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California Department of Public Health

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TO: California Vaccines for Children (VFC) Program Providers

FROM: Robert Schechter, M.D., Chief
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SUBJECT: Clesrovimab (Enflonsia) Now Available from VFC for Prevention of Severe RSV Disease in Infants

HIGHLIGHTS

- Clesrovimab, a long-acting monoclonal antibody, now recommended as another option to protect all infants from birth to 8 months old against severe RSV disease
- Clesrovimab has a single fixed dose, regardless of weight
- Infants younger than 8 months are eligible to receive 1 dose of either clesrovimab (Enflonsia) or nirsevimab (Beyfortus)

SUMMARY

Clesrovimab (Enflonsia) is now available to order as another option to prevent severe respiratory syncytial virus (RSV) disease in VFC-eligible infants up to 8 months of age.

Each year, an estimated 58,000 to 80,000 children are hospitalized and 100 to 300 children die due to RSV. Virtually all children get an RSV infection by the time they are 2 years old, and infants and younger children are at increased risk of severe disease.

On June 9, 2025, the US Food and Drug Administration (FDA) licensed clesrovimab a long-acting monoclonal antibody, for the prevention of severe respiratory syncytial virus (RSV) illness. On June 26, 2025, CDC's Advisory Committee on Immunization Practices (ACIP) voted to recommend use of clesrovimab as another option for infants younger than 8 months of age during the RSV season. In clinical trials, clesrovimab had approximately 60% efficacy in preventing medically attended RSV-associated lower respiratory tract infection and 84% efficacy in preventing hospitalization for RSV infection. Protection from a dose of clesrovimab is expected to last at least 5 months.

CDPH encourages VFC providers to review information on RSV immunizations. It is important to educate all staff regarding the storage, preparation, age indications, dose schedule, administration, and recordkeeping for all immunization products in your practice.

RECOMMENDATIONS FOR PRODUCT IMMUNIZING USE

Eligible Groups

Infants younger than 8 months of age born during or entering their first RSV season are eligible to receive 1 dose of either clesrovimab (Enflonsia) or nirsevimab (Beyfortus) if:

- The mother did not receive RSV vaccine during pregnancy
- The mother's RSV vaccination status is unknown
- The infant was born less than 14 days after maternal RSV vaccination

Infants younger than 8 months can receive either nirsevimab or clesrovimab. For American Indian and Alaska Native (AI/AN) children, Indian Health Service (IHS) guidance for the 2025-26 season (PDF) is the preferential use of nirsevimab. For children who are not AI/AN, there is no preferential recommendation for either product.

Only nirsevimab is recommended for the following children aged 8 through 19 months old who are at increased risk for severe RSV disease shortly before or during their second RSV season, (regardless of which product they received for their first RSV season):

- American Indian or Alaska Native children
- Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season.
- Children who are severely immunocompromised.
- Children with cystic fibrosis who have either:
    - Severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable)
    - Weight-for-length that is <10th percentile

Children ages 8 months and older who are not at increased risk of severe RSV disease should not receive nirsevimab or clesrovimab.

Contraindications and Precautions

Clesrovimab is contraindicated in infants with a history of serious hypersensitivity reactions, including anaphylaxis, to any component in the product.

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

Clesrovimab may interfere with some immunologically-based RSV diagnostic assays (e.g., rapid antigen tests) as observed in laboratory studies. Confirmation using a reverse

transcriptase polymerase chain reaction (RT-PCR) assay is recommended when rapid antigen assay results are negative and clinical observations are consistent with RSV infection.

Administration with Other Immunizations

Simultaneous administration of clesrovimab with age-appropriate vaccines is recommended in accordance with general best practices for immunization.

Prior to the administration of clesrovimab, parents or guardians of patients must be provided with an RSV Immunization Information Statement (as opposed to a Vaccine Information Statement [VIS]).

Packaging and Presentation

Enflonsia™ (clesrovimab) is available in the following presentations:

- 1 pack – 1 dose syringe, NDC:00006-5073-01
- 10 pack – 1 dose syringe, NDC: 00006-5073-02

Dosage and Administration

Single-dose, manufacturer-filled syringe

- 105 mg/0.7 mL
- Same dose for all infants regardless of weight
- Route - Intramuscular injection
- Administration Site
  - Vastus lateralis muscle of anterolateral thigh
  - The gluteal muscle should not be used

Storage and Handling

- Store refrigerated between 2°C and 8°C (36°F and 46°F).
- Use within 48 hours of removing from refrigerator.
  - May be kept at room temperature, between 20°C and 25°C (68°F and 77°F), for a maximum of 48 hours. After this timeframe, it must be discarded.
- Do not freeze.
- Protect from light.

Timing

For infants born April through September

- Optimal timing is shortly before the RSV season begins (i.e., October through November)

For infants born October through March

- Administer in the first week of life—*ideally during the birth hospitalization.*
- Infants with prolonged birth hospitalizations due to prematurity or other causes should be immunized shortly before or promptly after discharge.
- If not given in the hospital, administer in outpatient settings.

BACKGROUND AND COMPOSITION

Clesrovimab is a respiratory syncytial virus F protein-directed fusion inhibitor. Clesrovimab is a fully human immunoglobulin G1 kappa (IgG1κ) monoclonal antibody produced in recombinant Chinese hamster ovary (CHO) cells.

Clesrovimab-cfor injection is a sterile, preservative-free, clear to slightly opalescent, colorless to slightly yellow solution for intramuscular injection.

Each 0.7 mL contains 105 mg of clesrovimab-cfor, arginine hydrochloride (10.33 mg), histidine (0.55 mg), L-histidine monohydrochloride monohydrate (0.74 mg), polysorbate 80 (0.14 mg), sucrose (35 mg) and water for injection (USP). The pH is 6.0.

REACTOGENICITY AND ADVERSE EVENTS

The most commonly reported adverse events at 1-5 days after immunization were irritability and somnolence. Most adverse events were mild or moderate and there were no potentially life threatening solicited adverse events. Local and systemic reactions, including fever, were comparable between clesrovimab and placebo.

Reporting of vaccine adverse events

If RSV antibody is administered alone, report suspected adverse events to MedWatch.

If RSV antibody is administered simultaneously with any vaccine, report suspected adverse events to Vaccine Adverse Event Reporting System (VAERS). Additional reporting to MedWatch is not necessary.

REPORTING VACCINE ADMINISTRATION TO CAIR

All active participants of California's VFC Program are required to enter all vaccine doses administered into CAIR or RIDE, in accordance with AB 1797, and as indicated in the VFC Provider Participation Agreement. Please make sure all doses of clesrovimab administered to patients are reported to the California Immunization Registry (CAIR or Healthy Futures/RIDE) AND the appropriate VFC Eligibility category is recorded.

Please ensure CAIR Accepted Values for VFC Eligibility Funding Status are reported with your clinic's data exchange information when documenting vaccine administration in the clinic's electronic medical record system and exchanging information with CAIR or Healthy Futures.

Refer patients to the California Digital Vaccine Record (DVR) portal to request copies of their vaccination record. Information is available in multiple languages.

The CVX code for clesrovimab is 332.

VFC IMMUNIZATION ORDERING

Available Products

The VFC Program has the following products available for ordering:

- Clesrovimab (Enflonsia), 1-pack 1 dose syringe, NDC: 00006-5073-01
- Clesrovimab (Enflonsia), 10-pack 1 dose syringe, NDC: 00006-5073-02

Initial Orders

Now that clesrovimab is available, the California VFC Program is processing approved initial RSV Pre-Book orders until at least 50% has been shipped. These initial orders will arrive in multiple shipments. Providers that pre-booked clesrovimab do NOT need to submit a VFC order form to receive their initial shipments.

Open Ordering with Allocations

After initial orders have shipped, the remaining approved pre-book will be allocated to provider accounts. Providers that did not pre-book RSV monoclonal antibodies will be allocated doses based on available supply. Once doses are allocated, you may request RSV immunization on your myCAvax routine VFC order form. Continue to request RSV doses throughout the remainder of the RSV season, up to your allocated amount.

BILLING FOR VFC VACCINE

Medi-Cal FFS

The administration fee for clesrovimab is billed using CPT code 90382 and modifier SL. A *Treatment Authorization Request* (TAR) is **not** required for reimbursement.

For specific information and details on Medi-Cal billing, please refer to the Medi-Cal provider manual on VFC. Providers with questions on Medi-Cal billing policies and procedures may call the Telephone Service Center (TSC) at 1-800-541-5555.

Medi-Cal Managed Care

Please contact the specific Medi-Cal managed care health plan for information on immunization billing and reimbursement.

RESOURCES

- CDPH Nirsevimab Letter for VFC Providers (PDF)
- Enflonsia Prescribing Information (PDF)
- CDC MMWR: 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
- American Academy of Pediatrics Respiratory Syncytial Virus (RSV) Prevention