



MEDICAL COVERAGE POLICY

SERVICE: Nirsevimab-alip (Beyfortus™)

Policy Number: 305

Effective Date: 1/1/2025

Last Review: 10/14/2024

Next Review: 10/14/2025

Important note: Unless otherwise indicated, medical policies will apply to all lines of business.

Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.

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PRIOR AUTHORIZATION: Required

POLICY: Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for details.

For Medicare plans, please refer to appropriate Medicare NCD (National Coverage Determination) or LCD (Local Coverage Determination). Medicare NCD or LCD specific InterQual criteria may be used when available. If there are no applicable NCD or LCD criteria, use the criteria set forth below.

For Medicaid plans, please confirm coverage as outlined in the [Texas Medicaid Provider Procedures Manual | TMHP](#) (TMPPM). Texas Mandate HB154 is applicable for Medicaid plans.

BSWHP members who meet the criteria below may be eligible to receive nirsevimab-alip (Beyfortus™) during the Respiratory Syncytial Virus (RSV) season. These criteria are based on the criteria established by the Centers for Disease Control and Prevention (CDC) and Advisory Committee on Immunization Practices (ACIP) as published in the Immunization Schedules.

Nirsevimab (Beyfortus™) may be medically necessary for the prevention of RSV when both criteria are met:

1. The member meets CDC/ACIP recommendations as defined by one of the following:
 - a. The member is younger than 8 months of age born during or entering their first RSV season and meet one of the following:
 - i. Pregnant parent did not receive RSVpreF vaccine; OR
 - ii. Pregnant parent's RSVpreF vaccination status is unknown; OR
 - iii. Born <14 days after the pregnant parent's RSVpreF vaccination; OR
 - iv. Born to pregnant people who might not have mounted an adequate immune response to vaccination (eg, persons with immunocompromising conditions) or who have conditions associated with reduced transplacental antibody transfer (eg, persons living with HIV infection); OR
 - v. Experienced loss of transplacentally acquired antibodies, such as those who have undergone cardiopulmonary bypass or extracorporeal membrane oxygenation; OR



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- vi. Substantially increased risk for severe RSV disease (eg, hemodynamically significant congenital heart disease or intensive care admission requiring oxygen at hospital discharge)

OR

- b. The member is 8 to 19 months of age entering their second RSV season with increased risk for severe RSV disease as defined by one of the following:
 - i. Children who were born prematurely and have chronic lung disease of prematurity requiring medical support (e.g., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before start of the second RSV season
 - ii. Children with severe immunocompromise
 - iii. Children with cystic fibrosis with weight for length <10th percentile or manifestation of severe lung disease (e.g., previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable)
 - iv. American Indian and Alaska Native children

OR

- c. The member is undergoing cardiac surgery with cardiopulmonary bypass during or entering their first or second RSV season are eligible for an additional dose of nirsevimab after surgery.

AND

- 2. The member has received fewer than five doses of palivizumab (Synagis®) in the current RSV season.

During periods of nirsevimab (Beyfortus™) limited availability, the CDC/ACIP interim recommendations may differ from this policy. BSWHP expects health care providers to apply the interim recommendations at their discretion based on nirsevimab (Beyfortus™) availability.

Newer recommendations from the AAP or ACIP (Advisory Committee on Immunization Practices) on palivizumab not listed in this policy will be followed for medical necessity.

BACKGROUND:

Nirsevimab-alip (Beyfortus™) is a respiratory syncytial virus (RSV) F protein-directed fusion inhibitor monoclonal antibody indicated for the reduction of lower respiratory tract disease caused by RSV. The CDC and ACIP publish recommendations for use of nirsevimab within immunization schedules. Further guidance is from the American Academy of Pediatrics (AAP) regarding use of nirsevimab and palivizumab.

Per AAP/CDC recommendations, if nirsevimab is not available or not feasible to administer, high-risk infants who are recommended to receive palivizumab in the first or second year of life should receive



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palivizumab, as previously recommended, until nirsevimab becomes available. These children should receive palivizumab per AAP recommendations.

CODES:

Important note: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes:	90380 Respiratory syncytial virus, monoclonal antibody, seasonal dose; 0.5 mL dosage, for intramuscular use 90381 Respiratory syncytial virus, monoclonal antibody, seasonal dose; 1 mL dosage, for intramuscular use
HCPCS Codes:	
ICD10 codes:	
ICD10 Not covered:	

POLICY HISTORY:

Status	Date	Action
New	10/26/2023	New policy
Updated	10/14/2024	Updated to reflect most recent AAP/ACIP recommendations used.

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. BSWHP will continue to review clinical evidence related to this policy and make modifications based upon the evolution of the published clinical evidence. Should additional scientific studies become available, and they are not included in the list, please forward the reference(s) to BSWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

- American Academy of Pediatrics. "ACIP and AAP Recommendations for the Use of the Monoclonal Antibody Nirsevimab for the Prevention of RSV Disease." August 15, 2023. <https://publications.aap.org/redbook/resources/25379/> Accessed October 19, 2023.
- American Academy of Pediatrics Red Book 2024: 713-721.
- American Academy of Pediatrics. Resources: AAP Recommendations for the Prevention of RSV Disease in Infants and Children. February 21, 2024. <https://publications.aap.org/redbook/resources/25379/AAP-Recommendations-for-the-Prevention-of-RSV>. Accessed August 28, 2024.
- Beyfortus™ (nirsevimab-alip) [prescribing information]. Swiftwater, PA: Sanofi Pasteur, Inc. July 2023.



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5. Caserta, Mary T et al. "Palivizumab Prophylaxis in Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection." *Pediatrics* vol. 152,1 (2023): e2023061803. doi:10.1542/peds.2023-061803
6. Centers for Disease Control and Prevention. Child and Adolescent Immunization Schedule by Age – Recommendations or Ages 18 Years or Younger, United States, 2023. August 3, 2023. <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>. Accessed October 20, 2023.
7. Centers for Disease Control and Prevention. Limited Availability of Nirsevimab in the United States—Interim CDC Recommendations to Protect Infants from Respiratory Syncytial Virus (RSV) during the 2023–2024 Respiratory Virus Season. October 23, 2023. <https://emergency.cdc.gov/han/2023/han00499.asp>. Accessed October 24, 2023.
8. Centers for Disease Control and Prevention. Respiratory Syncytial Virus (RSV) Immunizations. August 30, 2023. <https://www.cdc.gov/vaccines/vpd/rsv/index.html>. Accessed October 20, 2023.
9. Jenco, Melissa. "AAP releases nirsevimab guidance, calls for continued access to palivizumab." *AAP News*. August 15, 2023. <https://publications.aap.org/aapnews/news/25400/AAP-releases-nirsevimab-guidance-calls-for>. Accessed October 19, 2023.

Note:

Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plan.

RightCare STAR Medicaid is offered through Scott and White Health Plan in the Central Texas Medicaid Rural Service Area (MRSA); FirstCare STAR is offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSA; and FirstCare CHIP is offered through FirstCare in the Lubbock Service Area.