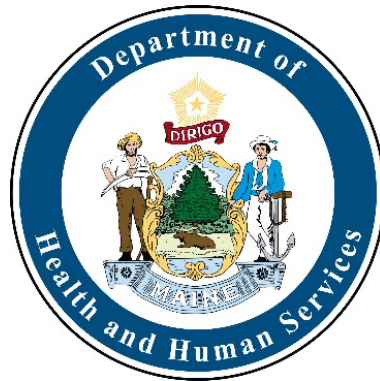


# 2025 - 2026 Respiratory Syncytial Virus (RSV) Immunization Recommendations

Maine Immunization Program

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# Objectives

- Introduction to the 2025- 2026 Respiratory Syncytial Virus (RSV) Season
- Timing of RSV Immunizations
- NEW product – Enflonsia (clesrovimab)
  - Recommendations and Dosage
  - Storage and Handling
- Beyfortus (nirsevimab)
  - Recommendations and Dosage
  - Storage and Handling
- Comparison of RSV Immunizations
- Coadministration with Other Vaccines
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# 2025 – 2026 Respiratory Syncytial Virus (RSV) Season

Respiratory Syncytial Virus (RSV) infection can cause a variety of respiratory illnesses and symptoms in infants and young children. It most commonly causes a cold-like illness but can also cause lower respiratory infections, like bronchiolitis and pneumonia.

Two to three percent of infants under 6 months of age are hospitalized with RSV every year. Severe disease most commonly occurs in very young infants, including healthy babies without underlying conditions.



**RSV is the  
LEADING CAUSE  
of infant  
hospitalization  
in the U.S.**

# Timing of RSV Immunization for Infants and Pregnant Women

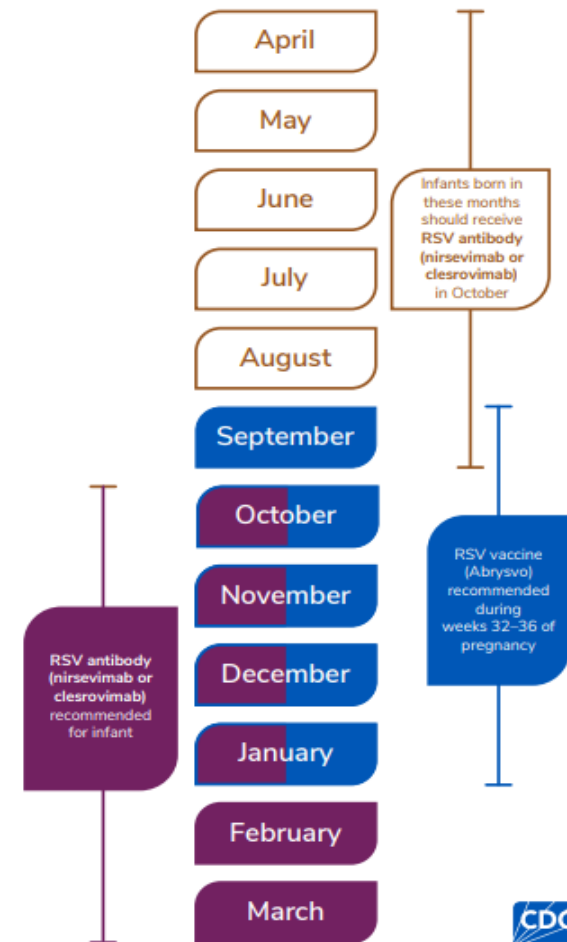
## Timing for Infant RSV Immunization:

- Infants born during the seasonal administration window (**starting October 1st through the end of March 31st**) should get an infant RSV antibody within one week after birth – ideally during the birth hospitalization.
- Throughout March, any eligible infant or young child who has not yet received a recommended dose should receive an infant RSV monoclonal antibody at the earliest opportunity.
- For infants born *outside* of the seasonal administration window (which is April through September) and for young children who are at increased risk for severe RSV disease and entering their second RSV season, the optimal timing for infant RSV antibody administration is shortly before the RSV season begins (e.g., October or November).

## Timing of Maternal RSV Immunization:

- Maternal vaccination for RSV prevention is recommended starting September – January and must be administered during weeks 32-36 of pregnancy.
- An RSV monoclonal antibody immunization is not indicated when the maternal dose is received 14 days after birth.

## Timing of RSV Immunizations for Infants and Pregnant Women



# NEW RSV Product – Enflonsia (Clesrovimab)

Enflonsia is indicated for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants who are born during or entering their first RSV season. Enflonsia is a preventive, long-acting monoclonal antibody (mAb) indicated for the prevention of respiratory syncytial virus (RSV) designed to provide protection through 5 months, a typical RSV season, with the same dose regardless of weight.

Enflonsia (clesrovimab) has been recently recommended as a second long-acting monoclonal antibody product that could be used for prevention of RSV among infants aged <8 months who are born during or entering their first RSV season and who are not protected through maternal RSV vaccination.

- ❖ *Clesrovimab is not recommended for children over 8 months of age and does not have FDA approval for children entering their second RSV season.*



# Enflonsia (Clesrovimab)

## Recommendations and Dosage

Enflonsia (clesrovimab) is recommended for neonates and infants born during or entering their first RSV season. Enflonsia (clesrovimab) is administered using the same dose regardless of weight (105 mg/0.7 mL in a prefilled syringe, single intramuscular (IM) injection) and is designed to provide protection through 5 months, a typical RSV season.

### Recommendations:

- For neonates and infants born during the RSV season (October – March), Enflonsia is to be administered within the first week of life.
- For infants born *outside* of the RSV season (April – September), Enflonsia should be administered shortly before the start of the first RSV season begins.



- ❖ *Enflonsia will be available for all enrolled provider sites to order starting in early October. MIP will provide updates as soon as doses become available for ordering*

# Enflonsia (Clesrovimab)

## Storage and Handling

### Storage and Handling:

- Store prefilled syringes under refrigeration at 36°F to 46°F (2°C to 8°C).
- Keep the prefilled syringe in the original carton to protect from light until time of use.
- Enflonsia (clesrovimab) may be kept at room temperature between 68°F to 77°F (20°C to 25°C) for a maximum of 48 hours. After removal from the refrigerator, Enflonsia (clesrovimab) must be used within 48 hours or discarded.
- Before injection, remove Enflonsia (clesrovimab) from the refrigerator and allow the prefilled syringe to come to room temperature for approximately 15 minutes.
- Enflonsia (clesrovimab) has a 30-month shelf life
- Do not freeze. Do not shake



# Beyfortus (Nirsevimab)

## RSV Antibody Beyfortus (Nirsevimab):

Beyfortus (nirsevimab) is an injectable monoclonal antibody that provides immediate protection against RSV disease in infants and young children and last up to 5 months.

Nirsevimab is recommended for all babies younger than 8 months of age born to mothers who did not receive a maternal RSV vaccine (Pfizer's Abrysvo) during pregnancy.

Nirsevimab is also recommended for a small group of young children 8 through 19 months of age who are at increased risk for severe RSV. This nirsevimab dose should be given shortly before the child's second RSV season.

This group includes:

- Children who were born prematurely and have chronic lung disease
- Children with severe immunocompromise
- Children with severe cystic fibrosis
- American Indian and Alaska Native children

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

# Beyfortus (Nirsevimab) Recommendations

## Dosage and Administration

The recommended dosage of nirsevimab in neonates and infants born during or entering their first RSV season is based on body weight and is administered as one single intramuscular (IM) injection.

### Age less than 8 months:

- 50 mg for infants weighing <5 kg [<11 lb]
- 100 mg for infants weighing  $\geq$ 5 kg [ $\geq$ 11 lb]

### Age 8 through 19 months:

- 200 mg; administered as two 100 mg injections

Recommended Dosage of Beyfortus in Neonates and Infants Born During or Entering Their First RSV Season <sup>5</sup>	
Body Weight at Time of Dosing	Recommended Dosage
Less than 5 kg	50 mg by IM injection
5 kg and greater	100 mg by IM injection



50 mg by  
IM injection



100 mg by  
IM injection

# Beyfortus (Nirsevimab) Storage and Handling

## Storage and Handling:

- Nirsevimab should be stored in the fridge between 36°F and 46°F .
- Once removed from the fridge, nirsevimab must be used within 8 hours or discarded.



# Comparison of RSV Immunizations

	<u>Maternal Vaccine</u> (Pfizer's Abrysvo)	<u>Enflonia</u> (clesrovimab)	<u>Beyfortus (nirsevimab)</u>
<b>Who is it recommended for?</b>	<ul style="list-style-type: none"> <li>Women who are 32–36 weeks pregnant</li> </ul>	<ul style="list-style-type: none"> <li>Babies (ages &lt;8 months) born to mothers who did not get a maternal RSV vaccine.                             <ul style="list-style-type: none"> <li>No weight restrictions</li> <li>Not to be given after ages &lt;8 months</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Babies (ages &lt;8 months) born to mothers who did not get a maternal RSV vaccine.</li> <li>A small group of young children (ages 8–19 months) at increased risk of severe RSV (nirsevimab only).                             <p>*High-risk criteria include the following:</p> <ul style="list-style-type: none"> <li>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</li> <li>Children with severe immunocompromise</li> <li>Children with cystic fibrosis who have either:                                     <ul style="list-style-type: none"> <li>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</li> <li>weight-for-length that is less than the 10th percentile</li> </ul> </li> <li>American Indian or Alaska Native children</li> </ul> </li> </ul>
<b>How does it work?</b>	Mom passes protection (antibodies) to baby during pregnancy	Baby receives protection (antibodies) directly	Baby receives protection (antibodies) directly
<b>When is it recommended in most of continental U.S.?</b>	September – January	October – March	October – March
<b>Who does it protect from severe RSV?</b>	Baby	Baby	Baby
<b>How long does protection last?</b>	Approximately 6 months after birth	At least 5 months after immunization	At least 5 months after immunization

# Coadministration with Other Vaccines

- Infant RSV monoclonal antibody (nirsevimab or clesrovimab) and routine childhood vaccines can be administered during the same visit.
- No interval between infant RSV monoclonal antibodies and live vaccines (such as measles, mumps, and rubella [MMR] and varicella) is necessary.



# Inventory Management

- Many enrolled provider locations still have nirsevimab doses on hand from last 2024 - 2025 RSV season.
  - Our goal is for providers to utilize existing inventory until expiration date, ensuring doses are stored at the appropriate temperature.
- Separate orders **MUST** be placed from other vaccine orders in ImmPact for RSV monoclonal antibody.
  - Combined orders with other vaccines will be denied
- Nirsevimab and clesrovimab are not currently included on the MIP replacement policy. Any doses that are wasted do not go against a sites



❖ *Enflonsia will be available for all enrolled provider sites to order starting in early October. MIP will provide updates as soon as doses become available.*

# Resources

- [Clinical Guidance for RSV Immunizations and Vaccines | RSV | CDC](#)
  - [RSV Immunization Guidance for Infants and Young Children | RSV | CDC](#)
- [RSV in Infants and Young Children | RSV | CDC](#)
- [Immunizations to Protect Infants | RSV | CDC](#)
- [Talking with Patients About Respiratory Virus Season | Respiratory Illnesses | CDC](#)
- [Timing of RSV for Infants\\_Maternal\\_RSVImmunoCalendar](#)
- [ENFLONZIA™ \(clesrovimab-cfor\) | Official HCP Web Site](#)
- [Beyfortus® \(nirsevimab-alip\) for RSV | For US HCPs](#)
  - [Nirsevemab-Visual-Guide.pdf](#)
- [Immunization Information Sheet-RSV Preventive Antibody: What You Need to Know-September 25, 2023](#)

# Questions?

## **Maine Immunization Program Contacts:**

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[www.ImmunizeME.org](http://www.ImmunizeME.org)

