AvMed

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 1-877-535-1391**. 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: Enflonsia™ (clesrovimab-cfor) **(90382) (Medical)**

Prior authorization is NOT required for members < 8 months of age. Enflonsia is available through the Vaccines For Children (VFC) program.

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

Member Name: _____

Member AvMed #: _____ **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.

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.

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- ❑ Enflonsia™ will be utilized for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants entering their first RSV season.
- ❑ Member is 8 months to 12 months of age at time of request. **NOTE:** The safety and effectiveness of Enflonsia™ have not been established in children older than 12 months of age.
- ❑ Documentation has been submitted to confirm **ALL** the following criteria:
  - ❑ Member has **NOT** previously received a nirsevimab-alip (Beyfortus™) or palivizumab ((Synagis®) dose
  - ❑ Enflonsia™ will **NOT** be administered to members who have received maternal RSV vaccination
  - ❑ Enflonsia™ will **NOT** be used for prophylaxis in members with verified RSV infection previously in the same RSV season
  - ❑ Enflonsia™ will **NOT** be used for treatment of RSV
  - ❑ Member has **NOT** experienced prior serious hypersensitivity reaction to any component of Enflonsia™

Recommended Dosing and Quantity Limits:

Enflonsia™ is available as 105 mg/0.7 mL single-dose prefilled syringe.

RSV Season	Dosing and Quantity Limit
First RSV season:	• Infants: IM 105 mg as a single dose • Administer clesrovimab from birth in infants born during RSV season or prior to start of RSV season for infants born outside the RSV season. • Quantity Limit: One (1) injection per lifetime

- For infants undergoing cardiac surgery with cardiopulmonary bypass during or entering their first RSV season, an additional dose of Enflonsia™ may be needed.

References:

1. Enflonsia™ intramuscular injection [prescribing information]. Rahway, NJ: Merck; June 2025.
2. Centers for Disease Control and Prevention. About RSV. Available at: https://www.cdc.gov/rsv/about/index.html. Updated on August 30, 2024. Accessed on June 11, 2025.
3. American Academy of Pediatrics. Red Book: 2021-2024 report of the Committee on Infectious Diseases (32nd edition). Respiratory syncytial virus. Pages: 628-636.
4. National Library of Medicine; Bethesda, MD. Efficacy and safety of clesrovimab (MK-1654) in infants (MK-1654-004) (CLEVER). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Available at: https://clinicaltrials.gov/study/NCT04767373#participation-criteria. NLM Identifier: NCT04767373.
5. National Library of Medicine; Bethesda, MD. Clesrovimab (MK-1654) in infants and children at increased risk for severe respiratory syncytial virus (RSV) disease (MK-1654-007) (SMART). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Available at: https://clinicaltrials.gov/study/NCT04938830#participation-criteria. NLM Identifier: NCT04938830.

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

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

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed'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.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.