Pharmacy Management Drug Policy

SUBJECT: Respiratory Syncytial Virus (RSV) Prophylaxis- Synagis (palivizumab), Beyfortus (nirsevimab) and Enflonsia (clesrovimab)
POLICY NUMBER: PHARMACY-51
EFFECTIVE DATE: 08/2008
LAST REVIEW DATE: 11/19/2025

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application		
Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☒ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☒ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☒ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Respiratory syncytial virus (RSV) is the leading cause of lower respiratory illness in children. The risk of serious RSV illness is highest among children with prematurity, chronic lung disease, congenital heart disease, multiple congenital anomalies and certain immunodeficiencies. In the United States, RSV infection accounts for more than 90,000 pediatric hospitalizations and 4,500 deaths annually.

Prophylaxis to prevent RSV infection in infants and children at increased risk for severe disease is available using Synagis (palivizumab), Beyfortus (nirsevimab) and Enflonsia (clesrovimab):

Synagis is an intramuscularly administered monoclonal antibody preparation. It is administered in a dose of 15 mg/kg once a month during the RSV season (usually considered beginning around November and terminating around the beginning of April). Number of doses varies based on risk factors, gestational age, and age at the start of season.

In recent years, the national median duration of RSV season has been 17 weeks or less. For most children in the appropriate high-risk categories, five monthly doses of Synagis will result in substantially more than 20 weeks of protective serum antibody concentrations for most of the RSV season, even with variation in season onset and conclusion.

Beyfortus and **Enflonsia** are intramuscularly administered monoclonal antibody preparations, recommended to be given to patients younger than 8 months old born during or entering their *first* RSV season. **Beyfortus** is also indicated for infants 8 months through 24 months entering their second RSV season who remain at high risk of severe RSV disease. A single dose of Beyfortus or Enflonsia given prior to the start of or during the RSV season provides a duration of protection of at least 5 months, enough to cover the length of the typical RSV season. **Please note: Beyfortus and Enflonsia are covered without prior authorization.**

Start and Duration of RSV prophylaxis therapy *varies by regional and seasonal rates of infection. CDC reporting of percent positive PCR testing for specific regions will be monitored throughout the season. Typically, a 3% PCR positivity rate is considered epidemic*

Current levels can be found at Respiratory Virus Activity Levels (cdc.gov) except where noted otherwise

On December 31, 2025, SYNAGIS (palivizumab) will no longer be manufactured, distributed, or available for purchase. This discontinuation applies to all settings of care and indicated patient populations, including infants with a history of premature birth (<35 weeks gestational age), those with bronchopulmonary dysplasia (BPD), and those with congenital heart disease (CHD).

The prior authorization approval of SYNAGIS will NOT be authorized due to the product discontinuation and unavailability. No prior authorization is required for BEYFORTUS and ENFLONSIA.

POLICY GUIDELINES:

1. Synagis will not be approved in the same RSV season for any patients that have already received Beyfortus or Enflonsia. Per the FDA labeling for Beyfortus and Enflonsia, Palivizumab should not be administered to infants who have already received Beyfortus or Enflonsia in the same season.
2. Prior authorization is contract dependent.
3. Synagis is paid under the medical benefit.
4. All indications other than those listed in the policy section above are not covered.
5. Synagis Prophylaxis against RSV should be initiated at the onset of the RSV season and terminated at the end of the RSV season. In most seasons in the Northeast, the start of the season occurs mid-November, and ends mid-March to April 1. For those children meeting criteria for 5 monthly doses, the last dose should be administered at the beginning of March, which will provide protection through April.
6. The number of Synagis doses approved will be based on start date of the initial dose. Doses for months outside of the Synagis season will not be approved. For infants born during the RSV season, fewer than 5 monthly doses may be needed.
    a. For individuals who reside in states outside of New York, approval will be based upon RSV trends within that state.
7. Currently policy guidelines are based on available RSV trends and guidance from the American Academy of Pediatrics (AAP) guidelines. This information will be regularly reviewed and subject to change based on evolving evidence and guidance.
8. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
9. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.
10. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, imaging and other objective or subjective measures of benefit which support continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment

alternatives as they become available (i.e., generics, biosimilars, or other guideline supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
- Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition.

11. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
12. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
13. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html

Synagis Approval Time Periods:

Line of Business	Medical approval time-period
SafetyNet (Medicaid, HARP, CHP, Essential Plan)	Maximum of 5 doses through 3/31/2026
Commercial/Exchange	Maximum of 5 doses through 3/31/2026
Medicare	Maximum of 5 doses through 3/31/2026

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

HCPCS:

Drug Name	J-Code (If assigned)
Synagis	90378
Beyfortus	90380, 90381
Enflonsia	90382

UPDATES:

Date	Revision
11/19/2025	Revised
11/13/2025	P&T Committee Review & Approval
10/01/2025	Revised
08/29/2025	Revised
07/25/2025	Revised
03/06/2025	Revised
12/19/2024	Revised
11/21/2024	P&T Committee Review & Approval
09/13/2024	Revised
06/25/2024	Revised
06/20/2024	Revised
11/30/2023	P&T Committee Review & Approval
11/09/2023	Reviewed
10/26/2023	Revised
10/20/2023	Revised
09/22/2023	Revised
09/12/2023	Revised
08/10/2023	Revised
11/17/2022	P&T Committee Review & Approval
11/2022	Revised
10/2022	Revised
1/2022	Revised
11/2021	P&T Committee Review & Approval
8/2021	Revised
07/2021	Revised
06/30/2021	Revised
06/2021	Revised
05/2021	Revised
03/2021	Revised
11/2020	P&T Committee Review & Approval
08/20	Reviewed
08/19	Revision
10/18	Revision
10/17	Reviewed
9/16	Revised
10/15	Revised
9/15	Revised
8/14	Revised
10/13	Reviewed
9/12	Revised
9/11	Reviewed
9/10	Reviewed
10/09	Revised
9/09	Revised
9/08	Revised

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