Beyfortus (nirsevimab-alip) and Enflonsia (clesrovimab-cfor)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Respiratory syncytial virus (RSV) is a common (typically seasonal) viral respiratory infection and the leading cause of bronchiolitis and pneumonia in infants and young children. Almost all children will have an RSV infection by 2 years of age, and reinfection is common. For most, RSV causes mild cold-like symptoms. However, RSV can also lead to serious lower respiratory tract infections like bronchiolitis and pneumonia, especially in certain high-risk groups like premature infants, those with chronic lung disease or congenital heart disease, and children with weakened immune systems.

Beyfortus (nirsevimab-alip) is a monoclonal antibody that binds to the RSV fusion protein, preventing the virus from entering host cells.

In July 2022, the FDA approved Beyfortus (nirsevimab-alip) for all neonates and infants born during or entering their first RSV season based on these clinical trials. Beyfortus (nirsevimab-alip) is also approved for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. It offers a major advance in RSV prevention, moving from needing monthly injections of palivizumab in high-risk infants to a single dose providing season-long protection. In August 2022, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended Beyfortus (nirsevimab-alip) for all infants entering their first RSV season. For high-risk infants entering their second RSV season, ACIP recommends replacing monthly palivizumab injections with a single dose of Beyfortus (nirsevimab-alip), which provides similar protection.

In June 2025, the FDA approved Enflonsia (clesrovimab-cfor). Enflonsia (clesrovimab-cfor) is a monoclonal antibody with anti-RSV activity indicated for the prevention of RSV lower respiratory tract disease in neonates and infants who are born during or entering their first RSV season.

Beyfortus (nirsevimab-alip) and Enflonsia (clesrovimab-cfor) have an extended half-life, providing RSV protection for an entire season (about 5 months) from a single intramuscular (IM) injection.

While Beyfortus (nirsevimab-alip) and Enflonsia (clesrovimab-cfor) are intended to be administered once per season, an exception occurs in children undergoing cardiac surgery with cardiopulmonary bypass. In this case, an additional dose is required, and dosing is based on which season it is being administered in (first or second), time since last dose, and weight, if applicable (see Appendix A).

Definitions

"Advisory Committee on Immunization Practices (ACIP)" is a group within the Centers for Disease Control and Prevention (CDC) that provides advice and guidance on effective control of vaccine-preventable diseases.

"Bronchiolitis" is a common lung infection in young children and infants 3, usually caused by a virus like RSV. It inflames the bronchioles, which are small airways in the lungs.

"Cardiac Bypass Surgery" is a type of surgery that improves blood flow to the heart. Surgeons use blood vessels from another area of your body to bypass the damaged arteries.

"Chronological Age" refers to the amount of time since the infant's actual date of birth.

"Corrected Age" refers to the age of a child, corrected for prematurity. It's calculated by subtracting the number of weeks born before 40 weeks of gestation from the child's current age.

"Immunization" is the action of making a person immune to infection, typically by vaccination.

"Monoclonal Antibodies" are laboratory-made molecules that can mimic the immune system's ability to fight off harmful pathogens such as viruses.

"Palivizumab" is another monoclonal antibody used for RSV prevention in high-risk infants. It is typically given in monthly injections during RSV season.

"Pneumonia" is an infection that inflames the air sacs in one or both lungs, which may fill with fluid or pus. It can be caused by many different pathogens, including RSV.

"Respiratory Syncytial Virus (RSV)" is a common virus that causes infections in the lungs and respiratory tract. It's especially severe in infants and young children.

"RSV Prophylaxis" are measures taken to prevent RSV infection, which can include the use of vaccines or drugs like nirsevimab.

"[s]" indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Clinical Review

General Medical Necessity Criteria

The Plan considers Beyfortus (nirsevimab-alip) or Enflonsia (clesrovimab-cfor) medically necessary when ALL of the following criteria are met:

1. Administered shortly before OR during the RSV season (i.e., typically fall through spring, beginning on October 1 and concluding on March 31)[~] as defined by CDC surveillance data OR state/local health departments*; AND*

   [~]*The recommended timing of administration may vary by geography. In most of the continental United States, based on pre-COVID-19 patterns, administration from October through March would cover the typical RSV season. However, onset, peak, and decline of RSV activity can differ locally. Providers should consult CDC surveillance data, state/local health departments, or other*

guidance to determine optimal timing for their region. RSV seasonality in tropical climates and southern Florida may not follow continental patterns.

2. Request is for prevention of respiratory syncytial virus (RSV) lower respiratory tract disease*; AND*
3. Member has not previously received any RSV prophylaxis including Beyfortus (nirsevimab-alip)[↔⇋], Enflonsia (clesrovimab-cfor)[⇋], Synagis (palivizumab)[↕], other monoclonal antibody, or RSV vaccination*; AND*

   [↔]Prior administration of Beyfortus (nirsevimab-alip) is appropriate if a member has received it in their first RSV season and are eligible for a dose in their second RSV season (see Indication-Specific Criteria, Infants and children aged ≥8 months).

   [⇋]Additionally, a second dose of Beyfortus (nirsevimab-alip) or Enflonsia (clesrovimab-cfor) is appropriate in children undergoing cardiac surgery with cardiopulmonary bypass, see (Additional Doses After Cardiac Bypass Surgery).

   [↕]*If an infant or child started palivizumab but received less than 5 doses, the Plan will cover 1 dose of nirsevimab-alip or clesrovimab-cfor if requested, instead of completing the palivizumab regimen. No further palivizumab doses should be given. The Plan will cover transition to nirsevimab-alip or clesrovimab-cfor if partially through palivizumab regimen; however, the Plan will NOT cover overlapping nirsevimab-alip or clesrovimab-cfor and palivizumab (i.e., completed, 5 or more doses) in the same season.*
4. Member does not have active RSV infection or prior RSV infection in the current season*; AND*
5. The requested product is being prescribed at a dose and frequency that is within FDA approved labeling (see Appendix A) OR is supported by compendia or evidence-based published dosing guidelines for the requested indication*; AND*
6. The member meets the applicable Initial Indication-Specific Criteria listed below:

Initial Indication-Specific Criteria

Beyfortus (nirsevimab-alip) or Enflonsia (clesrovimab-cfor) for Infants aged <8 months[↕]

The Plan considers Beyfortus (nirsevimab-alip) or Enflonsia (clesrovimab-cfor) medically necessary when ALL of the following criteria are met:

7. The member meets the above General Medical Necessity Criteria; *AND*
8. The member is an infant aged <8 months who is born during or entering their first RSV season (as defined above in General Medical Necessity Criteria)*; AND*
9. The member meets ONE of the following:
   a. Maternal RSV vaccine was not received during pregnancy*; or*
   b. Maternal RSV vaccination status is unknown*; or*
   c. Maternal RSV vaccine was received and the infant was born less than (<) 14 days after maternal vaccination*; or*
   d. Maternal RSV vaccine was received more than or equal to (≥) 14 days prior to birth and meets ONE of the following:
      i. Infants born to mothers who may not mount an adequate immune response to RSV vaccination (e.g., people with immunocompromising conditions)*; or*

ii. Infants born to mothers who have medical conditions associated with reduced transplacental antibody transfer (e.g., people living with HIV infection)*; or*
iii. Infants who have undergone cardiopulmonary bypass or extracorporeal membrane oxygenation (ECMO), or exchange transfusion, leading to loss of maternal antibodies*; or*
iv. Infants with substantial increased risk for severe RSV disease (e.g., hemodynamically significant congenital heart disease, intensive care admission with a requirement of oxygen at discharge)*; or*
v. Other clinical rationale documented by the provider.

<u>If the above prior authorization criteria are met, the requested product will be authorized for a single dose.</u>[s]

[‡]*For preterm infants, chronological age rather than corrected age should be used to determine eligibility and timing of nirsevimab-alip or clesrovimab-cfor administration, per general best practices for immunization.*

<u>Beyfortus (nirsevimab-alip) for Infants and children aged ≥8 months</u>[‡]

The Plan considers <u>Beyfortus (nirsevimab-alip)</u> medically necessary when ALL of the following criteria are met:

6. The member meets the above General Medical Necessity Criteria; *AND*
7. The member is an infant or child aged 8–19 months entering their second RSV season (as defined above)*; AND*
8. The member is at increased risk for severe disease, defined as an infant or child characterized by ONE of the following:
    a. American Indian or Alaska Native children*; or*
    b. 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*; or*
    c. Children with cystic fibrosis who have either:
        i. 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*
        ii. weight-for-length less than (<) 10th percentile*; or*
    d. Children with severe immunocompromise.

<u>If the above prior authorization criteria are met, the requested product will be authorized for a single dose.</u>[s]

[‡]*Infants 8 months and older have likely experienced one RSV season and therefore have decreased risk of severe RSV disease compared to younger infants without prior exposure. Children 20 months and*

older have likely experienced two RSV seasons and have lower risk of severe RSV disease compared to younger children with only one RSV season.

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

Respiratory Syncytial Virus (RSV)

The Plan considers Beyfortus (nirsevimab-alip) medically necessary when ALL of the following criteria are met:

1. It has been at least 5 months since the previous authorization*; AND*
2. A new RSV season has started based on CDC/state/local health department data*; AND*
3. The member meets the above applicable General Medical Necessity Criteria and/or Initial Clinical Review for their second RSV season (as defined above)*; AND*
4. The member has not yet received any RSV prophylaxis in the current season.

If the above reauthorization criteria are met, the requested product will be authorized for a single dose.[s]

Additional Doses After Cardiac Bypass Surgery

ONE additional dose of Beyfortus (nirsevimab-alip) or Enflonsia (clesrovimab-cfor) after cardiac bypass surgery is considered medically necessary when:

1. Surgery occurs within current authorized RSV season (as defined above in General Medical Necessity Criteria)*; AND*
2. Additional age-appropriate dose is given within FDA approved labeling (see Appendix A) OR is supported by compendia or evidence-based published dosing guidelines for the requested indication.

Experimental / Investigational, or unproven[s]

Beyfortus (nirsevimab-alip) or Enflonsia (clesrovimab-cfor) for any other indication or use is considered experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Treatment of Respiratory Syncytial Virus (RSV) Infection. They are not intended for the treatment of RSV, only the prevention of an RSV infection during the season in which it is administered.
- For prevention of hospital-acquired RSV infection. Per the 2023 Advisory Committee on Immunization Practices, there is not enough evidence to support use for the prevention of hospital-acquired RSV infections, and it is not recommended for this indication.
- Enflonsia (clesrovimab-cfor) specifically is not indicated for children who remain vulnerable to RSV disease through their second RSV season.

Applicable Billing Codes

Table 1	
CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
90380	Beyfortus Respiratory syncytial virus, monoclonal antibody, seasonal dose; 0.5 mL dosage, for intramuscular use
90381	Beyfortus Respiratory syncytial virus, monoclonal antibody, seasonal dose; 1 mL dosage, for intramuscular use
90382	Enflonsia Respiratory syncytial virus, monoclonal antibody, seasonal dose, 0.7 mL, for intramuscular use
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
96380	Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection, with counseling by physician or other qualified health care professional
96381	Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection
S9562	Home injectable therapy, palivizumab or other monoclonal antibody for RSV, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

Table 2	
ICD-10 codes considered medically necessary with Table 1 (CPT/HCPCS) codes if criteria are met:	
Code	*Description*
Z29.11	Encounter for prophylactic immunotherapy for respiratory syncytial virus (RSV)

Table 3	
CPT/HCPCS Codes considered experimental, investigational, or unproven:	
Code	*Description*
90461	Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care

	professional; each additional vaccine or toxoid component administered (List separately in addition to code for primary procedure)
90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid)
90472	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); each additional vaccine (single or combination vaccine/toxoid) (List separately in addition to code for primary procedure)

Table 4	
ICD-10 codes considered experimental, investigational, or unproven with Table 3 (CPT/HCPCS) codes:	
Code	*Description*
Z23	Encounter for immunization

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Appendix A

Beyfortus (nirsevimab-alip) Dosing

- Administered as a one-time intramuscular injection available as a 50 mg/0.5 ml or 100 mg/1ml single-dose pre-filled syringe. The following dose recommendations are as follows:

Table 5: Recommended Dosage of Beyfortus for the First RSV Season [i.e., neonates (starting at birth) and infants born during or entering their first RSV season]

Body Weight at Time of Dosing	Recommended Dosage
Less than 5 kg	50 mg by IM injection
5 kg and greater	100 mg by IM injection

- Timing for Table 5

- For infants born during the RSV season, Beyfortus should be given within the first week of life (during the birth hospitalization or in the outpatient setting).
- For infants born outside of the RSV season, Beyfortus should be given shortly before the anticipated start of the local RSV season.
- Beyfortus may be given at any point during the RSV season in infants who have not yet received a dose.

Table 6: Recommended Dosage of Beyfortus for the Second RSV Season for Children Who Remain at Increased Risk for Severe RSV Disease (i.e., children up to 24 months of age, regardless of body weight, who remain vulnerable through their *second* RSV season)

Child's Age at Time of Dosing	Recommended Dosage
Up to 24 months of age	200 mg administered as two IM injections of (2 x 100 mg) at the same time

- Timing for Table 6
  - Shortly before the anticipated start of the local RSV season or at any point during the RSV season if the member has not yet received a dose.

- First and Second RSV Season 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. The recommended dosage of Beyfortus is administered as an IM injection.
  - 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. Refer to Table 5 for weight-based dosing.
    - 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.

<u>Enflonsia (clesrovimab-cfor) Dosing</u>

- Recommended dose for neonates and infants born during or entering their first RSV season is 105 mg administered as a single intramuscular (IM) injection.

- For neonates and infants born during the RSV season, administer Enflonsia once starting from birth. For infants born outside the RSV season, administer Enflonsia once prior to the start of their first RSV season considering the duration of protection provided by Enflonsia.
- Infants Undergoing Cardiac Surgery with Cardiopulmonary Bypass
    - During or entering their first RSV season, an additional 105 mg dose administered as an IM injection is recommended as soon as the infant is stable after surgery to ensure adequate clesrovimab-cfor serum levels.

Clinical Guideline Revision / History Information

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