BACKGROUND


http://pediatrics.aappublications.org/content/134/5/e1474.full.html

The authors of the Guideline conclude that there is a limited role, with evidence grade B, for the use of palivizumab in the prevention of severe Respiratory Syncytial Virus (RSV) infections in certain high risk infants. The role as defined in the 2014 CPG is more narrowly defined than in prior years, based on additional research and post-release market data on the efficacy and safety of palivizumab published since the initial guideline of 2006.

REQUIRED REVIEW AND APPROVALS

Prior authorization by the Community Health Plan of Washington (CHPW) Medical Director or his/her designee is required.

This service also requires a referral to CHPW’s Case Management department for evaluation of care coordination and support potentially required by high risk infants and their families.

DEFINITIONS

In Washington State (and the Pacific Northwest not including Alaska), peak RSV activity typically occurs between November and April. The duration of RSV season is 5 months.

CRITERIA:

For Washington APPLE Health (Medicaid) CHPW uses this Clinical Coverage Criteria document. There are currently no CMS National or Local Coverage Determinations on use of palivizumab. Thus, for Commercial and Medicare Advantage members, CHPW uses this Clinical Coverage Criteria document.
INDICATIONS:

Palivizumab (Synagis) will only be authorized when the following criteria are met:

I. Prematurity:
   1. In the first year of life, palivizumab prophylaxis is considered medically necessary for infants born before 29 weeks, 0 days’ gestation.
   2. Palivizumab prophylaxis is considered not medically necessary for otherwise healthy infants born at or after 29 weeks, 0 days’ gestation.

II. Chronic Lung Disease (CDL) of Prematurity:
   1. In the first year of life, palivizumab prophylaxis is considered medically necessary for preterm infants with chronic lung disease (CLD) of prematurity defined as birth at <32 weeks, 0 days’ gestation and a requirement for greater than 21% oxygen for at least 28 days after birth.
   2. Palivizumab prophylaxis is considered medically necessary in the second year of life for children with CLD who required at least 28 days of supplemental oxygen after birth and who continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy) during the 6-month period before the start of the second RSV season.
   3. Palivizumab prophylaxis is considered not medically necessary for infants with CLD who do not continue to require medical support in the second year of life.

III. Hemodynamically Significant Congenital Heart Disease:
   1. Palivizumab is considered medically necessary in the first year of life for the following infants with hemodynamically significant congenital heart disease:
      a. infants with cyanotic heart disease;
      b. infants with moderate to severe pulmonary hypertension;
      c. infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures.
   2. Palivizumab is considered medically necessary for Infants younger than 2 years who undergo cardiac transplantation during the RSV season.
3. Palivizumab is considered not medically necessary for the following infants with congenital heart disease:

   a. Infants 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); and infants with lesions adequately corrected by surgery who do not continue to require medication for congestive heart failure; infants with mild cardiomyopathy who are not receiving medical therapy for the condition.

IV. Anatomic Pulmonary Abnormalities or Neuromuscular Disorders: In the first year of life, palivizumab prophylaxis is considered medically necessary for children with anatomic pulmonary abnormalities or neuromuscular disease that impairs the ability to clear secretions from the upper airways because of ineffective cough.

V. Immunocompromised Children: Palivizumab prophylaxis is considered medically necessary for children younger than 24 months who will be profoundly immunocompromised during the RSV season (e.g., severe combined immunodeficiency or severe acquired immunodeficiency syndrome, acute myeloid leukemia/acute lymphoblastic leukemia, hematopoietic stem cell transplant recipients).

VI. Cystic Fibrosis:

   i. Palivizumab prophylaxis is considered medically necessary for infants with cystic fibrosis only if there is clinical evidence of CLD and/or nutritional compromise (weight for length <10th percentile) in the first year of life.

   ii. Use of palivizumab prophylaxis for a second RSV season is considered medically necessary for infants with cystic fibrosis 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.

   iii. Routine use of palivizumab prophylaxis in infants and children with cystic fibrosis, including neonates diagnosed with cystic fibrosis by newborn screening, is considered not medically necessary unless other indications are present.
VII. Palivizumab prophylaxis is considered not medically necessary for all other indications (e.g., Down syndrome, asthma, treatment of RSV disease, prevention of care-associated RSV disease, and prophylaxis against RSV in immunocompromised adults).

VIII. Dosing of Palivizumab:

A. Up to a maximum of 5 monthly doses of palivizumab (15 mg/kg per dose) are considered medically necessary during the RSV season for infants who qualify for prophylaxis in the first year of life. For infants born during the RSV season, fewer than 5 monthly doses are considered medically necessary. (For example, infants born in January would receive their last dose in April.)

B. Palivizumab prophylaxis for sporadic RSV infections outside of RSV season is considered not medically necessary.

C. A postoperative dose of palivizumab (15 mg/kg) is considered medically necessary after cardiac bypass or at the conclusion of extracorporeal membrane oxygenation (ECMO) for infants and children younger than 24 months who are receiving palivizumab prophylaxis and who continue to require palivizumab prophylaxis.

D. Except for extra dosing after cardiopulmonary bypass or ECMO, administration of palivizumab more frequently than monthly (every 30 days) is not medically necessary.

E. Continued monthly palivizumab prophylaxis is considered not medically necessary for any infant or young child who experiences a breakthrough RSV hospitalization, because of the extremely low likelihood of a second RSV hospitalization in the same season.

F. CHPW considers home administration of palivizumab a medically necessary alternative to office- or clinic-based administration.

SPECIAL CONSIDERATIONS
None.

LIMITATIONS/EXCLUSIONS
Please refer to each product line’s certificate of coverage for benefit limitations and exclusions for these services.
REFERENCES

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REFERENCES

Clinical Practice Guideline: The Diagnosis, Management, and Prevention of Bronchiolitis
Pediatrics 2014;134;e1474; originally published online October 27, 2014; DOI 10.1542/peds.2014-2742

CITATIONS AND REFERENCES

| CFR |  |
| WAC |  |
| RCW |  |

| CONTRACT CITATION | ☑ APPLE HEALTH MEDICAID |
| nowrap> | ☑ MEDICARE ADVANTAGE |

OTHER REQUIREMENTS

| NCQA ELEMENTS |  |

REVISION HISTORY

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