Immunization Protocol

Respiratory Syncytial Virus (RSV) Monoclonal Antibody (mAb) Injection, nirsevimab (Beyfortus™) or clesrovimab (Enflonsia™)	
Last Reviewed	11 Aug 2025
Last Revised	11 Aug 2025
This order expires	30 Jun 2027

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1. What's new

The ACIP recently approved clesrovimab for the prevention of RSV disease in newborns. Either clesrovimab or nirsevimab may be used in the infant's first RSV season.

2. Oregon immunization protocol

A. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs RSV mAb or any vaccines. Check mother's ALERT record for RSV vaccination status.

B. Screen clients for contraindications and precautions.

C. Provide a current Patient Information handout (Appendix A), answering any questions.

D. Record all required data elements in the client's permanent health record.

E. Verify needle length for intramuscular (IM) injection.

F. To avoid injury related to injection administration, make sure staff who administer injections recognize the anatomic landmarks for identifying the vastus lateralis muscle and use proper IM administration technique.

G. May be given with all ACIP-recommended childhood vaccines[3]. See section 8 for additional information.

H. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.

I. Ensure epinephrine hydrochloride solution (1:1,000), oxygen and other appropriate agents and equipment are available for immediate use in case of anaphylactic or acute hypersensitivity reaction. Refer to Guidelines for Managing Adverse Events Following Immunization.

Health Officer Signature Date

Health Officer Signature Date

3. Vaccine schedule for RSV monoclonal antibody

Nirsevimab[1,4]

Infant <8 months and born during or entering first RSV season* Dose and Route: 50 mg if <5 kg, or 100 mg if ≥5 kg, IM			
Dose	**Preferred age**	**Minimum acceptable age**	**Timing**
1	<8 months	Birth	Shortly before (or during) the start of the first RSV season
Child 8–19 months and at increased risk for severe RSV disease entering second RSV season† Dose and Route: 200 mg (2 x 100 mg injections), IM			
Dose	**Preferred age**	**Minimum acceptable age**	**Timing**
1	8–19 months and at increased risk for severe RSV disease	8 months	Shortly before (or during) the start of the second RSV season

†See section 5 for severe RSV disease risk factors.

Clesrovimab[2]

Infant <8 months and born during or entering first RSV season* Dose and Route: 105 mg IM			
Dose	**Preferred age**	**Minimum acceptable age**	**Timing**
1	<8 months	Birth	Shortly before (or during) the start of the first RSV season

*RSV season typically occurs fall through spring in most of the continental United States. Oregon's RSV activity is published in OHA's RSV Surveillance Report, and individuals may sign up here to receive RSV reports and updates during the RSV season.

4. Licensed RSV mAb Products[1,2] *

Trade Name	**Presentation**	**Acceptable Age Range**
Beyfortus (nirsevimab) injection[1]	50 mg/0.5 mL & 100 mg/1.0 mL, single-dose pre-filled syringes	Birth–24 months

Enflonsia (clesrovimab) injection[2]	105 mg/0.7 mL single-dose pre-filled syringes	Birth-8 months

*Synagis (palivizumab) injection is also licensed by the FDA for children at high risk of severe RSV disease. Use of Synagis is not covered by this protocol.

5. Recommendations for use[4,5]

A. Infants aged <8 months born during or entering their first RSV season are recommended to receive one dose of either monoclonal antibody if:

- Mother did not receive RSV vaccine; or
- It's unknown whether mother received RSV vaccine; or
- Mother was vaccinated but infant was born <14 days after vaccination.

B. Children aged 8–19 months who are at increased risk of severe RSV disease and entering their second RSV season are recommended to receive one dose of nirsevimab.

Clesrovimab is not approved for use in the second RSV season, but children at increased risk who received clesrovimab in their first RSV season may receive nirsevimab in their second RSV season.[2]

C. For children undergoing cardiac surgery with cardiopulmonary bypass, an additional dose of either nirsevimab or clesrovimab is recommended as soon as the child is stable after surgery to ensure adequate serum levels.[1,2]

D. Children aged 8–19 months who are at increased risk of severe RSV disease include:

1. 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.
2. Children with severe immune compromise.
3. Children with cystic fibrosis who have 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 <10th percentile; and
4. American Indian and Alaska Native children.

6. Contraindications

History of serious hypersensitivity reactions, including anaphylaxis, to any component of the monoclonal antibody.

Vaccine	Vaccine Excipient Summary

Beyfortus (nirsevimab)[1]	arginine hydrochloride, histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sucrose, and water
Enflonsia (clesrovimab)[2]	arginine hydrochloride, histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose, and water

7. Warnings and precautions[1,2]

A. Serious hypersensitivity reactions, including anaphylaxis, have been observed with other human immunoglobulin G1 (IgG1) monoclonal antibodies. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, initiate appropriate medications and/or supportive therapy.

B. As with any other IM injection, use caution if administered to infants and children with thrombocytopenia, any coagulation disorder, or to individuals on anticoagulation therapy.

8. Other considerations[1,2,4,5]

A. The RSV season in most of the continental United States typically occurs during the fall through spring. However, because RSV activity may vary, providers should adjust administration schedules based on local epidemiology. Additionally, providers may use clinical judgment in determining when to give nirsevimab outside of October through March. Special circumstances may include travel to areas with increased RSV activity or concerns that the infant or child may not return for a visit when nirsevimab should ideally be administered.

B. Either maternal RSV vaccination during pregnancy at 32–36 weeks' gestation **or** monoclonal antibody immunization for infants aged <8 months is recommended but administration of both products is not needed for most infants**.**

C. Children born shortly before or during the RSV season should receive monoclonal antibody **within one week of birth**. Monoclonal antibody products may be administered during the birth hospitalization or in an outpatient setting.

D. Infants with prolonged birth hospitalizations due to prematurity or other causes should receive monoclonal antibody shortly before or promptly after discharge.

E. Children who have received nirsevimab or clesrovimab must not receive palivizumab during the same RSV season.

F. Infants born to vaccinated mothers may receive nirsevimab or clesrovimab when clinically warranted:[5]

- Conditions in pregnant people resulting in an inadequate immune response to vaccine or decreased transplacental antibody transfer

- Infants who have undergone cardiopulmonary bypass, leading to loss of maternal antibodies
- Infants with sufficiently increased risk for severe disease to warrant nirsevimab or clesrovimab because of the potential increased benefit

G. **Coadministration with vaccines**: Coadministration of monoclonal antibody products with age-appropriate vaccines is recommended. In clinical trials, when licensed products were given concomitantly with routine childhood vaccines, the safety and reactogenicity profile of the coadministered regimen was similar to that of the childhood vaccines given alone.[1,2] When coadministered with other injectable vaccines, monoclonal antibody should be given at a separate injection site.[1,2]

H. Administer IM anterolateral aspect of the thigh/vastus lateralis. If two injections are required use a different injection site.

9. Side effects and adverse reactions[1,2]

Adverse Event	Frequency
Injection site events (pain at the injection site, redness, swelling)	Up to 4%
Rash (occurring within 14 days post-dose)	Up to 2.3%

10. Storage and handling

All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 800-980-9431.

Vaccine	Temp	Storage Issues	Notes
Beyfortus[1]	Refrigerate between 2°C to 8°C (36°F to 46°F)	Store in original carton and protect from light. Do not freeze. Do not shake. Do not expose to heat.	May be kept at room temperature 68ºF to 77ºF (20ºC to 25ºC) for a maximum of 8 hours after removal from refrigerator. Discard after 8 hours.
Enflonsia[2]			May be kept at room temperature 68ºF to 77ºF (20ºC to 25ºC) for a maximum of 48 hours after removal from refrigerator. Discard after 48 hours.

11. Adverse events reporting

If monoclonal antibody was given at the same visit with one or more vaccinations, report adverse events to VAERS at https://vaers.hhs.gov/reportevent.html.

If monoclonal antibody was given alone with no other vaccinations on the same visit, report to MedWatch at www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting.

12. References

1. AstraZeneca. Beyfortus™ package insert, 2023. Available at: www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf. Accessed 30 Jun 2025.
2. Merck. Enflonsia™ package insert, 2025. Available at: https://www.merck.com/product/usa/pi_circulars/e/enflonsia/enflonsia_pi.pdf. Accessed 30 Jun 2025.
3. Esposito S, Abu-Raya B, Bonanni P, et al. Coadministration of anti-viral monoclonal antibodies with routine pediatric vaccines and implications for nirsevimab use: a white paper. Frontiers in Immunology, August 11, 2021. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8386277/. Accessed 30 Jun 2025.
4. Jones J, Fleming-Dutra K, Prill M, et al. 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. MMWR 2023;72:930–5. Available at www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm. Accessed 30 Jun 2025.
5. Centers for Disease Control and Prevention. RSV Immunization Guidance for Infants and Young Children, August 30, 2024. Available at www.cdc.gov/rsv/hcp/vaccine-clinical-guidance/infants-young-children.html. Accessed 30 Jun 2025.
6. Centers for Disease Control and Prevention. General Best Practice Guidelines for Immunization, July 25, 2024. Available at https://www.cdc.gov/vaccines/hcp/imz-best-practices/?CDC_AAref_Val=https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html. Accessed 30 Jun 2025.
7. Fleming-Dutra KE, Jones JM, Roper LE, et al. Use of the Pfizer respiratory syncytial virus vaccine during pregnancy for the prevention of respiratory syncytial virus–associated lower respiratory tract disease in infants: recommendations of the Advisory Committee on Immunization Practices—United States, 2023. MMWR ePub: 6 October 2023. Available at

http://dx.doi.org/10.15585/mmwr.mm7241e1. Accessed 30 Jun 2025.

To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 800-980-9431 and 711 for TTY. For other questions, consult with the vaccine recipient's primary health care provider or a consulting physician.

Electronic copy of this immunization protocol is available at: www.oregon.gov/oha/ph/preventionwellness/vaccinesimmunization/immunizationproviderresources/pages/stdgordr.aspx

13. Appendix A – Patient Information Handout[1]

PATIENT INFORMATION
BEYFORTUS™ (Bay for tus)
(nirsevimab-alip)
injection, for intramuscular use

What is BEYFORTUS?

BEYFORTUS is a prescription medicine that is used to help prevent a serious lung disease caused by Respiratory Syncytial Virus (RSV) in:

- newborns and babies under 1 year of age born during or entering their first RSV season.
- children up to 24 months of age who remain at risk of severe RSV disease through their second RSV season.

BEYFORTUS is an antibody that contains nirsevimab-alip which is used to help prevent RSV disease for 5 months.

It is not known if BEYFORTUS is safe and effective in children older than 24 months of age.

Your child should not receive BEYFORTUS if your child has a history of serious allergic reactions to nirsevimab-alip or any of the ingredients in BEYFORTUS. See the end of this Patient Information leaflet for a complete list of ingredients in BEYFORTUS.

Before your child receives BEYFORTUS, tell your healthcare provider about all of your child's medical conditions, including if your child:

- has ever had a reaction to BEYFORTUS.
- has bleeding or bruising problems. If your child has a problem with bleeding or bruises easily, an injection could cause a problem.

Tell your child's healthcare provider about all the medicines your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your infant should not receive a medicine called palivizumab if they have already received BEYFORTUS in the same RSV season.

How is BEYFORTUS given?

- BEYFORTUS is given as an injection, usually in the thigh (leg) muscle, by your child's healthcare provider.
- **Your child should receive BEYFORTUS before or during the RSV season.** RSV season is the time of year when RSV infections are most common, usually occurring fall through spring. Your healthcare provider can tell you when the RSV season starts in your area.
- **Your child may still get RSV disease after receiving BEYFORTUS**. Talk to your child's healthcare provider about what symptoms to look for.
- If your child has heart surgery, your child's healthcare provider may need to give your child an additional BEYFORTUS injection soon after surgery.

What are the possible side effects of BEYFORTUS?

- **Serious allergic reactions** have happened with other medicines like BEYFORTUS. Get medical help right away if your child has any of the following signs or symptoms of a serious allergic reaction:
  - swelling of the face, mouth, or tongue
  - difficulty swallowing or breathing
  - unresponsiveness
  - bluish color of skin, lips or under fingernails
  - muscle weakness
  - severe rash, hives or itching

The most common side effects of BEYFORTUS include rash, and pain, swelling or hardness at the site of your child's injection.

These are not all of the possible side effects of BEYFORTUS.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of BEYFORTUS.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about BEYFORTUS that is written for health professionals.

What are the ingredients in BEYFORTUS?

Active ingredient: nirsevimab-alip

Inactive ingredients: arginine hydrochloride, histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sucrose and water for injection.

Manufactured by: AstraZeneca AB, Södertälje, Sweden SE-15185

US License No. 2059

Distributed by: Sanofi Pasteur, Inc., Swiftwater, PA 18370 USA

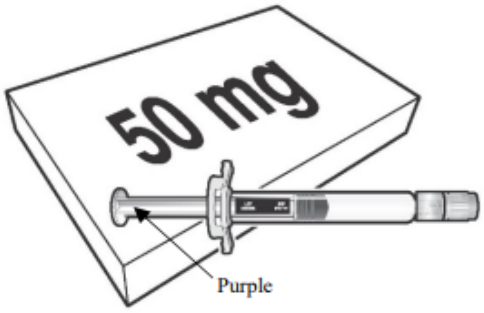
BEYFORTUS is a trademark of the Sanofi group of companies.

For more information, go to https://www.Beyfortus.com or call 1-855-239-3678 (1-855-BEYFORTUS).

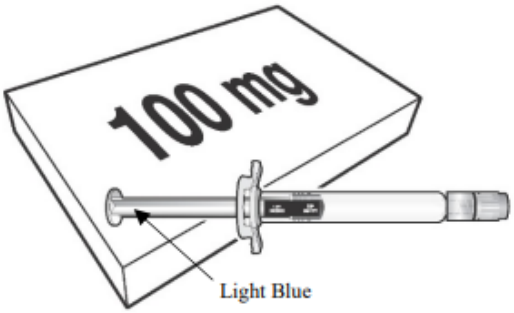
This Patient Information has been approved by the U.S. Food and Drug Administration. Issued: July 2023

14. Appendix B – Beyfortus™ preparation[1]

BEYFORTUS 50 mg (50 mg/0.5 mL) pre-filled syringe with a purple plunger rod.

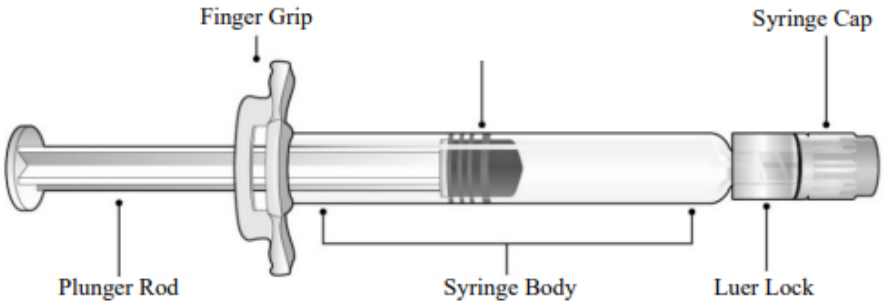


BEYFORTUS 100 mg (100 mg/mL) pre-filled syringe with a light blue plunger rod.



Refer to Figure 1 for pre-filled syringe components.

Figure 1 Luer Lock Syringe Components



Step 1: Holding the Luer lock in one hand (avoid holding the plunger rod or syringe body), unscrew the syringe cap by twisting it counter-clockwise with the other hand.

Step 2: Attach a Luer lock needle to the pre-filled syringe by gently twisting the needle clockwise onto the pre-filled syringe until slight resistance is felt.

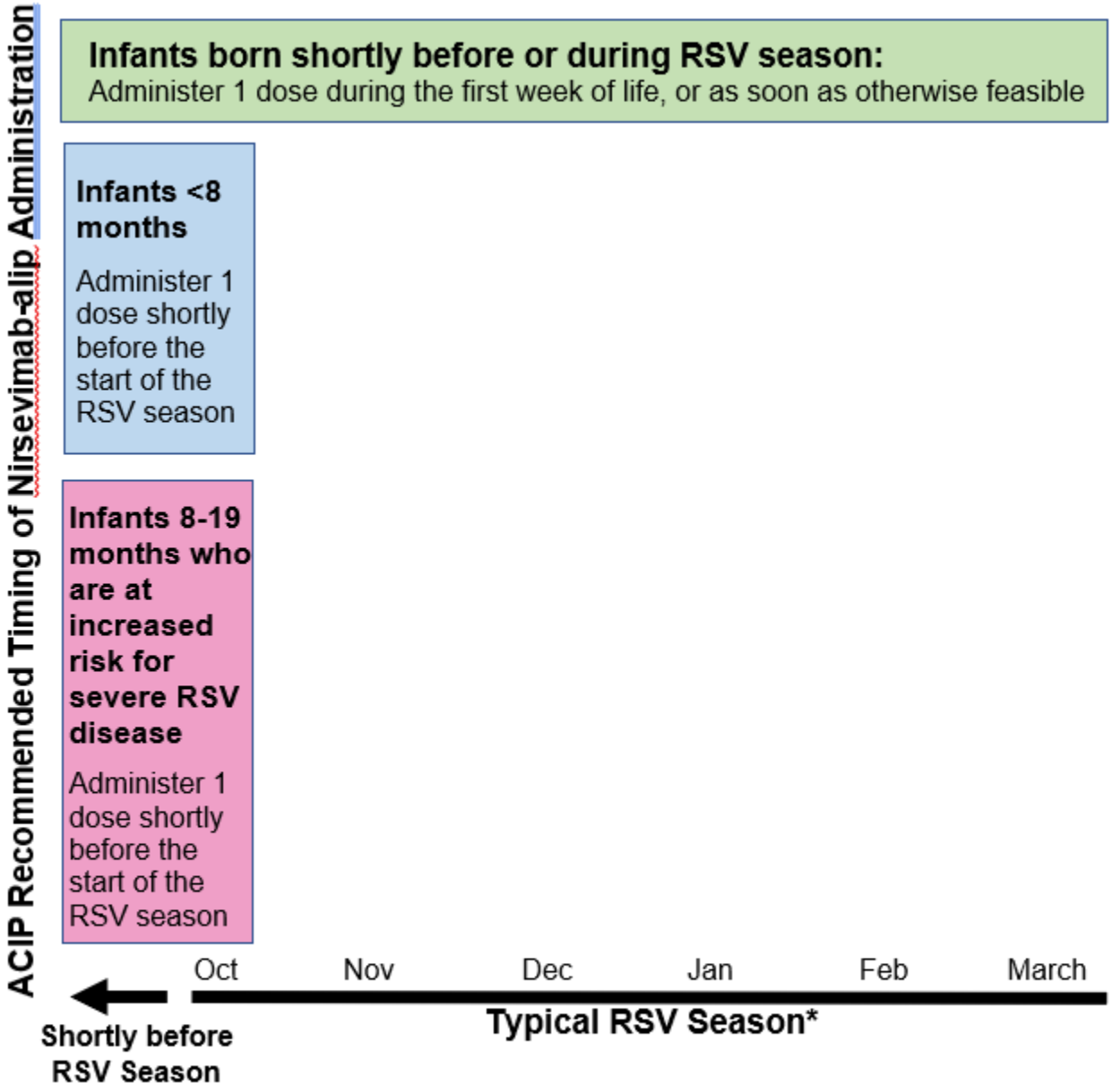
Step 3: Hold the syringe body with one hand and carefully pull the needle cover straight off with the other hand. Do not hold the plunger rod while removing the needle cover or the rubber stopper may move. Do not touch the needle or let it touch any surface. Do not recap the needle or detach it from the syringe.

Step 4: Administer the entire contents of the BEYFORTUS pre-filled syringe as an IM injection, preferably in the anterolateral aspect of the thigh. The gluteal muscle should not be used as an injection site because of the risk of damage to the sciatic nerve.

Step 5: Discard syringe into a sharps container.

If two injections are required, repeat Steps 1-5 in a different injection site.

15. Appendix C – Timing of Nirsevimab Administration



* Nirsevimab may be administered outside of October through March using clinical judgment based on local RSV activity and other special circumstances.