list-style-type: none"> <li>• Children younger than 24 months who are profoundly immunocompromised during respiratory syncytial virus season</li> </ul>  |
| <b><i>Prophylaxis not recommended</i></b>   |
| <ul style="list-style-type: none"> <li>• Healthy infants born at or after 29 weeks, 0 days of gestation</li> </ul>  |
| <ul style="list-style-type: none"> <li>• There is insufficient evidence for children with cystic fibrosis or Down syndrome without other risk factors</li> </ul>  |

## Policy History

| Date           | Action  |
|----------------|---|
| 11/2023        | Updated format and references   |
| 10/2020        | References updated.   |
| 4/2020         | Removed BriovaRx from the Provider section.   |
| 10/2019        | References updated.   |
| 9/2018         | Added Accredo and BriovaRx to the Provider section.   |
| 7/2018         | Clarified coding information.   |
| 11/2017        | Added the State Standard PA form to the policy.   |
| 10/2017        | Updated to change Walgreens Specialty Name.   |
| 6/2017         | Updated address for Pharmacy Operations.  |
| 10/2016        | Clarified second course of therapy Criteria.  |
| 10/2015        | Updated to add Walgreens as a Specialty Rx Vendor.  |
| 8/2014         | Update to include 2014 AAP practice guidelines.   |
| 7/2014         | Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.                                     |
| 9/2013         | Updated to include 2013-14 vendor information.  |
| 9/2012         | Updated: 9/2012 to update 2012 AAP guidelines and update HIT and Specialty Retail Pharmacy Network contact information. |
| 11/2011-4/2012 | Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.             |
| 9/2011         | Updated to include update HIT and Specialty Retail Pharmacy Network contact information.                                |
| 5/2011         | Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.                        |



|         |  |
|---------|--|
| 10/2010 | Updated to include preferred vendor information for 2010-2011 RSV season.                        |
| 5/2010  | Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements. |
| 10/2009 | Updated to include new 2009 AAP practice guidelines and UM requirements.                         |
| 5/2009  | Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements. |
| 5/2008  | Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements. |
| 9/2007  | Updated to include additional references for 2006 American Academy of Pediatric Guidelines.      |
| 5/2007  | Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements. |
| 2/1997  | New policy, issued 2/1997, describing covered and non-covered indications.                       |

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use ref](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

## Forms

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

<https://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf>

OR

Print and fax, **Massachusetts Standard Form for Medication Prior Authorization Requests #434**

## References

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