



MASSACHUSETTS

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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:²

- 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 season²

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:² 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.²

Congenital heart defects:² 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/children younger than 24 months of age 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/children younger than 24 months of age 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
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
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 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.

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:	www.acariahealth.com
Accredo (Specialty Only)	Telephone:	1-877-482-5927, Option 3
	Fax:	1-866-489-1907
	Website:	www.accredo.com
BriovaRx (Specialty Only)	Telephone:	1-844-284-9462
	Fax:	1-866-496-1196
	Website:	www.briovarx.com
CVS Specialty (Caremark, Inc.) (Specialty and HIT)	Telephone:	1-800-237-2767
	Fax:	1-800-323-2445
	Website:	www.caremark.com

- 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.

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

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT code above if medical necessity criteria are met:

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
B97.4	Respiratory syncytial virus as the cause of diseases classified elsewhere
J12.1	Respiratory syncytial virus pneumonia
J20.5	Acute bronchitis due to respiratory syncytial virus
J21.0	Acute bronchiolitis due to respiratory syncytial virus
Z23	Encounter for immunization
Z29.11	Encounter for prophylactic immunotherapy for respiratory syncytial virus (RSV)

Policy History

Date	Action
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.

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.

3. See the American Academy of Pediatrics 1997 recommendations about RSV-IVIg at their web site, <http://www.aap.org>.
4. See the FDA labeling from Palivizumab (Synagis™), approved by the FDA on June 19, 1998:
5. See the American Academy of Pediatrics 1998 Guidelines for the use of palivizumab for RSV prophylaxis at www.aap.org.
6. Respiratory syncytial virus immune globulin for prophylaxis against respiratory syncytial virus disease in infants and children with congenital heart disease, by EA Simoes et al and the Cardiac Study Group, *The Journal of Pediatrics* v1998 vol. 133, no 4, pp492-9.
7. See <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.
10. The American Academy of Pediatrics 2003 Guidelines for the use of palivizumab for RSV prophylaxis.
11. The American Academy of Pediatrics Clinical Practice Guidelines for the Diagnosis and Management of Bronchiolitis, *Pediatric*, October 2006, Vol.18, No.4. p. 1774-1793. Found at Immunoprophylaxis <http://aappolicy.aappublications.org/cgi/content/full/pediatrics;118/4/1774>. There were no clinical recommendation changes from the 2003 guidelines.
12. American Academy of Pediatrics. Respiratory Syncytial Virus. In: Pickering LK, ed. *Red Book: 2009 Report of the Committee on Infectious Diseases*. 28th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2009:560-569. Available at: <http://aapredbook.aappublications.org/cgi/content/full/2009/1/3.110>. Accessed September 17, 2009.
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>

Massachusetts Standard Form for Synagis Prior Authorization Requests (eForm)

Browser information:

- Use **Internet Explorer 7, 8, 9, or Firefox**. You may not be able to see or submit the eForm if you use another browser.
- If you use **Internet Explorer 8.0**, select “No” when you see a pop-up box that says, “Stop running this script” so you can continue with your submission.

If NOT logged into Provider Central use this link:

[Massachusetts Standard Form for Synagis Prior Authorization Requests eForm](#)

(Also found on Provider Central at **Forms > Authorization – Pharmacy**)

If logged into Provider Central use this link:

[Provider Central Link to Pharmacy Forms](#)

(Also found on Provider Central by clicking **Forms** on the top of the page, then choose **Authorization – Pharmacy**)

Tips for using this eForm:

- Fill out completely and submit it. You won't be able to start the form and save it for later.
- You can attach documents to support your request. Please have them ready.
- You'll be able to print a copy for your patient's medical record at the end.