Synagis (palivizumab)

Line(s) of Business: HMO; PPO; QUEST Integration
Original Effective Date: 11/13/2001
Current Effective Date: 09/01/2019

POLICY
A. INDICATIONS
The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
- Prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) infection in pediatric patients at high risk of RSV disease

B. CRITERIA FOR APPROVAL
Prevention of Respiratory Syncytial Virus (RSV) Disease
Authorization of up to 5 doses may be granted to pediatric members who are prescribed Synagis when ALL of the following criteria are met:
  a. Synagis is prescribed for the prevention of serious lower respiratory tract disease caused by RSV
  b. Member has ANY of the following diagnoses and meets ALL of the criteria pertaining to the diagnosis:
     i. Prematurity
     ii. Congenital Heart Disease (CHD) (See Appendix) and/or persistent pulmonary hypertension
     iii. Chronic Lung Disease (CLD) of Prematurity
     iv. Congenital Airway Abnormality
     v. Neuromuscular Condition
     vi. Immunocompromised patients

1.1 Prematurity
   ALL of the following criteria must be met:
   a. Member’s gestational age is ≤ 28 weeks, 6 days
   b. Member’s chronological age at the start of RSV season is <12 months.

1.2. CHD and/or Persistent Pulmonary Hypertension
   ALL of the following criteria must be met:
   a. CHD and/or persistent pulmonary hypertension is hemodynamically significant
   b. Member meets ONE of the following criteria:
i. Member’s chronological age at the start of RSV season is < 12 months
ii. Member’s chronological age at the start of RSV season is between 12 to < 24 months AND member will be undergoing cardiac transplantation during RSV season

1.3 CLD of Prematurity
ALL of the following criteria must be met:
   a. Member’s gestational age is ≤ 31 weeks, 6 days
   b. Member requires > 21% oxygen for at least the first 28 days after birth
   c. Member meets ONE of the following criteria:
      i. Member’s chronological age at the start of RSV season is < 12 months
      ii. Member’s chronological age at the start of RSV season is between 12 to < 24 months and member continues to require medical support (e.g., chronic corticosteroids, diuretic therapy, supplemental oxygen) during the 6-month period prior to the start of the 2nd RSV season

1.4 Congenital Airway Abnormality
ALL of the following criteria must be met:
   a. The condition compromises handling of respiratory secretions
   b. Member’s chronological age at the start of RSV season is < 12 months

1.5 Neuromuscular Condition
ALL of the following criteria must be met:
   a. The condition compromises handling of respiratory secretions
   b. Member’s chronological age at the start of RSV season is < 12 months

1.6 Immunocompromised patients
ALL of the following criteria must be met:
   a. The patient must be severely immunocompromised (e.g., has received a solid organ transplant, chemotherapy)
   b. Member’s chronological age at the start of RSV season is < 24 months

C. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Dosing limits:
• RSV season requests: maximum of 5 doses per RSV season
• Off-season requests: 1 dose per request up to a maximum of 5 doses per RSV season

D. OTHER
The HMSA Synagis Season for 2019-2020 will be September 1, 2019 to March 31, 2020.

For all off-season Synagis requests, the RSV activity for the requested region according to the CDC National Respiratory and Enteric Virus Surveillance System (NREVSS) is ≥ 10%. The local health department or the CDC NREVSS will be consulted to assess the RSV activity for that region (https://www.cdc.gov/surveillance/nrevss/rsv/default.html).
E. APPENDIX

**Examples of Congenital Heart Anomalies***
- Atrial or ventricular septal defect
- Coarctation of aorta
- Tetralogy of Fallot
- Pulmonary or aortic valve stenosis
- Tricuspid atresia
- Ebstein’s anomaly
- Pulmonary atresia
- Transposition of great arteries
- Truncus arteriosus
- Hypoplastic left/right ventricle
- Single ventricle
- Double-outlet right ventricle
- Total anomalous pulmonary venous return

*Must be hemodynamically significant. Examples of infants and children who are most likely to benefit from Synagis include those with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures, and those with moderate to severe pulmonary hypertension.

F. IMPORTANT REMINDER

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA's determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

G. REFERENCES


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