BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE: 11/16/23**
SECTION: SPECIALTY MEDICAL DRUGS	**LAST REVIEW DATE:**
	CURRENT EFFECTIVE DATE: 11/16/23
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NEXT ANNUAL REVIEW DATE: 4TH QTR 2024	**ARCHIVE DATE:**

BEYFORTUS™ (nirsevimab-alip)

Non-Discrimination Statement is located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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Criteria:

Refer to FDA website for current indications and dosage.

- **Criteria for therapy:** Beyfortus (nirsevimab-alip) for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual is **ONE** of the following:

     - Less than 8 months of age born during or entering their first RSV season
     - Aged 8 through 24 months who are at increased risk of severe RSV disease entering their second RSV season defined as individual with **ONE** of the following:

       a. Chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 5-month period before the start of the second RSV season
       b. Severely immunocompromised
       c. Cystic fibrosis who has either:

          - Manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable)
          - Weight-for-length less than 10th percentile

       d. American Indian or Alaska Native

  2. Individual has not received a complete (i.e., 5 doses) Synagis (palivizumab) series during the same RSV season (see Definitions section)

  3. There are **NO** contraindications, including history of serious hypersensitivity reactions, including anaphylaxis, to nirsevimab-alip or to any of the excipients

  Approval duration: One Beyfortus dose per RSV Season [Note: additional doses may be approved for individuals undergoing cardiac surgery with cardiopulmonary bypass (see Definitions section)

  Individual < 8 months in first RSV season
  - 50 mg if less than 5 kg in body weight
  - 100 mg if greater than or equal to 5 kg in body weight.

  Individual 9-24 months during second RSV season
  - 200 mg (2 x 100 mg injections)

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- Beyfortus (nirsevimab-alip) for all other indications not previously listed is considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:

  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting.

  These indications include, *but are not limited to:*

  - Treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, or duration.

Description:

Beyfortus (nirsevimab-alip) is a respiratory syncytial virus (RSV) F protein-directed fusion inhibitor indicated for the prevention of RSV lower respiratory tract disease in:

- Neonates and infants born during or entering their first RSV season.
- Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

Although the United States Food and Drug Administration (FDA) approval for Beyfortus is up to 24 months of age, the Advisory Committee on Immunization Practices (ACIP) has recommended nirsevimab for all infants aged < 8 months who are born during or entering their first RSV season and for infants and children aged 8–19 months who are at increased risk for severe RSV disease and are entering their second RSV season. On the basis of pre–COVID-19 pandemic patterns, nirsevimab could be administered in most of the continental United States from October through the end of March. Nirsevimab can prevent severe RSV disease among infants and young children at increased risk for severe RSV disease. Infants born shortly before or during RSV season should receive nirsevimab within 1 week of birth. Nirsevimab administration can occur during the birth hospitalization or in the outpatient setting. Optimal timing for nirsevimab administration is shortly before the RSV season begins.

Because the timing of the onset, peak, and decline of RSV activity might vary geographically, providers can adjust administration schedules based on local epidemiology. Providers should consult state, local, or territorial guidance on timing of nirsevimab administration.

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Definitions:

Beyfortus versus Synagis: Some considerations for the 2023–2024 RSV season with regard to SYNAGIS (palivizumab) versus BEYFORTUS (nirsevimab) administration for high-risk infants during the same RSV season

1. If nirsevimab is administered, palivizumab should not be administered later that season.
2. If palivizumab was administered initially for the season and <5 doses were administered, the infant should receive 1 dose of nirsevimab. No further palivizumab should be administered.
3. If palivizumab was administered in season 1 and the child is eligible for RSV prophylaxis in season 2, the child should receive nirsevimab in season 2, if available. If nirsevimab is not available, palivizumab should be administered as previously recommended.

Children Undergoing Cardiac Surgery with Cardiopulmonary Bypass:

For children undergoing cardiac surgery with cardiopulmonary bypass, an additional dose of Beyfortus is recommended as soon as the child is stable after surgery to ensure adequate nirsevimab-alip serum levels.

First RSV Season:

- If surgery is within 90 days after receiving Beyfortus, the additional dose should be based on body weight at the time of the additional dose.
- If more than 90 days have elapsed since receiving Beyfortus, the additional dose should be 50 mg regardless of body weight.

Second RSV Season:

- If surgery is within 90 days after receiving Beyfortus, the additional dose should be 200 mg, regardless of body weight.
- If more than 90 days have elapsed since receiving Beyfortus, the additional dose should be 100 mg, regardless of body weight

History:	Date:	Activity:
Pharmacy and Therapeutics Committee	11/16/23	Approved guideline
Clinical Pharmacist	10/03/23	Development

Coding:

CPT: 90380, 90381, 93680, 93681

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Resources:

Literature reviewed 11/16/23. We do not include marketing materials, poster boards and non-published literature in our review.

1. American Academy of Pediatrics. ACIP and AAP recommendations for the use of monoclonal antibody nirsevimab for the prevention of RSV disease. Red Book Online. Published August 15, 2023. Accessed October 04, 2023. https://publications.aap.org/redbook/resources/25379?autologincheck=redirected

2. Beyfortus (nirsevimab-alip) prescribing information, revised by Alnylam Pharmaceuticals, Inc. 07/2023. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed October 03, 2023.

3. Jones JM, Fleming-Dutra KE, Prill MM, et al. Use of nirsevimab for the prevention of respiratory syncytial virus disease among infants and young children: recommendations of the Advisor Committee on Immunization Practices – United States, 2023. *MMWR* 2023;72:920-925.

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Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html