STANDING ORDERS FOR

Administering Nirsevimab RSV Preventive Antibody to Infants (2023–24 Season Only)

Purpose

To reduce morbidity and mortality from respiratory syncytial virus (RSV) by immunizing all infants who meet the criteria established by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) with a long-acting monoclonal antibody against RSV.

2023-24 Season Note: Due to strong early demand and limited supply of nirsevimab (Beyfortus, Sanofi), particularly 100-mg manufacturer-filled syringes (MFS), on October 24, 2023, CDC issued a Health Advisory with revised recommendations for use of nirsevimab during the 2023-24 season (see CDC Health Alert at https://emergency.cdc.gov/han/2023/han00499.asp). ACIP recommendations for infants weighing less than 5 kg are unchanged. This template follows CDC's limited nirsevimab recommendations for infants weighing 5 kg or more for the 2023-24 season. A routine template will be posted once restricted use is no longer recommended by CDC. Interim CDC recommendations are subject to change as new information becomes available.

RSV Vaccine Note: Between September 1 and January 31 each season, prevention of severe RSV disease in infants is recommended through administration of RSVpreF vaccine (Abrysvo, Pfizer) to the pregnant person between gestational week 32 and week 36 and 6 days, as an alternative to nirsevimab. If conditions (e.g., product availability) allow for the option of maternal vaccination or nirsevimab, the pregnant person may choose the preferred option. The standing order template for maternal vaccination with Abrysvo is available at www.immunize.org/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 monoclonal 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 nirsevimab 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; no history of palivizumab in the past 30 days

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

- RSVpreF vaccine was not administered, *or*
- RSVpreF administration history is unknown, *or*
- RSVpreF administration occurred less than 14 days before delivery, *or*
- RSVpreF 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

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Note: If maternal vaccination with RSVpreF was considered effective (i.e., none of the preceding criteria were met), do not give nirsevimab.

If infant weighs less than 5 kg and above criteria are met: Proceed with immunization protocol.

If infant weighs 5 kg or more, proceed with additional eligibility criteria:

- Infant is less than 6 months zero days of age, or
- Infant is American Indian or Alaskan native and less than 8 months zero days of age, or
- Infant is between age 6 months and 8 months zero days, and has a condition that puts them at high risk of severe RSV disease, including:
  - Premature birth at less than 29 weeks' gestation
  - Chronic lung disease of prematurity
  - Hemodynamically significant congenital heart disease
  - Severe immunocompromise
  - Severe cystic fibrosis (either manifestations of severe lung disease or weight-for-length ratio is less than 10th percentile)
  - Neuromuscular disease or congenital pulmonary abnormalities that impair the ability to clear secretions

Note: If infant weighs 5 kg or more and does not meet above criteria, do not give nirsevimab using standing order (may consider referral for additional clinical evaluation and determination based upon available nirsevimab supply and current recommendations).

1b. **Risk-based immunization of children age 8 months through 19 months during their second RSV season** (must meet *all* criteria, may require additional guidance from local public health or health authorities):

Timing: Generally, October 1 through March 31, unless use of nirsevimab 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.

High risk and ineligible for palivizumab: American Indian or Alaskan Native and living in remote regions, where access to medical care may be challenging, or where there are known high rates of severe disease among older infants and toddlers.

Due to the limited supply of nirsevimab 100-mg manufacturer-filled syringes, do not give nirsevimab to children in this age group during the second RSV season who are eligible per AAP recommendations for palivizumab for RSV prevention (see https://doi.org/10.1542/peds.2023-061803). Refer for palivizumab.

2 Screen for contraindications and precautions

Do not give nirsevimab to persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a nirsevimab component. For a list of nirsevimab components, refer to the manufacturer's package insert (www.immunize.org/fda) 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 nirsevimab Immunization Information Statement (IIS, a VIS-like document). At this time, the RSV preventive antibody is not 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/vis. (For information about how to document that the IIS was given, see section 6 titled "Document Immunization.")

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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 2 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 infants 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

Note: Only one dose of nirsevimab is recommended for any child for a single RSV season. Nirsevimab 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 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 nirsevimab 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 vaccination 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 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)