UnitedHealthcare Community Plan

Synagis® Dosing and Prior Authorization Requirements

Synagis is a therapy indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in children at high risk of RSV disease. Its safety and efficacy were established in children with chronic lung disease of prematurity (formerly termed bronchopulmonary dysplasia), infants with a history of premature birth (less than or equal to 35 weeks gestational age), and children with hemodynamically significant congenital heart disease.[1] Immunoprophylaxis with Synagis can help reduce the risk of RSV-related hospitalizations for high-risk infants and children.[2]

RSV Season and Synagis Availability

RSV surveillance data suggests there's a seasonal peak for RSV activity, typically between November and March for most of the United States. The onset may vary in some regions of the country but the duration in all areas is five months.

American Academy of Pediatrics (AAP) Recommendations for Synagis [3,4]

- Children who qualify for Synagis for the entire RSV season should receive monthly injections only during those five months.
- 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 the prophylaxis is most effective.
- Infants born during 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 the five doses per season
- In doses greater than needed to provide protection
- To children other than those defined as high risk

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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 a Synagis prior authorization form to our Pharmacy Prior Authorization Department at **866-940-7328**. You can find the form at UHCprovider.com > Prior Authorization and Notification > Clinical Pharmacy and Specialty Drugs > Community Plan Pharmacy Prior Authorization Forms.

We'll notify you by fax of our prior authorization decision. If your request is approved, we will coordinate Synagis delivery through our contracted specialty pharmacy provider, BriovaRx.

We're Here to Help

If you have questions about Synagis delivery, please contact BriovaRx at **855-427-4682.** If you have questions about the prior authorization process, please call us at **800-310-6826.** Thank you.

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

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