Medical Drug Clinical Criteria

Subject:	Enflonsia (clesrovimab-cfor)		
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Overview

This document addresses the use of Enflonsia (clesrovimab-cfor), 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.

In June 2025, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) recommended one dose of Enflonsia for infants whose mothers are not protected by maternal RSV vaccination. This recommendation will be official once finalized by the CDC Director or Health and Human Services Secretary.

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/nrevss/php/dashboard/index.html?CDC_AAref_Val=https://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.

Enflonsia (clesrovimab-cfor)

Requests for Enflonsia (clesrovimab-cfor) 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 Enflonsia (ACIP).

Requests for Enflonsia (clesrovimab-cfor) 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. Individual has received Beyfortus (nirsevimab-alip) during the same RSV season; **OR**
IV. May not be approved when the above criteria are not met and for all indications.

Approval duration: Enflonsia approval is limited to shortly before or during RSV season as determined by CDC surveillance data (http://www.cdc.gov/nrevss/php/dashboard/index.html?CDC_AAref_Val=https://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

Enflonsia (clesrovimab-cfor) Quantity Limit

Drug	Limit
Enflonsia (clesrovimab-cfor) 105 mg/0.7 mL	One syringe, one time only
Override Criteria	
One additional dose may be approved for individuals undergoing cardiac surgery with cardiopulmonary bypass.	

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.

CPT

90382	Respiratory syncytial virus, monoclonal antibody, seasonal dose, 0.7 mL, for intramuscular use [Enflonsia]

ICD-10 Diagnosis

Z29.11	Encounter for prophylactic immunotherapy for respiratory syncytial virus (RSV)

Document History

New: 8/15/2025
Document History:

- 8/15/2025 – Annual Review: New clinical criteria and quantity limit for Enflonsia. Coding Reviewed: Added CPT 90382, ICD-10-CM Z29.11.

References

1. Centers for Disease Control and Prevention. CDC's Advisory Committee on Immunization Concludes Meeting with Joint Statement. https://www.cdc.gov/media/releases/2025/2025-cdcs-advisory-committee-on-immunization-concludes-meeting-with-joint-statement.html. Updated: June 26, 2025. Accessed: July 24, 2025.
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 24, 2025.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. 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 policies may take precedence over the application of this clinical criteria.