Synagis dosing and prior authorization requirements

Synagis® is a monoclonal antibody used to help prevent 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.

The safety and efficacy of Synagis has been established for the following 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]

Respiratory syncytial virus 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 5 months in every region of the country. The onset may vary in some regions of the country, but the duration in all areas is 5 months.

American Academy of Pediatrics recommendations for Synagis[2,3]

- Children who qualify for Synagis for the entire RSV season should receive monthly injections only during those 5 months
- Synagis can be used to prevent complications of RSV infection in high-risk patients for a maximum of 5 doses, 1 month apart. These doses should provide coverage during peak season when prophylaxis is most effective.
- Infants born during RSV season who qualify for Synagis need fewer than 5 doses for protection until the season ends in their region
- Results from clinical trials indicate that 5 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 provide at least 6 months of protective serum antibody concentration.

Based on the American Academy of Pediatrics recommendations, UnitedHealthcare concludes that Synagis is unproven and not medically necessary when administered in the following situations:

- Outside of the RSV season
- In excess of the 5 doses per season
- In doses greater than needed to provide protection

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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 prior authorization form to our Pharmacy Prior Authorization department at 866-940-7328. You can find the form at **Community Plan Pharmacy Prior Authorization For Prescribers.**

We'll send you a fax of our prior authorization decision. If your request is approved, we'll coordinate Synagis delivery through our contracted specialty pharmacy provider, Optum Specialty Pharmacy.

Questions? We're here to help.

For questions about Synagis delivery, please call Optum Specialty Pharmacy at 855-427-4682, 7 a.m.–11 p.m. CT, 7 days a week. For questions about the prior authorization process, please call us at **800-310-6826,** 7 a.m.–10 p.m. CT, Monday-Friday and Saturday 8 a.m.–5 p.m. You can also go to **prior authorizations** to learn more.

[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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