IOWA | Health and Human Services

Vaccines for Children (VFC) Program ENFLONSIA (Clesrovimab-cfor) Use in Children-Vaccine Summary October 2, 2025

Purpose

Effective October 2, 2025, Enflonsia (Clesrovimab-cfor), a long-acting monoclonal antibody, manufactured by Merck, is available to order through the Iowa VFC Program.

Food and Drug Administration (FDA)

In June 2025, the FDA approved Enflonsia (Clesrovimab-cfor) for the prevention of respiratory syncytial virus (RSV)-associated lower respiratory tract disease in infants and neonates who are born during or entering their first RSV season. Clesrovimab-cfor is administered as a 1-dose intramuscular injection shortly before or during RSV season.

ACIP Recommended Schedule

On June 26, 2025, CDC's Advisory Committee on Immunization Practices (ACIP) recommended the use of Enflonsia (Clesrovimab-cfor) as an option for RSV protection in infants aged < 8 months born during or entering their first RSV season who are not protected by maternal vaccination. There is no preferential recommendation between Nirsevimab and Clesrovimab-cfor.

Use of Clesrovimab for Prevention of Severe Respiratory Syncytial Virus–Associated Lower Respiratory Tract Infections in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2025

VFC Program Resolution

The Federal VFC Program follows the ACIP recommendations for the use of Enflonsia (Clesrovimab-cfor) in eligible children.

Recommended Dosage and Administration

Enflonsia (Clesrovimab-cfor) is supplied as a 105 mg/0.7 mL single dose pre-filled syringe.

Administer as an IM injection. Before injection, remove from the refrigerator and allow the prefilled syringe to come to room temperature for approximately 15 minutes. Inspect for particulate matter and discoloration prior to administration. Enflonsia (Clesrovimab-cfor) is a clear to opalescent, colorless to slightly yellow solution. Do not inject if the liquid is cloudy, discolored, or it contains large particles or foreign particulate matter. Do not use the prefilled syringe if it has been dropped or damaged or the security seal on the carton broke.

Vaccine Storage and Handling

- Store refrigerated at 2°C - 8°C (36°F - 46°F).
- May be kept at room temperature between 20°C to 25°C (68°F to 77°F) for a maximum of 48 hours. After removal from the refrigerator, it must be used within 48 hours or discarded.
- Do not freeze.
- Do not shake.
- Store in the original carton to protect from light until the time of use.
- Do not use product if exposed to out-of-range temperatures.
- Do not use after expiration date shown on the label.

Enflonsia (Clesrovimab) Package Insert

Precautions

- Moderate or severe acute illness with or without fever.
- When administering to children with increased risk for bleeding, follow CDC General Best Practice Guidelines for Immunization.

Contraindications

- Severe allergic reaction (e.g. anaphylaxis) to any product component or following a previous dose.

Always consult the package insert for precautions, warning and contraindications and the most current guidance from CDC.

Reporting of Adverse Events

If adverse reactions occur following administration of Enflonsia (Clesrovimab-cfor) alone, report to MedWatch online, by fax, by mail, or by contacting FDA at 1-800-FDA-1088.

If adverse reactions occur following administration of Enflonsia (Clesrovimab-cfor) when co-administered with a vaccine, report to the Vaccine Adverse Event Reporting System (VAERS). Reports can be submitted to VAERS online, by fax, or by mail. Additional information about VAERS is available by telephone (1-800-822-7967) or online (https://vaers.hhs.gov).

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