Synagis® (palivizumab)

When requesting Synagis® (palivizumab), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications or approved compendial uses and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

Synagis is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients with:

- A history of premature birth,
- Bronchopulmonary dysplasia (e.g., chronic lung disease),
- Hemodynamically significant congenital heart disease (CHD).

Approved Off-label Compendial Uses

Synagis is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients with:

- Congenital abnormality of the airway,
- A neuromuscular disorder,
- Immunocompromised status,
- A previous or upcoming cardiac transplantation.

Coverage Guidelines

The individual is requesting Synagis for the prevention of lower respiratory tract infection caused by respiratory syncytial virus (RSV).

Preterm infant
The individual must meet both of the following criteria for approval:

- Is born before 29 weeks, 0 days gestation (i.e., ≤ 28 weeks, 6 days gestation);
- Will be less than 12 months of age at the start of the RSV season.

Chronic lung disease of prematurity
The individual must meet all of the following criteria for approval:

- Is born before 32 weeks, 0 days gestation;
- Has required greater than 21% oxygen for at least the first 28 days after birth;
- Will be less than 12 months of age at the start of the RSV season OR will be less than 24 months of age at the start of the RSV season and has required medical therapy (e.g., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the second RSV season.

Congenital heart disease (CHD)
The individual must meet all of the following criteria for approval:
- Will be less than 12 months of age at the start of the RSV season;
- Synagis is prescribed by or in consultation with a cardiologist or intensivist;
- Has at least one of the following conditions:
  - Has hemodynamically significant cyanotic CHD; OR
  - Has acyanotic heart disease and is receiving medication to control heart failure and will require cardiac surgical procedures; OR
  - Has lesions that have been adequately corrected by surgery and continues to require medication for congestive heart failure; OR
  - Has moderate to severe pulmonary hypertension.

Anatomic Pulmonary Abnormalities or Neuromuscular disorders
The individual must meet both of the following criteria for approval:
- The individual's condition impairs the ability to clear respiratory secretions;
- Will be less than 12 months of age at the start of the RSV season.

Immunocompromised child
The individual must meet all of the following criteria for approval:
- Is/will be profoundly immunocompromised during the RSV season (e.g., receiving chemotherapy, hematopoietic stem cell or solid organ transplant);
- Will be less than 24 months of age at the start of the RSV season;
- Synagis is prescribed by or in consultation with an immunologist or an infectious disease specialist.

Cardiac transplant
The individual must meet all of the following criteria for approval:
- Has undergone or will undergo cardiac transplantation during the current RSV season;
- Will be less than 24 months of age at the start of the RSV season;
- Synagis is prescribed by or in consultation with a cardiologist, intensivist, or transplant physician.

Duration of Approval: Approve up to maximum 5 monthly doses

For off-season Synagis requests, authorization of one dose per request may be granted if the RSV activity for the requested region is greater than or equal to 10% with rapid antigen testing or greater than or equal to 3% with real-time polymerase chain reaction (PCR) test within two weeks of the intended dose according to the Central Disease Control (CDC) National Respiratory and Enteric Virus Surveillance System (NREVSS).

Dosing Recommendation

The recommended dose is 15 mg/kg of body weight, administered intramuscularly prior to commencement of the RSV season and remaining doses administered monthly throughout the RSV season.

References

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