



## Additional supplies of RSV immunization to be released; shortages remain likely

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Melissa Jenco, News Content Editor

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Pediatricians may have new opportunities to stock respiratory syncytial virus (RSV) immunization nirsevimab (Beyfortus). However, the additional supplies likely won't meet demand.

Federal health officials announced Thursday they are releasing more than 77,000 of the 100 milligram (mg) doses after identifying a batch awaiting final clearance and expediting processing. The Centers for Disease Control and Prevention (CDC) said the doses would be available to physicians and hospitals through commercial channels and the Vaccines for Children (VFC) program. Sanofi said it would reach out to affected customers in early December. In addition, Sanofi reopened ordering for 50 mg doses Thursday, but they will be distributed on a limited allocation basis for the private market.

The long-awaited monoclonal antibody product to protect infants from the leading cause of hospitalization received [CDC approval](#) in early August. However, it has been in short supply. The CDC has been using an allocation system for VFC distribution. On the commercial side, Sanofi stopped taking orders for 100 mg doses in October and [paused the ordering](#) of 50 mg doses Nov. 2.

"CDC and FDA are committed to expanding access to this important immunization so that more parents have peace of mind during the winter virus season," CDC Principal Deputy Director Nirav D. Shah, M.D., J.D., said in a [press release](#).

For 50 mg doses, a Sanofi spokesperson confirmed its direct ordering platform reopened Thursday as planned. Only customers with an assigned allocation will be able to place a new order, and Sanofi is in

contact with providers about distribution. It has said its goal is to distribute doses equitably. The spokesperson declined to disclose how many doses would be available. Customers with questions can contact their representative or call 855-BEYFORTUS.

The CDC has [provided guidance](#) on prioritizing limited supplies of nirsevimab.

- Give nirsevimab to infants at highest risk of severe disease, including the youngest infants, those with certain underlying medical conditions and those who are American Indian or Alaska Natives.
- Refer patients to other providers when your practice does not have available stock.
- Encourage [maternal vaccination](#) during 32-36 weeks of pregnancy.
- Do not use two 50 mg doses for children who need 100 mg. Doing so is not part of FDA approval and may not be covered by insurance.

The AAP has been working closely with federal officials and Sanofi on supply issues and other logistical hurdles to using nirsevimab including payment. The Centers for Medicare & Medicaid Services recently [established payment rates](#) similar to other pediatric immunization administration services.

### **Resources**

- [Recording of the AAP webinar on nirsevimab supply issues](#)
- [CDC guidance on use of nirsevimab while supply is limited during the 2023-'24 season](#)
- [AAP RSV resources, including information on ordering, dosing, coding and a visual guide for nirsevimab administration](#)
- [AAP News article "How to use new CPT codes for administration of RSV immunizations"](#)
- [VFC operations guide addendum for nirsevimab](#)
- [Information for clinicians from the CDC on nirsevimab](#)
- [Information for parents from HealthyChildren.org on RSV immunization availability](#)
- [Information for parents from HealthyChildren.org on RSV symptoms and when to call a doctor](#)