Drug FAQs for Members
FREQUENTLY ASKED QUESTIONS

Nirsevimab (Beyfortus)
to Prevent Respiratory Syncytial Virus Disease in Infants and Young Children

What is Respiratory Syncytial Virus (RSV)?

- RSV is a very common viral infection that affects babies and children. It can cause respiratory illness, including serious lung infections. Symptoms can include nasal congestion, cough, sneezing, runny nose, sometimes fever and muscle aches.
- RSV affects about 90% of children within their first 2 years of life. RSV infection is the leading cause of hospital stays for babies under 1 year of age.
- The virus is easily spread through droplets of an infected person when they cough or sneeze through the eyes, nose, and mouth. RSV can also stay infectious on hard surface areas and on the skin for several hours.
- RSV is most common during the months of October through March.

What is nirsevimab and how does it work?

- Nirsevimab (also known as Beyfortus) is a type of medicine known as an antibody. It provides immediate and short-term protection from RSV disease.
- Nirsevimab works by blocking RSV from entering healthy cells, especially cells in the lungs. This helps to prevent RSV infection.
- Nirsevimab is given directly to the newborn as an injection into the muscle, preferably within one week of birth, when born during RSV season (usually October through March).
- One dose of nirsevimab helps to prevent RSV disease for 5 months which is the length of a typical RSV season.

Is nirsevimab a vaccine?

- Nirsevimab is not a vaccine. It is an antibody that is recommended as part of routine childhood immunizations.
- Nirsevimab offers passive immunity to RSV. Passive immunity is when a person is given antibodies that provide immediate but short-term protection to a disease.
- In contrast, vaccines provide active immunity and “train your immune system” to make antibodies to the disease. Active immunity with vaccines usually takes a few weeks to provide protection but this protection is long-lasting.

Who should receive nirsevimab?

- To help protect against RSV disease, the Centers for Disease Control and Prevention (CDC) recommends immunization with nirsevimab in the following individuals:
  - Infants below 8 months of age born during or entering their first RSV season.
  - Infants and children aged 8 to 19 months who are at increased risk of severe RSV disease and are entering their second RSV season.

What are other options for prevention of severe RSV disease in babies?

- Maternal RSV vaccine (Abrysvo) was recently approved by the Unites States Food and Drug Administration (FDA) and recommended by the Centers for Disease Control and Prevention (CDC) for use in people who are 32 to 36 weeks pregnant to protect their baby from birth to age 6 months from the risk of severe lung disease caused by RSV.
- Getting the vaccine allows pregnant people to protect their baby from severe RSV disease.
- The RSV vaccine works by helping the pregnant person's immune system recognize and target RSV. This immune response to RSV is then passed on to the baby before birth. This helps to protect babies against severe lung disease caused by RSV for up to 6 months after birth when babies are at highest risk. Because Abrysvo is given to the pregnant person, it is called maternal RSV vaccine.

What are the pros and cons of the maternal RSV vaccine and nirsevimab?

	Pros	Cons
Maternal RSV Vaccine	• Protects baby right after they are born • Might be more effective than nirsevimab against changes in the virus	• Protection may be less if the pregnant person is immunocompromised or baby is born less than 14 days after vaccination • Possible risk for preterm birth and serious high blood pressure disorders of pregnancy
Nirsevimab	• Baby receives antibodies directly (does not need to be transferred from pregnant person to baby) • No risk of harm to pregnancy • RSV protection may decrease slower with nirsevimab than with the maternal RSV vaccine • Can time the dose for when baby enters RSV season	• Supply of nirsevimab may be limited during the 2023–2024 RSV season • Requires injection to the baby

Is nirsevimab needed if the mother gets the maternal RSV vaccine?

- Nirsevimab is not needed for most babies if Abrysvo was given to the mother 14 or more days before delivery.
- If a baby is born less than 14 days after the mother was given Abrysvo, the CDC recommends the baby receive nirsevimab within the first week of life. This is because 14 days or more after the Abrysvo dose are needed for the mother to develop and transfer the RSV immune response to the baby.
- In rare situations, nirsevimab may be considered for a baby born to vaccinated mothers. For example, if the baby was born to a mother with an immunocompromising condition.
- It is recommended that pregnant people talk with their healthcare provider to decide if they prefer to get the RSV vaccine during pregnancy or wait until the baby is born so that the baby will receive nirsevimab.

What is recommended if my baby is born outside the RSV season?

- Babies born outside of the RSV season (April through September) to unvaccinated pregnant people are recommended to receive nirsevimab if they are less than 8 months old at the start of their first RSV season.

How effective is nirsevimab?

- In clinical trials nirsevimab has been shown to decrease the risk for a baby to require medical attention for respiratory illness due to RSV.
  - One study in preterm infants showed this risk to be about 10% in babies who received placebo (no active drug) compared to about 3% in babies who received nirsevimab. This difference amounts to about a 70% lower risk of severe RSV-related disease that required medical attention for babies in the first five months after getting nirsevimab.
  - Another study in full term and late-preterm infants showed this risk to be about 5% in babies who received placebo compared to about 1% in babies who received nirsevimab. This difference amounts to about a 75% lower risk of severe RSV-related disease that required medical attention for babies in the first five months after getting nirsevimab.
- Nirsevimab has not been studied in children older than 24 months of age.

What are common side effects of nirsevimab?

- The most common side effects of nirsevimab include rash and pain, swelling or hardness at the injection site.
- Rare side effects include muscle weakness, blue or gray skin or nails, allergic reaction to the drug.

How is nirsevimab given?

- Nirsevimab is given by a healthcare provider as an injection into the thigh muscle.
- For babies born during the RSV season, one dose of nirsevimab is recommended to be given in the first week after birth. It may be offered anytime during the RSV season to those who have not yet received a dose.
- For babies less than 8 months of age who were born shortly before or are entering their first RSV season (usually fall through spring), one dose of nirsevimab is recommended shortly before the start of their first RSV season. It may be offered anytime during the RSV season to those who have not yet received a dose.
- For certain children ages 8 months through 19 months who are at high risk of severe RSV disease, one dose of nirsevimab is recommended shortly before the start of their second RSV season. It may be offered anytime during the second RSV season to those who have not yet received a dose.

When will nirsevimab be available?

- Nirsevimab is expected to be available late-October or November 2023 for administration during the RSV season.
- The manufacturer may have only limited supply of nirsevimab for the 2023-2024 RSV season.