Medical Drug Clinical Criteria

Subject:	Beyfortus (nirsevimab)		
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Overview

This document addresses the use of Beyfortus (nirsevimab), a respiratory syncytial virus (RSV) F protein-directed fusion inhibitor approved by the Food and Drug Administration (FDA) for the prevention of RSV lower respiratory tract disease in neonates and infants born during or entering their first RSV season and pediatric individuals up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

In August 2023, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) provided recommendations on the use of Beyfortus for prevention of RSV lower respiratory tract disease. A summary of the ACIP recommendations follows:

First RSV Season Prophylaxis
• Infants aged <8 months born during or entering their first RSV season are recommended to receive one dose of Beyfortus • 50 mg for infants < 5 kg and 100 mg for infants 5 kg or greater
Second RSV Season Prophylaxis
• Children aged 8–19 months who are at increased risk of severe RSV disease and entering their second RSV season are recommended to receive one 200 mg dose of Beyfortus: • Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season • Children with severe immunocompromise • Children with cystic fibrosis who have 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) or weight-for-length <10th percentile • American Indian and Alaska Native children

In September 2023, ACIP recommended use of maternal vaccination with Abrysvo during 32 through 36 weeks gestation to prevent RSV lower respiratory tract infection in infants. ACIP advised that either maternal vaccination or Beyfortus is recommended for RSV prevention in infants but both agents in combination are not needed in most cases.

In February 2024, the American Academy of Pediatrics (AAP) issued guidance for prevention of RSV disease. AAP recommendations for use of Beyfortus are in alignment with the ACIP recommendations. Additionally, AAP states that Beyfortus is preferred over Synagis because of its efficacy, duration and convenience.

Specific information about national and regional RSV trends, especially pertaining to the peak variations in Florida and Alaska, is available from the National Respiratory and Enteric Virus Surveillance System (NREVSS) at: http://www.cdc.gov/surveillance/nrevss/rsv/index.html.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Beyfortus (nirsevimab)

Requests for Beyfortus (nirsevimab) may be approved if the following criteria are met:

I. Individual is using for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease;

AND

II. Individual is less than 8 months of age and has not previously received a dose of Beyfortus (ACIP);

OR

III. Individual is 8 – 19 months of age and entering their second RSV season (ACIP); **AND**

IV. Individual meets one of the following criteria:

- A. Documentation is provided indicating the individual was a preterm infant born at less than 32 weeks, 0 days gestation who required at least 28 days of oxygen after birth AND continues to require medical intervention within 6 months of the start of the second RSV season (including supplemental oxygen, chronic corticosteroid therapy or diuretics); **OR**
- B. Documentation is provided indicating cystic fibrosis with severe lung disease (history of hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable) or weight for length less than tenth percentile; **OR**
- C. Documentation is provided indicating profoundly immunocompromised (including severe combined immunodeficiency, advanced acquired immunodeficiency syndrome, undergoing organ or hematopoietic stem cell transplant, or an absolute lymphocyte count of less than 100 cells/mm^3); **OR**
- D. Individual is an American Indian; **OR**
- E. Individual is an Alaska Native.

Requests for Beyfortus (nirsevimab) may not be approved for the following:

I. Treatment of RSV disease; **OR**

II. Individual has received five doses or more of Synagis (palivizumab) during the same RSV season; **OR**

III. May not be approved when the above criteria are not met and for all indications.

Approval duration: Beyfortus approval is limited to shortly before or during RSV season as determined by CDC surveillance data (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) or local health department. One dose may be approved during the months of October through March

Quantity Limits

Beyfortus (nirsevimab) Quantity Limits

Drug	Dosing Limit	Quantity Limit
Beyfortus (nirsevimab) 50 mg/0.5 mL	First RSV season: one 50 mg syringe if less than 5 kg	One syringe, one time only
Beyfortus (nirsevimab) 100 mg/mL	First RSV season: one 100 mg syringe if 5 kg or greater	Two syringes per 6 months
	Second RSV season: two 100 mg syringes	
Override Criteria		
One additional dose may be approved for individuals undergoing cardiac surgery with cardiopulmonary bypass. I. First RSV season A. If surgery is within 90 days of receiving Beyfortus, may approve additional dose based on current body weight (one 50 mg syringe if less than 5 kg OR one 100 mg syringe if 5 kg or greater). B. If surgery is more than 90 days after receiving Beyfortus, may approve one 50 mg syringe. II. Second RSV season A. If surgery is within 90 days of receiving Beyfortus, may approve two 100 mg syringes. B. If surgery is more than 90 days after receiving Beyfortus, may approve one 100 mg syringe.		

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS	
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
96380	Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection, with counseling by physician or other qualified health care professional. *Inclusion of this code in the clinical policy is informational only and does not denote a request for pre or post service medical necessity review.
96381	Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection. *Inclusion of this code in the clinical policy is informational only and does not denote a request for pre or post service medical necessity review.
ICD-10 Diagnosis	
Z23	Encounter for immunization
Z29.11	Encounter for prophylactic immunotherapy for respiratory syncytial virus (RSV)

Document History

Revised: 8/16/2024

Document History:

- 8/16/2024 – Annual Review: Remove criteria to address maternal RSV vaccination. Wording and formatting changes. Coding Reviewed: No changes.
- 11/17/2023 – Select Review: Remove may not approve criteria for prior RSV infection. Add quantity limit override criteria for cardiopulmonary bypass. Coding Reviewed: No changes. Effective 10/6/2023 Remove CPT 96372. Added CPTs 96380, 96381.
- 10/2/2023 – Select Review: Update criteria to address maternal RSV vaccination. Update approval duration language. Coding Reviewed: Added CPTs 90380, 90381, 96372. Added ICD-10-CM Z23, Z29.11. Removed HCPCS J3490, J3590, J9999, C9399.
- 8/18/2023 – Annual Review: New clinical criteria and quantity limit for Beyfortus. Coding Reviewed: Added HCPCS J3490, J3590, J9999, C9399. All diagnoses pend.

References

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2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 7, 2024.
3. Domachowske J, Madhi SA, Simões EAF, et al. Safety of Nirsevimab for RSV in Infants with Heart or Lung Disease or Prematurity. *N Engl J Med*. 2022;386(9):892-894.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Griffin MP, Yuan Y, Takas T, et al. Single-Dose Nirsevimab for Prevention of RSV in Preterm Infants [published correction appears in N Engl J Med. 2020 Aug 13;383(7):698]. *N Engl J Med*. 2020;383(5):415-425.
6. Hammitt LL, Dagan R, Yuan Y, et al. Nirsevimab for Prevention of RSV in Healthy Late-Preterm and Term Infants. *N Engl J Med*. 2022;386(9):837-846.
7. 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 Advisory Committee on Immunization Practices (ACIP) – United States, 2023. MMWR Morb Mortal Wkly Rep. 2023;72:920-925.

8. Jones, JM, on behalf of Respiratory Syncytial Virus Vaccines - Pediatric/Maternal Work Group. Proposed clinical considerations for maternal RSVPreF vaccine and nirsevimab. ACIP Presentation Slides: September 22, 2023 Meeting. Available at https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-09-22/07-Mat-Peds-Jones-508.pdf. Accessed: July 11, 2024.
9. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.