This template is consistent with the American Academy of Pediatrics 2026 Recommended Child and Adolescent Immunization Schedule. See www.immunize.org/official-guidance/hpo/rec-schedules/.

STANDING ORDERS FOR
Administering Clesrovimab RSV Preventive Antibody (Enflonsia, by Merck) to Infants

Purpose

To reduce morbidity and mortality from respiratory syncytial virus (RSV) by immunizing all infants younger than 8 months of age who meet the criteria established by the CDC's Advisory Committee on Immunization Practices (ACIP) and published by CDC in the August 28, 2025 *MMWR* for immunization with a long-acting preventive antibody against RSV (clesrovimab, brand name Enflonsia, by Merck).

Alternative options for infant RSV prevention

1. Nirsevimab (Beyfortus, by Sanofi) is a different preventive antibody option with the same indications as clesrovimab. It is also recommended for certain high-risk children entering their second RSV season. The standing order template for nirsevimab is available at www.immunize.org/catg.d/p3097.pdf.
2. RSVpreF vaccine (Abrysvo, by Pfizer) is an option for administration during pregnancy. Generally, vaccination during pregnancy (at 32 through 36 weeks 6 days gestation) is recommended as an option between September and the end of January. Local RSV seasonality and public health guidance may vary, especially in tropical areas and Alaska. The standing order template for maternal vaccination with Abrysvo is available at www.immunize.org/catg.d/p3096.pdf.

Policy

Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals to assess the need for administration of a long-acting preventive antibody product to infants who meet the criteria below.

Procedure

1 Assess **infants younger than age 8 months 0 days** in need of immunization against RSV disease in their first RSV season according to the following criteria:

1a. **Routine dose for infants younger than 8 months and 0 days (must meet all criteria):**

Timing: October 1 through March 31, unless use of RSV preventive antibody outside of this time is currently recommended by regional experts or health authorities in response to local RSV activity. This seasonality is less likely outside the continental United States.

Infant immunization history: No history of nirsevimab or clesrovimab; no history of palivizumab in the past 30 days

No history of effective maternal Abrysvo vaccination for one of the following reasons:

- It was not administered during this infant's gestation, or
- Administration history is unknown, or
- It was administered before pregnancy with this infant, or
- Administration occurred less than 14 days before delivery, or
- Administration occurred 14 or more days before delivery, but protection may be inadequate for one of the following reasons *(evaluation may require referral):*
  - Mother is immunocompromised or living with HIV, or
  - Infant has undergone cardiopulmonary bypass or extracorporeal membrane oxygenation, or
  - Infant has hemodynamically significant congenital heart disease, or
  - Infant has had an intensive care admission requiring oxygen at hospital discharge

Note: If maternal vaccination with Abrysvo was considered effective (i.e., none of the preceding criteria were met), do not give any RSV preventive antibody in the infant's first RSV season.

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2 Screen for contraindications and precautions

Do not give clesrovimab to persons with a history of severe allergic reaction (e.g., anaphylaxis) to a clesrovimab component. For a list of clesrovimab components, refer to the manufacturer's package insert (www.immunize.org/official-guidance/fda/pkg-inserts/) or go to www.accessdata.fda.gov/drugsatfda_docs/label/2025/761432s000lbledt.pdf.

3 Provide Immunization Information Statement

Provide each patient's parent or legal representative a copy of the most current federal RSV Preventive Antibody Immunization Information Statement (IIS, a VIS-like document). RSV preventive antibody products are not currently part of the National Vaccine Injury Compensation Program (VICP), therefore, use of the IIS is not required by federal law. However, Vaccines for Children (VFC) program providers must give the IIS to parents in the same way that a VIS is provided. Provide non-English speaking parents/legal representatives with a copy of the IIS in their native language if one is available and desired; available translations can be found at www.immunize.org/vaccines/vis/iis-rsv/. (For information about how to document that the IIS was given, see section 6 titled "Document Immunization.")

4 Prepare to Administer Clesrovimab

Choose the needle gauge, needle length, and injection site according to the following chart.

AGE	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
Newborns (1st 28 days)	22–25	⅝"	Anterolateral thigh muscle
Infants age 2 through 7 months	22–25	1"	Anterolateral thigh muscle

5 Administer Clesrovimab

Clesrovimab is available as a 105-mg manufacturer-filled syringe (MFS). Administer one 105-mg dose by the intramuscular (IM) route to the eligible infant. The dose is the same regardless of the infant's weight.

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 serum levels.

Note: Only one dose of clesrovimab is recommended for any child for a single RSV season with the single exception of infants who undergo cardiopulmonary bypass noted above. Clesrovimab may be coadministered with any recommended live or non-live vaccines, at separate injection sites, or at any time before or after administration of any live or non-live vaccine.

6 Document Immunization

Document each patient's clesrovimab administration information and follow-up in the following places:

Medical record: Record the date it was administered, the manufacturer and lot number, the administration site and route, and the name and address and, if appropriate, the title of the person administering it. Also document, in the patient's medical record or office log, the publication date of the IIS and the date it was given to the patient, in the same way that a VIS is documented. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If an RSV preventive antibody was not administered, record the reason(s) for non-receipt (e.g., not indicated due to maternal vaccination, medical contraindication, patient refusal). Plan to discuss at the next visit, if the infant remains eligible and RSV protection remains indicated.

Personal immunization record card: Record the date of immunization and the name/location of the administering clinic.

Immunization Information System or "registry": Report administration to the appropriate state or local immunization information system, if available.

7 Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of a monoclonal antibody (e.g., a risk of anaphylaxis) by having a written emergency medical protocol available, as well as equipment and medications. For Immunize.org's "Medical Management of Vaccine Reactions in Children and Teens in a Community Setting," go to www.immunize.org/catg.d/p3082a.pdf.

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8 Report Adverse Events to MedWatch or VAERS

Adverse events that occur after administration of clesrovimab alone: Report to MedWatch online (www.fda.gov/medwatch), by fax, by mail, or by contacting FDA at 1-800-FDA-1088.

Adverse events that occur after coadministration of clesrovimab with one or more vaccines: Report to the Federal Vaccine Adverse Event Reporting System (VAERS). Submit a VAERS report online (preferred) or download a writable PDF form at www.vaers.hhs.gov/reportevent.html. Further help is available by calling (800) 822-7967. ***Note:*** After reporting to VAERS, additional reporting of the same adverse reaction to MedWatch is not necessary.

Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the _____ (NAME OF PRACTICE OR CLINIC)

effective _____ (DATE) until rescinded or until _____ (DATE) .

Medical Director _____ (PRINT NAME) / _____ (SIGNATURE) _____ (DATE)