Beyfortus (nirsevimab-alip)

Summary

Respiratory syncytial virus (RSV) is a common 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. 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.

Nirsevimab (Beyfortus) is a newly approved monoclonal antibody that binds to the RSV fusion protein, preventing the virus from entering host cells. It was designed specifically to have an extended half-life, providing RSV protection for an entire season from a single intramuscular injection. Nirsevimab was studied in several clinical trials in infants during their first RSV season and shown to significantly reduce RSV lower respiratory tract infections requiring medical care by 70-80% compared to placebo when given as a single dose. The most common side effects were rash and injection site reactions.

In July 2022, the FDA approved nirsevimab for all infants entering their first RSV season based on these clinical trials. 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 nirsevimab 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 nirsevimab, which provides similar protection.

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.

Medical Necessity Criteria for Authorization

The Plan considers **Beyfortus (nirsevimab-alip)** 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)[ℵ] as defined by CDC surveillance data **OR** state/local health departments***; AND***

   [ℵ]*The recommended timing of nirsevimab 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 nirsevimab, palivizumab↕, other monoclonal antibody, or RSV vaccination***; AND***

   ↕*If an infant or child started palivizumab but received less than 5 doses, the Plan will cover 1 dose of nirsevimab if requested, instead of completing the palivizumab regimen. No further palivizumab doses should be given. The Plan will cover transition to nirsevimab if partially through palivizumab regimen; however, the Plan will NOT cover overlapping nirsevimab 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 member meets the applicable indication-specific criteria listed below:

Infants aged <8 months↕

6. The member is an infant aged <8 months who are born during or entering their first RSV season (as defined above)***; AND***
7. Dosage and administration is within FDA approved labeling **OR** is supported by compendia or evidence-based published dosing guidelines for the requested indication.

a. Recommended Dosage:
    i. 50 mg IM injection for infants weighing <5 kg.
    ii. 100 mg IM injection for infants weighing ≥5 kg.
b. Timing:
    i. For infants born during the RSV season, nirsevimab should be given within the first week of life.
    ii. For infants born outside of the RSV season, nirsevimab should be given shortly before the anticipated start of the local RSV season.
    iii. Nirsevimab may be given at any point during the RSV season in infants who have not yet received a dose.

Infants and children aged ≥8 months[‡]

6. The member is an infant or child aged 8–19 months entering their second RSV season (as defined above)***; AND***
7. The member is at increased risk for severe disease, defined as an infant or child characterized by **ANY** of the following:
    a. American Indian or Alaska Native children***; or***
    b. 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. 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 <10th percentile***; or***
    d. severe immunocompromise***; AND***
8. Dosage and administration is within FDA approved labeling **OR** is supported by compendia or evidence-based published dosing guidelines for the requested indication.
    a. Recommended dosage: 200 mg administered as two 100 mg IM injections***; and***
    b. Timing: 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.

If the above prior authorization criteria are met, the requested product will be authorized for a single dose.

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

- *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.*

Medical Necessity Criteria for Reauthorization

Reauthorization for **ONE** dose of **Beyfortus (nirsevimab-alip)** may be granted when **ALL** of the following criteria are met:

1. It has been at least 6 months since the previous authorization***; AND***
2. A new RSV season has started based on CDC/state/local health department data***; AND***
3. Member continues to meet indication-specific criteria for their second RSV season (as defined above)***; AND***
4. Member has not yet received any RSV prophylaxis in the current season***; AND***
5. Dose and administration align with FDA-approved labeling for second RSV season:
    a. 200 mg IM as two 100 mg injections.

Additional Doses After Cardiac Bypass Surgery

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

1. Surgery occurs within current authorized RSV season (as defined above)***; AND***
2. Additional age-appropriate dose is given per FDA-approved labeling:
    a. If within 90 days of prior dose in season, additional dose should be weight-based for first season or 200 mg for second season***; AND***
    b. If over 90 days have passed since the prior dose in season, additional dose should be 50 mg for the first season or 100 mg for second season.

Experimental or Investigational / Not Medically Necessary

Beyfortus (nirsevimab-alip) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Treatment of Respiratory Syncytial Virus (RSV) Infection
- For prevention of hospital-acquired RSV infection

Applicable Billing Codes (HCPCS/CPT Codes)

Service(s) name	
CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
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
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
CPT/HCPCS Codes NOT considered medically necessary:	
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)
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
Z29.11	Encounter for prophylactic immunotherapy for respiratory syncytial virus (RSV)
ICD-10 codes NOT considered medically necessary:	
Code	*Description*
Z23	Encounter for immunization

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