

Clinical Policy: palivizumab (Synagis)

Reference Number: NM.CP.PHAR.10

Effective Date: 1/1/19

Last Review Date: 1/11/23

[Revision Log](#)

Description and FDA Approved Indication(s)

Palivizumab (Synagis) is a recombinant humanized mouse immunoglobulin monoclonal antibody which provides passive immunity against respiratory syncytial virus (RSV).

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.*

Product Availability

Intramuscular Solution for Injection

Brand: Synagis (palivizumab) single-dose vials: 100 mg/1 ml & 50 mg/0.5 ml

Policy/Criteria

Western Sky Community Care (WSCC) follows the criteria of the [New Mexico Pediatric Society \(NMPS\)](#) for approval of Synagis. The universal [New Mexico Synagis Prior Authorization/Statement of Medical Necessity/Order Form](#) **is required to be used and submitted by all providers.** RSV season is determined yearly by the New Mexico Pediatric Society (NMPS).

Synagis is medically necessary when the following criteria are met:

For Initial Therapy:

A. RSV prophylaxis (dosed 15 mg/kg IM monthly). **At least one of the following criteria are met** with supporting documentation and diagnosis codes.

- 1) <12 months old (at the start of RSV season defined by NMPS) and with **hemodynamically significant congenital heart disease (CHD)**
- 2) Diagnosis of chronic lung disease (CLD) **(a or b):**

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- a. <12 months old (at the start of RSV season as defined by NMPS), < 32 weeks 0 days with **chronic lung disease (CLD) of prematurity** requiring oxygen of FiO₂ >21% for >28 days after birth
 - b. <24 months with **chronic lung disease (CLD)** and continues on supplemental oxygen, diuretic or corticosteroid
- 3) <24 months old (at the start of RSV season as defined by NMPS) and **with Severe Immunodeficiency** (provider must specify type)
 - 4) <12 months old (at the start of RSV season as defined by NMPS) **with Severe Neuromuscular Disease with inability to clear secretions**
 - 5) <12 months old (at the start of RSV season as defined by NMPS) with **congenital abnormality of the airway** with inability to clear secretions
 - 6) <12 months old (at the start of RSV season as defined by NMPS) and **born at 28 weeks, 6 days gestation or less**
 - 7) <24 months old (at the start of RSV season as defined by NMPS) and will undergo cardiac transplantation during the RSV season

Approval duration: Approve quantity/doses as recommended by AAP guidance and NM Pediatric Society through the end of the RSV season.

B. Other diagnoses/indications: Refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

For Continued therapy:

A. RSV prophylaxis (must meet all):

- 1) Member meets one of the following **(a or b)**:
 - a. Currently receiving medication or member has previously met initial approval criteria;
 - b. Documentation supports that member is currently receiving Synagis
- 2) Dose does not exceed 15 mg/kg IM monthly.

Approval duration: Approve quantity/doses as recommended by AAP guidance and NM Pediatric Society through the end of the RSV season.

B. Other diagnoses/indications: Refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

Appendices

Appendix A:

Dosage and Administration:

Indication	Dosing Regimen	Maximum Dose
RSV prophylaxis in pediatric patients	15 mg/kg IM monthly	15 mg/kg/month; up to 5 doses per typical RSV season (1 extra dose if cardio-pulmonary bypass)

References

1. Synagis Prescribing Information. Gaithersburg, MD: MedImmune, LLC; November 2021. Available at <https://synagishcp.com/synagis.pdf> . Accessed January 2023.
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. 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: October 28, 2022. Accessed January 2023.
5. New Mexico Pediatric Society (NM Chapter of American Academy of Pediatrics). Available at: <https://www.nmaap.org/>. Accessed January 2023.
6. New Mexico Synagis Prior Authorization/Statement of Medical Necessity/Order Form developed by New Mexico Pediatric Society. Available at: https://www.nmaap.org/_files/ugd/d4e41e_ec944c5877de4acd8b74f2da4f24717d.pdf
7. Updated Guidance: Use of palivizumab prophylaxis to prevent hospitalization from severe respiratory syncytial virus infection during the 2022-2023 RSV season. American Academy of Pediatrics. Last updated 11/17/2022. Available at: <https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/interim-guidance-for-use-of-palivizumab-prophylaxis-to-prevent-hospitalization/>. Accessed January 2023.

Revision Log

Reviews, Revisions, and Approvals	Date	Approval Date
New clinical policy created for WSCC based on New Mexico Pediatric Society	12/1/18	12/1/18
Changed “The 2018-2019 RSV season for NM ends on April 30 th , 2019” to “The 2018-2019 RSV season for NM ends on April 1st, 2019.” Per NM pediatric society update. Will inform P&T Committee next quarter.	3/21/19	3/21/19
Edited the RSV season for NM to reflect year 2019-2020.	9/24/19	
Approved by WSCC P&T Committee		10/9/19
Corrected Reference number (policy number) from NM.CP.PPA.10 to NM.CP.PHAR.10	10/15/19	
Reviewed and approved by WSCC P&T Committee		10/23/19
Removed specific dates for RSV season and reviewed and approved by WSCC P&T Committee.	1/29/20	1/29/20
Updated link to 2020-2021 Synagis PA Form and references.	10/13/20	
Reviewed and approved by WSCC P&T Committee		10/21/20
Annual Review. Reviewed and approved by WSCC P&T Committee		1/20/21
Updated approval duration to include as recommended by AAP and NM Pediatric Society through end of RSV season, in light of atypical RSV season for 2021-2022.	1/7/22	
Annual Review. Reviewed and approved by WSCC P&T Committee.		1/12/22
Annual Review. Updated link to 2022-2023 Synagis PA Form references. Reviewed and approved by WSCC P&T Committee.	1/9/23	1/11/23