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Section:	Prescription Drugs	**Effective Date:**	October 1, 2025
Subsection:	Biologicals	**Original Policy Date:**	July 4, 2025
Subject:	Enflonsia	**Page:**	1 of 3

Last Review Date: September 19, 2025

Enflonsia

Description

Enflonsia (clesrovimab-cfor)

Background
Enflonsia (clesrovimab-cfor) is a recombinant human immunoglobulin G1 kappa (IgG1κ) monoclonal antibody with a YTE triple amino acid substitution (M252Y/S254T/T256E) in the Fc region which increases binding to the neonatal Fc receptor leading to an extended serum half-life. Passive immunity is provided by Enflonsia, which targets the extracellular domain of the RSV fusion (F) protein to prevent fusion of the viral and cellular membranes and viral entry (1).

RSV season is a term used to describe the time of year when RSV infections most commonly occur. RSV season generally lasts from November through April in most locations in the United States. The CDC website (CDC National Respiratory) may be used as a resource when the RSV season starts in a certain area (2).

Regulatory Status
FDA-approved indication: Enflonsia is a respiratory syncytial virus (RSV) F protein-directed fusion inhibitor indicated for the prevention of RSV lower respiratory tract disease in neonates and infants born during or entering their first RSV season (1).

Hypersensitivity reactions including anaphylaxis have been observed with other human IgG1 monoclonal antibodies. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, initiate appropriate medications and/or supportive therapy (1).

Safety and effectiveness in children older than 12 months of age have not been established (1).

Related policies
Beyfortus, Synagis

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Enflonsia may be considered **medically necessary** if the conditions indicated below are met.

Enflonsia may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnosis

Patient must have the following:

Prevention of infection caused by Respiratory Syncytial Virus (RSV)

AND following:

1. Less than 12 months of age at the start of RSV season*

*RSV season generally lasts from November through April in most locations in the United States. Consult the CDC National Respiratory and Enteric Virus Surveillance System (NREVSS) for RSV surveillance at https://www.cdc.gov/surveillance/nrevss/rsv/state.html.

Prior – Approval *Renewal* Requirements

None

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 6 months (PA may start 1 month prior to the RSV season)

Prior – Approval *Renewal* Limits

None

Rationale

Summary

Enflonsia is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV disease. Hypersensitivity reactions including anaphylaxis may occur with Enflonsia use (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Enflonsia while maintaining optimal therapeutic outcomes.

References

1. Enflonsia [package insert]. Rahway, NJ: Merck Sharp & Dohme LLC; June 2025.
2. The National Respiratory and Enteric Virus Surveillance System (NREVSS) Website. https://www.cdc.gov/surveillance/nrevss/rsv/state.html

Policy History

Date	Action
July 2025	Addition to PA
September 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 19, 2025 and is effective on October 1, 2025.