SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Beyfortus™ (nirsevimab-alip) **(90380, 90381) (Medical)**

Prior authorization is NOT required for members < 8 months of age.

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Gestational Age at Birth: _____ **Weeks:** _____ **Days:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Beyfortus™ will be utilized during (or entering) the RSV season
- ❑ Member is 8 months to 19 months of age and at increased risk of severe RSV disease such as (**must select <u>ONE</u> of the following and submit chart note documentation)**:
  - ❑ Member has chronic lung disease (CLD) of prematurity (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 support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the second RSV season **(verified by pharmacy paid claims and/or chart notes):**
    - ❑ Chronic corticosteroid therapy: date of last use: _____
    - ❑ Diuretic therapy: date of last use: _____
    - ❑ Supplemental oxygen: date of last use: _____
  - ❑ Member has hemodynamically significant congenital heart disease (CHD) with **<u>ONE</u>** of the following:
    - ❑ Member < 12 months old at the start of RSV season with hemodynamically significant heart disease defined by **<u>ONE</u>** of the following:
      - ❑ Acyanotic CHD, receiving treatment for congestive heart failure (CHF) and requires cardiac surgery
      - ❑ Moderate to severe pulmonary hypertension (PH, PAH)
      - ❑ Cyanotic CHD and Beyfortus is recommended by a pediatric cardiologist
    - ❑ Member is in the first year or second year of life who are undergoing cardiac transplant or cardiac bypass **<u>DURING</u>** the RSV season
  - ❑ Member is severely immunocompromised
  - ❑ Member has neuromuscular disorder
  - ❑ Member has cystic fibrosis with 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
  - ❑ Member is Alaska Native
  - ❑ Member is American Indian
- ❑ Member has **<u>NOT</u>** received a dose of Enflonsia™ (clesrovimab)
- ❑ Member has **<u>NOT</u>** received 5 or more doses of palivizumab (Synagis®) for the current RSV season
- ❑ Beyfortus™ will **<u>NOT</u>** be administered to members who have received maternal RSV vaccination during current pregnancy
- ❑ Beyfortus™ will **<u>NOT</u>** be administered to members who have received maternal RSV vaccination and gave birth to an infant born greater than 14 days after maternal vaccination

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- ❑ Beyfortus™ will **NOT** be used for prophylaxis in members with verified RSV infection previously in the same RSV season
- ❑ Beyfortus™ will **NOT** be used for treatment of RSV
- ❑ Member has **NOT** experienced prior serious hypersensitivity reaction to any component of Beyfortus™

Recommended Dosing and Quantity Limits:

Beyfortus™ is available as 50 mg/0.5 mL in a single-dose pre-filled syringe and 100 mg/mL in a single-dose pre-filled syringe.

RSV Season	Dosing and Quantity Limit
First RSV season:	For infants ages < 8 months OR ≤ 90 days post cardiac surgery: • One x 50 mg prefilled syringe for infants weighing < 5 kg (< 11 lb) • One x 100 mg prefilled syringe for infants weighing ≥ 5 kg (≥ 11 lb)
Second RSV season:	For children ages 8 months to 19 months OR > 90 days post cardiac surgery: • Two x 100 mg prefilled syringes (administered at the same time)

- **For children Undergoing Cardiac Surgery with Cardiopulmonary Bypass, an additional dose of Beyfortus™ may be needed.**

ACIP/AAP considerations for the 2023-2024 RSV season with regard to palivizumab versus nirsevimab administration for high-risk infants during the same RSV season.

- If nirsevimab is administered, palivizumab should not be administered later that season.
- 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.
- 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.

References:

1. American Academy of Pediatrics. Respiratory Syncytial Virus. Available at: https://publications.aap.org/redbook/resources/25379/ACIP-and-AAP-Recommendations-for-Nirsevimab Last reviewed : August 15,2023. Accessed September 11, 2023.
2. Centers for Disease Control and Prevention. RSV in infants and young children. Reviewed August 4, 2023. Available at: https://www.cdc.gov/rsv/high- risk/infants-young-children.html. Last reviewed: August 15, 2023. Accessed September 11, 2023.
3. Griffin MP, Yuan Y, Takas T, et al. Single-dose nirsevimab for prevention of RSV in preterm infants. N Engl J Med 2020; 383:415-25. DOI: 10.1056/NEJMoa1913556.
4. 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; 386:837-46. DOI: 10.1056/NEJMoa2110275.

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Medication being provided by (check applicable box(es) below):

- ❑ **Physician's office** **OR** ❑ **Specialty Pharmacy**

For urgent reviews, practitioners should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.