Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	September 24, 2025

Enflonsia™ (clesrovimab-cfor)

LENGTH OF AUTHORIZATION: Per prescription

REVIEW CRITERIA:

- Patient must be < 8 months old; **AND**
- Enflonsia must be prescribed for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants who are born during or entering their **first** RSV season; **AND**
- Patient meets one of the following (*clinical documentation required*):
    - Pregnant parent did not receive RSV vaccine during this pregnancy; **OR**
    - Pregnant parent RSV vaccination status is unknown; **OR**
    - Infant was born < 14 days after the pregnant parent's RSV vaccination; **AND**
- Prescriber must follow the recommended dosage and administration:
    - For neonates and infants born during or entering their first RSV season, administer once starting from birth.
    - For infants born outside the RSV season, administer once prior to the start of their first RSV season considering the duration of protection provided by Enflonsia.
    - For infants undergoing cardiac surgery with cardiopulmonary bypass during or entering their first RSV season, an additional 105 mg dose administered as an IM injection is recommended as soon as the infant is stable after surgery to ensure adequate clesrovimab-cfor serum levels.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 105 mg/0.7 mL in a single-dose prefilled syringe.