IOWA | Health and Human Services

Vaccines for Children (VFC) Program Nirsevimab (Beyfortus) Use in Children - Vaccine Summary October 2, 2023

Purpose

Effective October 2, 2023, Nirsevimab (Beyfortus), a long-acting monoclonal antibody, manufactured by Sanofi and AstraZeneca, is available to order through the Iowa VFC Program.

Food and Drug Administration (FDA)

In July 2023, the FDA approved nirsevimab (Beyfortus) for the prevention of respiratory syncytial virus (RSV)-associated lower respiratory tract infections among infants and children < 24 months of age. Nirsevimab is administered as a 1-dose intramuscular injection shortly before or during RSV season.

VFC Program Resolution

The Federal VFC Program follows the ACIP recommendations for the use of nirsevimab (Beyfortus) in eligible children.

Advisory Committee on Immunization Practices (ACIP)

On August 3, 2023, CDC's Advisory Committee on Immunization Practices (ACIP) recommended the use of nirsevimab (Beyfortus) for infants aged < 8 months born during or entering their first RSV season and for infants and children aged 8-19 months who are at increased risk of severe RSV disease entering their second RSV season.

Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023

ACIP Recommended Schedule

- ACIP recommends 1 dose of nirsevimab for all infants aged <8 months born during or entering their first RSV season (50 mg for infants weighing <5 kg and 100 mg for infants weighing ≥5 kg).

- ACIP recommends 1 dose of nirsevimab (200 mg, administered as two 100 mg injections given at the same time at different injection sites) for infants and children aged 8–19 months who are at increased risk for severe RSV disease and entering their second RSV season.

Infants and Children aged 8-19 Months with Increased Risk for Severe Disease who are Recommended to Receive Nirsevimab (Beyfortus) When Entering Their Second RSV Season:

- 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 with severe immunocompromise.
- Children with cystic fibrosis who have either 1) 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 2) weight-for-length <10th percentile.
- American Indian or Alaska Native children.

Recommended Dosage and Administration

Nirsevimab (Beyfortus) is supplied as either a 50 mg/0.5 mL single dose pre-filled syringe (purple plunger rod) or a 100 mg/mL single dose pre-filled syringe (light blue plunger rod).

Administer as an IM injection. Inspect for particulate matter and discoloration prior to administration. Nirsevimab (Beyfortus) is a clear to opalescent, colorless to yellow solution. Do not inject if the liquid is cloudy, discolored, or it contains large particles or foreign particulate matter.

1 dose of nirsevimab (Beyfortus) for all infants aged <8 months born during or entering their first RSV season (50 mg for infants weighing <5 kg [<11 lb] and 100 mg for infants weighing ≥5 kg [≥11 lb]).

1 dose of nirsevimab (Beyfortus) (200 mg, administered as two 100 mg injections given at the same time at different injection sites) for infants and children aged 8–19 months who are at increased risk for severe RSV disease and entering their second RSV season.

Timing of Nirsevimab (Beyfortus)

Optimal timing is shortly before RSV season begins; however, it may be administered to age-eligible infants and children who have not yet received a dose at any time during the RSV season (October through the end of March). Only a single dose is recommended for an RSV season.

Coadministration with Routine Childhood Vaccines

Simultaneous administration of nirsevimab (Beyfortus) with age-appropriate vaccines is recommended.

Vaccine Storage and Handling

- Store refrigerated at 2 - 8°C (36 - 46°F).
- Do not freeze.
- Do not shake.
- Do not expose to heat.
- Store in the original carton to protect from light until time of use.
- After removal from refrigerator, use within 8 hours or discard.
- Do not use product if exposed to out-of-range temperatures.
- Do not use after expiration date shown on the label.

Nirsevimab BEYFORTUS Package Insert

Precautions

- Moderate or severe acute illness with or without fever.
- When administering to children with increased risk for bleeding, follow CDC General Best Practice Guidelines for Immunization.

Contraindications

- Severe allergic reaction (e.g. anaphylaxis) to any product component or following a previous dose

Always consult the package insert for precautions, warning and contraindications and the most current guidance from CDC.

Reporting of Adverse Events

If adverse reactions occur following administration of nirsevimab (Beyfortus) alone, report to MedWatch online, by fax, by mail, or by contacting FDA at 1-800-FDA-1088.

If adverse reactions occur following administration of nirsevimab (Beyfortus) when coadministered with a vaccine, report to the Vaccine Adverse Event Reporting System (VAERS). Reports can be submitted to VAERS online, by fax, or by mail. Additional information about VAERS is available by telephone (1-800-822-7967) or online (https://vaers.hhs.gov).

CPT Code

- 90380: Respiratory syncytial virus, monoclonal antibody, seasonal dose; 0.5 mL dosage, for intramuscular use

- 90381: Respiratory syncytial virus, monoclonal antibody, seasonal dose; 1 mL dosage, for intramuscular use