RXADVANCE
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Clinical Policy Title:	palivizumab
Policy Number:	RxA.500
Drug(s) Applied:	Synagis®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Palivizumab (Synagis®) is a respiratory syncytial virus (RSV) F protein inhibitor monoclonal antibody.

Synagis® is indicated for the prevention of serious lower respiratory tract disease caused by RSV in pediatric patients:

- With a history of premature birth (less than or equal to 35 weeks gestational age) who are 6 months of age or younger at the beginning of RSV season;
- With bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and who are 24 months of age or younger at the beginning of RSV season;
- With hemodynamically significant congenital heart disease and who are 24 months of age or younger at the beginning of RSV season.

Limitation(s) of use: The safety and efficacy of Synagis® have not been established for treatment of RSV disease.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
palivizumab (Synagis®)	RSV prophylaxis in pediatric patients	15 mg/kg of body weight IM prior to commencement of the RSV season and remaining doses administered monthly throughout the RSV season	15 mg/kg/month; up to 5 doses per RSV season (1 extra dose if cardio-pulmonary bypass).

Dosage Forms

- Single-dose vial: 50 mg/0.5 mL, 100 mg/1 mL

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Preterm Birth (must meet all)**:**

1. Diagnosis of preterm birth defined as gestational age < 29 weeks;

2. Age at onset of RSV season < 12 months;
3. Synagis® prescription is written for RSV prophylaxis;
4. Member has not been hospitalized with RSV disease during the current RSV season;
5. Dose does not exceed 15 mg/kg once a month by intramuscular (IM) administration.

Approval Duration
Commercial: Up to 5 doses per RSV season
Medicaid: Up to 5 doses per RSV season

B. Chronic Lung Disease of Prematurity (must meet all):
1. Diagnosis of chronic lung disease (CLD) of prematurity (i.e., BPD) defined as gestational age < 32 weeks and a requirement for > 21% oxygen for ≥ 28 days after birth;
2. Age at onset of RSV season (a or b):
   a. Age < 12 months;
   b. Age ≥ 12 months to < 24 months and continues to require supplemental oxygen, chronic systemic corticosteroid therapy, or diuretic therapy within 6 months of the start of the RSV season;
3. Synagis® prescription is written for RSV prophylaxis;
4. Member has not been hospitalized with RSV disease during the current RSV season;
5. Dose does not exceed 15 mg/kg once a month by IM administration.

Approval Duration
Commercial: Up to 5 doses per RSV season
Medicaid: Up to 5 doses per RSV season

C. Congenital Heart Disease (must meet all)**:**
1. Age and diagnosis at onset of RSV season (a or b):
   a. Age < 12 months and either (i or ii);
      i. Diagnosis of acyanotic heart disease and either (a or b):
         a) Receiving medication to control congestive heart failure AND will require a cardiac surgical procedure;
         b) Diagnosis of moderate to severe pulmonary hypertension;
      ii. Diagnosis of a cyanotic heart defect and RSV prophylaxis is recommended by a pediatric cardiologist;
   b. Age < 24 months and undergoing cardiac transplantation or cardio-pulmonary bypass during the current RSV season;
2. Synagis® prescription is written for RSV prophylaxis;
3. Member has not been hospitalized with RSV disease during the current RSV season;
4. Dose does not exceed 15 mg/kg once a month by IM administration.

Approval Duration
Commercial: Up to 5 doses per RSV season (6 doses if cardio-pulmonary bypass)
Medicaid: Up to 5 doses per RSV season (6 doses if cardio-pulmonary bypass)

D. Anatomic Pulmonary Abnormalities, Neuromuscular Disorders, Infants Profoundly Immunocompromised (must meet all)**:**
1. Age and diagnosis at onset of RSV season (a or b):
   a. Age < 12 months and diagnosis of an anatomic pulmonary abnormality or neuromuscular disorder that impairs the ability to clear secretions from the upper airway (e.g., due to ineffective cough);
   b. Age < 24 months and will be profoundly immunocompromised during the RSV season (e.g., due to solid organ or hematopoietic stem cell transplantation, chemotherapy, severe combined immunodeficiency, chronic granulomatous disease);

2. Synagis® prescription is written for RSV prophylaxis;
3. Member has not been hospitalized with RSV disease during the current RSV season;
4. Dose does not exceed 15 mg/kg once a month by IM administration

Approval Duration
Commercial: Up to 5 doses per RSV season
Medicaid: Up to 5 doses per RSV season

E. Cystic Fibrosis (must meet all)**:**
1. Diagnosis of cystic fibrosis and one of the following (a or b):
   a. Clinical evidence of nutritional compromise;
   b. Diagnosis of CLD of prematurity defined as gestational age < 32 weeks and requirement for > 21% oxygen for ≥ 28 days after birth;
2. Age at onset of RSV season (a or b):
   a. Age < 12 months;
   b. Age < 24 months and (i or ii):
      i. Manifestations of severe lung disease (e.g., previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable);
      ii. Weight for length < 10th percentile;
3. Synagis® prescription is written for RSV prophylaxis;
4. Member has not been hospitalized with RSV disease during the current RSV season;
5. Dose does not exceed 15 mg/kg once a month by IM administration.

Approval Duration
Commercial: Up to 5 doses per RSV season
Medicaid: Up to 5 doses per RSV season

F. Alaska Native and Other American Indian Infants (must meet all):
1. Medical director consultation is required for requests relating to Alaska native and other American Indian infants that fall outside the criteria outlined above;
2. Alaska native infants: Eligibility for prophylaxis may differ from the remainder of the U.S. on the basis of epidemiology of RSV in Alaska, particularly in remote regions where the burden of RSV disease is significantly greater than in the general U.S. population,
3. Other American Indian infants: Limited information is available concerning the burden of RSV disease among American Indian populations. However, special consideration may be prudent for Navajo and White Mountain Apache infants in the first year of life.
4. Synagis® prescription is written for RSV prophylaxis;
5. Member has not been hospitalized with RSV disease during the current RSV season;
6. Dose does not exceed 15 mg/kg once a month by IM administration.

Approval Duration
Commercial: Up to 5 doses per RSV season
Medicaid: Up to 5 doses per RSV season

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Synagis® prescription is written for RSV prophylaxis;

3. Member has not yet received 5 doses of Synagis® in the current RSV season (6 doses if cardio-pulmonary bypass);
4. Member has not been hospitalized with RSV disease during the current RSV season;
5. If request is for a dose increase, new dose does not exceed 15 mg/kg once a month by intramuscular administration.

Approval Duration
Commercial: Up to 5 doses per RSV season (6 doses if cardio-pulmonary bypass)
Medicaid: Up to 5 doses per RSV season (6 doses if cardio-pulmonary bypass)

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
BPD: bronchopulmonary dysplasia
FDA: Food and Drug Administration
CLD: chronic lung disease of prematurity
RSV: respiratory syncytial virus

APPENDIX B: Therapeutic Alternatives
- Not applicable

APPENDIX C: Contraindications/Boxed Warnings
- Contraindication(s):
  - Previous significant hypersensitivity reaction to Synagis®

- Boxed Warning(s):
  - None reported

APPENDIX D: General Information
- RSV Seasonal Durations across the United States:
  - The RSV season may commence as early as September and continue through May. In Florida, the RSV season may begin at any time throughout the year.

References

1. Synagis Prescribing Information. Gaithersburg, MD: MedImmune, LLC; May 2017. Available at https://www.synagis.com/synagis.pdf. Accessed September 14, 2020.
2. Policy Statement: Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. American Academy of Pediatrics Committee on Infectious Diseases; American Academy of Pediatrics Bronchiolitis Guidelines Committee. *Pediatrics.* August 2014; 134(2): e415-20. doi: 10.1542/peds.2014-1665.
3. Technical Report: Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. American Academy of Pediatrics Committee on Infectious Diseases; American Academy of Pediatrics Bronchiolitis Guidelines Committee. *Pediatrics.* August 2014; 134(2): e620-38. doi: 10.1542/peds.2014-1666.
4. Errata: RSV Policy Statement: Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. American Academy of Pediatrics. *Pediatrics.* December 2014; 134(6): 1221.
5. Respiratory syncytial virus infection (RSV): Trends and surveillance. Centers for Disease Control and Prevention website. Content source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral

Diseases. Available at http://www.cdc.gov/rsv/research/us-surveillance.html. Page last reviewed: June 26, 2018. Accessed September 14, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical Policy Title Table was updated. 2. Drug(s) Applied was updated. 3. Line of business policy applies was updated to All lines of business. 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. References was reviewed and updated. 6. Updated background: Palivizumab (Synagis®) is a respiratory syncytial virus (RSV) F protein inhibitor monoclonal antibody. 7. Updated dosing information: 15 mg/kg of body weight IM prior to commencement of the RSV season and remaining doses administered monthly throughout the RSV season	09/14/2020	12/07/2020