Standing orders for other vaccines are available at www.immunize.org/standing-orders. NOTE: This standing orders template may be adapted per a practice's discretion without obtaining permission from Immunize.org. As a courtesy, please acknowledge Immunize.org as its source.

STANDING ORDERS FOR
Administering Nirsevimab RSV Preventive Antibody (Beyfortus, by Sanofi) to Infants and High-Risk Young Children

Purpose

To reduce morbidity and mortality from respiratory syncytial virus (RSV) by immunizing all infants and high-risk young children who meet the criteria established by the American Academy of Pediatrics (AAP) in September 2026 (https://doi.org/10.1542/peds.2026-079047), for immunization with a long-acting preventive antibody against RSV (nirsevimab, brand name Beyfortus, by Sanofi), with information provided on current CDC recommendations.

Alternative options for infant RSV prevention

1. Clesrovimab (Enflonsia, by Merck) is a different preventive antibody option with the same indications as nirsevimab for infants younger than 8 months. Clesrovimab is not recommended for high-risk children entering their second RSV season. The standing order template for clesrovimab is available at www.immunize.org/catg.d/p3099.pdf.
2. RSVpreF vaccine (Abrysvo, by Pfizer) is an option for administration during pregnancy. 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 and young children who meet the criteria below.

Procedure

1 Assess infants in need of immunization against RSV disease in their first or second RSV season according to the following criteria:

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

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

Refer for clinical evaluation of special circumstances (e.g., travel to areas of increased RSV activity, concern of failure to return for administration), for a decision to administer RSV antibody to an individual patient outside the months of October through March (or the local public health-directed time frame). Such decisions for individual patients do not require public health consultation.

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

Note: Refer for clinical assessment for a repeat dose, as recommended by AAP, during the first RSV season if the infant has undergone antibody-depleting treatments or procedures after the first dose, such as plasmapheresis, cardiopulmonary bypass, or extracorporeal membrane oxygenation (ECMO), that may result in the loss of RSV-specific antibodies.

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

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- 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 antibody-depleting procedures, such as plasmapheresis, cardiopulmonary bypass, or ECMO, or
  - Infant has substantially increased risk for severe RSV disease (e.g., hemodynamically significant congenital heart disease, intensive care admission with a requirement of oxygen at 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.

1b. **Risk-based immunization of children age 8 months through 19 months entering their second RSV season** (must be in at least one high-risk category). **Refer** to a clinician in cases where clinical evaluation is necessary to determine whether a child meets high-risk criteria.

Timing: Generally, October 1 through March 31, unless use of RSV preventive antibody outside of this timeframe is currently recommended by public health authorities in response to local RSV activity. This seasonality is less likely outside the contiguous United States.

Refer for clinical evaluation of special circumstances (e.g., travel to areas of increased RSV activity, concern of failure to return for administration), for a decision to administer RSV antibody to an individual patient outside the months of October through March (or the local public health-directed time frame). Such decisions for individual patients do not require public health consultation.

Infant immunization history: immunize regardless of RSV immunization history before or during the first RSV season.

Note: Refer for clinical assessment for a repeat dose during the same season (as recommended by AAP) if a child undergoes antibody-depleting treatments or procedures, such as plasmapheresis, cardiopulmonary bypass, or extracorporeal membrane oxygenation (ECMO), that may result in the loss of RSV-specific antibodies.

Presence of one or more of the following high-risk criteria defined by AAP:

- Children born preterm, at less than 32 weeks, 0 days' gestation, regardless of the need for medication or other support
- Children with chronic lung disease attributable to prematurity or to other significant neonatal conditions (e.g., meconium aspiration or congenital diaphragmatic hernia) who required medical support (i.e., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) at any time during the 6-month period before the start of the second RSV season
- Children with hemodynamically significant congenital heart disease (i.e., a defect that can result in symptoms and/or cardiac chamber dilation)
- Children with anatomic pulmonary abnormalities or neuromuscular disorders that put them at risk for severe RSV disease
- Children with severe immunocompromise
- Children with Down syndrome or other chromosomal differences placing them at higher risk of severe RSV disease
- Children with cystic fibrosis who have either:
  - manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year after birth or abnormalities on chest imaging that persist when stable), or
  - weight-for-length that is less than the 10th percentile
- American Indian or Alaska Native children

Note: CDC's high-risk criteria for administration in the second season are narrower than the criteria recommended by AAP in 2026. For those applying this template in settings where CDC criteria must be followed, the CDC criteria, published in 2023, for use of nirsevimab in the second RSV season are provided below:

- Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) at any time during the 6-month period before the start of the second RSV season

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- Children with severe immunocompromise
- Children with cystic fibrosis who have either:
  - manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable), or
  - weight-for-length that is less than the 10th percentile
- American Indian or Alaska Native children

2 Screen for contraindications and precautions

Do not give nirsevimab to persons with a history of severe allergic reaction (e.g., anaphylaxis) to a nirsevimab component. For a list of nirsevimab 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/2023/761328s000lbl.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 Nirsevimab

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 1 through 11 months	22–25	1"	Anterolateral thigh muscle
Age 12 through 19 months	22–25	1–1¼"	Anterolateral thigh muscle*
		⅝†–1"	Deltoid muscle of arm

* Preferred site.

† A ⅝" needle may be used for children for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

5 Administer the Appropriate Dose of Nirsevimab

Administer by the intramuscular (IM) route, according to the tables below, to eligible infants and toddlers. Nirsevimab is available in two formulations: a 50-mg (0.5 mL) manufacturer-filled syringe (MFS) or a 100-mg (1.0 mL) MFS. The 50-mg MFS should be reserved for use in infants weighing less than 5 kg: do not administer two 50-mg MFS doses to an infant weighing 5 kg or more.

Infants age younger than 8 months, 0 days:

CHILD'S WEIGHT	NIRSEVIMAB DOSE
Less than 5 kg (11 lbs)	50-mg MFS
Greater than or equal to 5 kg (11 lbs)	100-mg MFS

High-risk children age 8 months through 19 months eligible for nirsevimab during their second season:

CHILD'S WEIGHT	NIRSEVIMAB DOSE
Any	200 mg (total): administer two 100-mg MFS injections at the same visit at different injection sites

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Notes:

- Nirsevimab may be coadministered with any recommended live or non-live vaccines, in separate syringes and at separate injection sites, or at any time before or after administration of any live or non-live vaccine.
- For children undergoing cardiac surgery with cardiopulmonary bypass during or entering their first or second RSV season, an additional dose of nirsevimab administered as an IM injection is recommended as soon as the child is stable after surgery. For these and other children for whom a repeat dose is recommended by AAP following antibody-depleting procedures, refer to the nirsevimab package insert for specific dose guidance in these circumstances.

6 Document Immunization

Document each patient's nirsevimab 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.

8 Report Adverse Events to MedWatch or VAERS

Adverse events that occur after administration of nirsevimab 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 nirsevimab 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)