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Minute Market Insights

Minute Market Insights are intended to highlight changes that may impact drug product selection, drug product utilization or patient care.

Management Strategies

- CDC recommends prioritizing available nirsevimab 100 mg doses for infants at highest risk for severe RSV disease. Refer to ACIP 2023 guidelines, AAP 2023 guidance, and the CDC HAN advisory for more information on risk factors.
- Avoid using two 50 mg doses for infants ≥ 5 kg to preserve supply of 50 mg doses for infants weighing < 5 kg. Additionally, some insurers may not cover two 50 mg doses.
- CDC recommends providers suspend using nirsevimab in children age 8 to 19 months who would otherwise be eligible for palivizumab (see AAP guidelines). Nirsevimab should continue to be offered to American Indian and Alaska Native children in this age range, who are not palivizumab-eligible.
- Follow AAP recommendations for palivizumab-eligible infants < 8 months when nirsevimab is not available.
- CDC recommends pregnant individuals to receive the maternal RSV vaccination (Abrysvo), during 32 to 36 weeks gestation (note: administration of both maternal RSV vaccine and nirsevimab is not recommended in most cases).

Vizient Resources

- RSV mAb side-by-side comparison
- FAQ on pediatric RSV prevention
- Nirsevimab drug shortage mitigation strategy

To learn more, please contact
Vizient Center for Pharmacy Practice Excellence, Evidence-Based Medicine Group at
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Nirsevimab (Beyfortus) shortage

What is new?

On July 17, 2023, AstraZeneca and Sanofi's nirsevimab (Beyfortus) was approved. Nirsevimab is a new, long-acting monoclonal antibody (mAb) for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease (LRTD) in infants and children. Nirsevimab has a substantially longer half-life compared with palivizumab (Synagis), allowing for a single intramuscular dose for the entire RSV season as compared with palivizumab, which is administered monthly. In addition to use in high-risk patients, nirsevimab is also approved for use in healthy term infants for RSV LRTD prevention.

On August 3, 2023, the Advisory Committee on Immunization Practices (ACIP) met to vote on recommendations for the use of nirsevimab. The complete recommendations were published in the *Morbidity and Mortality Weekly Report* (*MMWR*) on August 25, 2023. The Committee recommended nirsevimab for use in all infants aged < 8 months who are born during or are entering their first RSV season and in children 8 to 19 months of age who are at increased risk of severe RSV disease and entering their second RSV season. On August 15, 2023, the American Academy of Pediatrics (AAP) published a guidance statement on the use of nirsevimab.

Nirsevimab is supplied as 50 mg and 100 mg prefilled syringes. The 50 mg dose is recommended for infants < 5 kg, while the 100 mg syringe is used for infants ≥ 5 kg (100 mg dose) and at-risk children entering their second RSV season (200 mg dose). **Due to supply shortages of the 100 mg prefilled syringe**, the Centers for Disease Control and Prevention (CDC) issued a Health Alert Network (HAN) advisory on October 23, 2023. Sanofi attributes the shortage to unprecedented demand for nirsevimab.

What is the impact of the shortage?

Sanofi is currently not taking additional orders for the 100 mg syringe. Any 100 mg syringes being shipped are fulfilling existing orders, and the remaining stock of the 100 mg syringe is expected to be depleted by the end of October/early November. It is currently unknown whether additional 100 mg syringes will be available for the 2023-24 RSV season. Nirsevimab is available through the Vaccines for Children (VFC) program; however, ordering of nirsevimab has been temporarily put on hold through the VFC program. CDC expects ordering to resume soon with an allocation system in place. Health systems will need to have a plan for allocating nirsevimab 100 mg syringes, as supply will be insufficient to provide nirsevimab to all eligible patients. There are currently no supply issues or restrictions with the 50 mg syringe.

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