**Prior Authorization Review Panel**
**MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.

Policies submitted without this form will not be considered for review.

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| **Plan:** Aetna Better Health | **Submission Date:** 9/1/2020 |
| **Policy Number:** | **Effective Date:** 12/1/2020<br>**Revision Date:** 8.2020 |
| **Policy Name:** Synagis (Non-PDL) | |
| **Type of Submission – Check all that apply:**<br><br>☐ **New Policy**<br>☐ **Annual Review – No Revisions**<br>**X Revised Policy** | |
| ***All revisions to the policy must be highlighted using track changes throughout the document.**<br><br>**Please provide any clarifying information for the policy below:**<br><br>Updated criteria per P&T annual review.<br><br>Thank you. | |
| **Name of Authorized Individual (Please type or print):**<br><br>**Natalie Nkurunziza, Pharm.D.** | **Signature of Authorized Individual:**<br><br>  |



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# AETNA BETTER HEALTH®

## Non-Formulary Prior Authorization guideline for Synagis® (palivizumab)

**NOTE:** This policy covers the situations commonly incorporating the use of Synagis (palivizumab) in the out-patient setting. The AAP guidelines (referenced at the end of this policy) are extensive and may cover a wider variety of situations and conditions than those incorporated in the following document. Request for coverage in medical scenarios not addressed in this document will be reviewed utilizing the full APP guideline or other applicable guidance for coverage determinations. An absence of a coverage statement in this document should not be interpreted to infer non-covered status.

### Authorization guidelines

For members who have the following:

1. **Preterm Infants without Chronic Lung Disease (CLD):**
   a. Gestational Age (GA) less than 29 weeks, 0 days

   **AND**

b. 12 months of age or younger at the start of Respiratory Syncytial Virus (RSV) season

2. **Preterm Infants with Chronic Lung Disease (CLD):**
   a. Gestational Age (GA) less than 32 weeks, 0 days

   **AND**

   b. Has required greater than 21% oxygen for at least 28 days after birth

   **AND**

   c. 12 months of age or younger at the start of RSV season

   **OR**

   d. 24 months of age at the start of RSV season AND continues to require medical support (e.g., supplemental oxygen, chronic systemic corticosteroid therapy, diuretic therapy, or bronchodilator therapy) within 6 months of the start of RSV season

3. **Infants with Hemodynamically Significant Congenital Heart Disease:**



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a. 24 months of age or younger AND has undergone cardiac transplantation during RSV season

b. 12 months of age or younger at the start of RSV season

**AND** Meets one of the following:

i. Diagnosis of acyanotic heart disease**.** Must be currently receiving medication to control congestive heart failure**.** Will require cardiac surgical procedure

ii. Diagnosis of cyanotic heart disease AND prophylaxis is recommended by a Pediatric Cardiologist

iii. Diagnosis of moderate to severe pulmonary hypertension

4. **Children with Anatomic Pulmonary Abnormalities or Neuromuscular Disorder:**

a. 12 months of age or younger

**AND**

b. Diagnosis of neuromuscular disease or congenital anomaly that impairs ability to clear secretions from the upper airway because of ineffective cough

5. **Immunocompromised Children:**

a. 24 months of age or younger at the start of RSV season

**AND**

b. Child is profoundly immunocompromised during RSV season

6. **Children with Cystic Fibrosis:**

Member meets one of the following:

a. Is 12 months of age or younger and has clinical evidence of chronic lung disease (CLD) and/or nutritional compromise in the first year of life

**AND**

b. Is 24 months of age or younger 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.



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***Note: Generally, the following groups are not at increased risk of RSV and should not routinely receive Synagis. All such cases will be sent to the medical director for review and consideration of extenuating circumstances against the full AAP guidelines.***

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 with cystic fibrosis (unless the above criteria is met)
5. Children with Down Syndrome (unless qualifying heart disease or prematurity)
6. Children who had met the criteria above but experienced break through Respiratory Syncytial Virus (RSV) hospitalization during the current season.

**Authorization and Limitations**
1 dose per month for a maximum of 5 doses per season
**Note: infants born during RSV season may require fewer than 5 doses**

**Additional Information:**
Synagis is NOT covered for members with the following criteria:

- Use not approved by the FDA; **AND**
- The use is unapproved and not supported by the literature or evidence as an accepted off-label use. **OR**
- The request does not meet the clinical criteria outlined above, and, in the professional judgment of the Medical Director, the services are not medically necessary.

**Medically Necessary** — A service or benefit is Medically Necessary if it is compensable under the MA Program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the

functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

Determination of Medical Necessity for covered care and services, whether made on a Prior Authorization, Concurrent Review, Retrospective Review, or exception basis, must be documented in writing.

The determination is based on medical information provided by the Member, the Member's family/caretaker and the Primary Care Practitioner, as well as any other Providers, programs, agencies that have evaluated the Member.

All such determinations must be made by qualified and trained Health Care Providers. A Health Care Provider who makes such determinations of Medical Necessity is not considered to be providing a health care service under this Agreement.

**References:**


1. Aetna.com. 2019. Clinical Policy Bulletin: Synagis (Palivizumab). [online] Available at: http://www.aetna.com/cpb/medical/data/300_399/0318.html, last reviewed 06/13/2019 [Accessed: 22 May 2020].
2. Perrin, MD, FAAP, J., Meissner, MD, FAAP, H. and Ralston, MD, FAAP, S. 2014. Updated AAP Guidance for Palivizumab Prophylaxis For Infants and Young Children at Increased Risk of RESPIRATORY SYNCYTIAL VIRUS (RESPIRATORY SYNCYTIAL VIRUS (RSV)) Hospitalization. [e-book] pp. 1-23. Available through: American Academy of Pediatrics http://www.aap.org/en-us/my-aap/Pages/Respiratory Syncytial Virus (RESPIRATORY SYNCYTIAL VIRUS (RSV)).aspx [Accessed: 22 May 2020].].
3. Ralston SL, Lieberthal AS, Meissner H. Clinical Practice Guideline: The Diagnosis, Management, and Prevention of Bronchiolitis.Pediatrics. 2014;134(5):e1474, Accessed online on 6/21/2019 at https://pediatrics.aappublications.org/content/134/5/e1474.long. [Accessed: 22 May 2020].
4. Synagis [package insert]. MedImmune, LLC, Gaithersburg, MD; May 2017. https://www.azpicentral.com/synagis/synagis.pdf#page=1. [Accessed: 22 May 2020]..
5. The American Academy of Pediatrics. RSV recommendations unchanged after review of new data. http://www.aappublications.org/news/2017/10/19/RSV101917.[Accessed: 22 May 2020].

6. Farber HJ, Buckwold FJ, Lachman B, et al. Observed Effectiveness of Palivizumab for 29–36-Week Gestation Infants. Pediatrics. 2016; e20160627; DOI: 10.1542/peds.2016-0627.



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