UnitedHealthcare Community Plan

Synagis® Dosing and Prior Authorization Requirements

Synagis is the only monoclonal antibody approved by the Food and Drug Administration (FDA) for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV). As an immunoprophylaxis, Synagis can help reduce the risk of RSV-related hospitalizations for high-risk infants and children.

Synagis safety and efficacy has been established for these groups:

- Children with chronic lung disease of prematurity (formerly termed bronchopulmonary dysplasia)
- Infants with a history of premature birth which is less than or equal to 35 weeks gestational age
- Children with hemodynamically significant congenital heart disease[1]

RSV Season and Synagis Availability

RSV surveillance data suggests there is a seasonal peak for RSV activity, which typically occurs between November and March for most of the United States. The season's duration is five months in every region of the country.

The American Academy of Pediatrics (AAP) Recommendations for Synagis [2,3]

- Children who qualify for Synagis for the entire RSV season should receive monthly injections only between November and March.
- Synagis can be used to prevent complications of RSV infection in high-risk patients for a maximum of five doses one month apart. These doses should provide coverage during the peak of the season when prophylaxis is most effective.
- Infants born during the RSV season who qualify for Synagis need fewer than five doses for protection until the season ends in their region.
- Results from clinical trials indicate that five monthly doses of Synagis will result in serum concentrations at or above protective levels for most infants, well beyond the last dose. Five monthly doses of Synagis provides at least six months of protective serum antibody concentration.

Based on the AAP recommendations, UnitedHealthcare concludes that Synagis is unproven and not medically necessary when administered in these situations:

- Outside of the RSV season
- In excess of five doses per season
- In doses greater than needed to provide protection
- To children other than those defined as high risk

1. Product information. Synagis® (palivizumab). MedImmune, Inc.
2. AAP updates guidance on use of palivizumab for RSV prophylaxis (Policy Statement). AAP News 2014; 35:8 1.
3. AAP updates guidance on use of palivizumab for RSV prophylaxis (Technical Report). AAP News 2014; 35:8 1.

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Requesting Prior Authorization for Synagis

Prior authorization is required for outpatient Synagis administration. To avoid delays in treatment, please complete and fax the Synagis prior authorization form to our Pharmacy Prior Authorization Department at **866-940-7328**. The form is available at **UHCprovider.com > Prior Authorization and Notification > Clinical Pharmacy and Specialty Drugs > Community Plan Pharmacy Prior Authorization Forms.**

We will notify you by fax of our prior authorization decision. You can obtain Synagis from any network pharmacy, including BriovaRx, a network specialty pharmacy for UnitedHealthcare Community Plan members.

We're Here to Help

If you have questions for BriovaRx, please call **855-427-4682.**

If you have questions about the prior authorization process, please call our Pharmacy Prior Authorization Department at **800-310-6826.**

1. Product information. Synagis® (palivizumab). MedImmune, Inc.
2. AAP updates guidance on use of palivizumab for RSV prophylaxis (Policy Statement). AAP News 2014; 35:8 1.
3. AAP updates guidance on use of palivizumab for RSV prophylaxis (Technical Report). AAP News 2014; 35:8 1.

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