



Hot Topics of the Month

9/14/2023

Updates on RSV Antibody, COVID and Flu Vaccines

Updates on recommendations and implementation on the [new RSV Antibody, Nirsevimab](#)

1. Is Nirsevimab a vaccine?
 - Not quite. While vaccines act through active immunization, Nirsevimab is a long-lasting RSV monoclonal antibody that directly protects infants through passive immunization. It lasts at least 5 months and has good efficacy, i.e., it is 80% effective in preventing significant RSV lower respiratory disease in children who would otherwise require hospitalization. It has been approved by both the Federal Drug Administration (FDA) and Advisory Committee on Immunization Practices (ACIP) this past summer. Clinical trials have shown reassuring safety reviews for Nirsevimab.
2. Who is eligible to receive Nirsevimab?
 - All infants who are born in the RSV season (October through March).
 - Children who are 8 to 18 months, at high risk, and entering their second RSV season.
 - The following children are considered high risk:
 - a) Children with chronic lung disease who have undergone therapy in the first 6 months of life.
 - b) Children with severe Cystic Fibrosis
 - c) Children who are severely immunocompromised.
 - d) American Indian & Native Alaskan children
 - Pregnant Women
 - a) Nirsevimab given to pregnant women has a similar efficacy to Nirsevimab given to infants in preventing severe RSV lower respiratory disease in infants.
 - b) Please note there is minimal incremental gain in receiving both Nirsevimab during pregnancy and to the infant after he/she is born.
3. How is Nirsevimab administered?
 - As an injection that comes in prefilled syringes
 - Dose is based on weight, so there will be different sizes.

- It will be administered as a single dose. This is an advantage to Palivizumab (current monoclonal antibody for RSV) which has been given as 5 doses.
 - Can be administered during pregnancy with the following exceptions:
 - a) Not effective if given one month before delivery
 - b) Not effective if given during pregnancy and baby was delivered before term.
 - Can be administered in the hospital after the baby is born or in the first visit in an ambulatory setting
4. What are the setbacks to administering Nirsevimab this fall to winter season of 2023/2024?
- Cost
 - a) \$495 for each dose
 - b) Insurance currently does not cover Nirsevimab.
 - Since it is recognized as a drug and not a vaccine, insurance companies are not set-up to deal with drug codes as opposed to vaccine codes.
 - Stocking Issues
 - a) Due to cost & coverage, many healthcare facilities do not have it in stock.
 - b) Conflict in who will administer it.
 - a. OB-GYN offices vs. Hospitals vs. Ambulatory settings
5. What is being done to correct these setbacks?
- Currently the American Medical Association (AMA) is working with the American Academy of Pediatrics (AAP) to set up effective billing codes for insurance companies.
 - The AAP is calling for a comprehensive strategy from federal officials and the CDC to ensure equitable access to Nirsevimab in hospitals, birthing centers, and ambulatory practice settings.
6. What can be done for children this fall/winter season?
- Parent(s) can continue to inquire at birthing centers and hospitals if Nirsevimab is available.
 - Although Nirsevimab may not be available in many settings this season, eligible high-risk children in their first or second year of life should receive the monoclonal antibody Palivizumab which includes a series of monthly doses.
 - Eligible high-risk children who qualify for palivizumab:
 - a) Infants born before 29 weeks gestation, 0 days' gestation and who are younger than 12 months at the start of the RSV season
 - b) Infants born less than 32 weeks, 0 days and develop chronic lung disease (CLD) of prematurity with a requirement of >21% oxygen in the first 28 days of life. During the second year of life, Palivizumab prophylaxis is recommended for those who satisfy the latter definition of CLD and continue to require support.
 - c) Infants with hemodynamically significant Congenital Heart Disease (CHD)

- i. Infants with acyanotic heart disease who require medical support to prevent congestive heart failure and will require cardiac surgical procedures
- ii. Infants with moderate to severe pulmonary hypertension
- d) Infants with a neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway are considered for prophylaxis during the first year of life.
- e) Infants who are profoundly immunocompromised during the RSV season and younger than 24 months of age
- f) Infants who have cystic fibrosis with CLD and/or nutritional compromise in the first year of life.

Updates on recommendations & implementation of the [COVID vaccine](#)

1. Is there a new COVID vaccine this fall/winter season of 2023 and what COVID strains does it cover?
 - The updated COVID-19 vaccine for 2023-2024 is a monovalent mRNA vaccine. It is intended to address waning protection and evolving strains. All circulating strains are omicron and most are from the XBB lineage. The updated vaccine contains the XBB 1.5 strain.
2. What if my child received the previous Bivalent COVID-19 vaccines or is in the middle of finishing their series?
 - As of September 12th, 2023, Bivalent mRNA (Pfizer-BioNTech and Moderna) COVID-19 vaccines are no longer authorized for use in the U.S.
 - Individuals 5 years and older regardless of previous vaccination are eligible to receive a single dose of the updated 2023-2024 monovalent COVID-19 vaccine. They can receive it at least 2 months since the last dose of any COVID-19 vaccine.
 - Children 6 months through 4 years of age who have been previously vaccinated against COVID-19 are eligible to receive one or two doses of the updated COVID-19 vaccine (timing and number of doses to administer depends on the previous COVID-19 vaccines received).
 - Unvaccinated children 6 months through 4 years of age are eligible to receive 3 doses of the updated authorized Pfizer-BioNTech COVID-19 Vaccine or 2 doses of the updated authorized Moderna COVID-19 vaccine.
3. What are the CDC recommendations for children in receiving the updated COVID-19 vaccine?
 - The CDC recommends any child 6 months or older to receive the updated COVID-19 vaccine.
 - Although the high-risk population of children are especially advised to stay current with the COVID-19 vaccine, the CDC chose a universal recommendation to help children avoid long COVID and school absences.
 - What is long COVID?

- a) Long COVID are signs, symptoms, conditions that continue to develop long after the initial acute infection of COVID-19.
- b) Common symptoms include fatigue that interferes with daily life, post-exertional malaise (symptoms get worse after mental or physical effort), fever, shortness of breath, cough, chest pain, heart palpitations, “Brain Fog” (difficulty concentrating), headache, sleep problems, dizziness when standing up, change in smell or taste, depression or anxiety, stomach pain/diarrhea and/or joint pain

Updates on recommendations of the [Flu vaccine](#)

1. Influenza Vaccines for the 2023-2024 season has been updated to include a new Influenza A component (H1N1) pdm09 component.
2. The Flu shot can be administered with the COVID vaccine at the same time
3. The Flu season has already started in the southern hemisphere (eg. Australia) and is anticipated to be increasing in burden in the Northern hemisphere this fall/winter season.
4. Flu vaccines are now available in our office. **Flu Clinics are scheduled for Tuesday, Sept 19th & Wednesday, Oct 11th (from 3-6PM).**
5. What is special about our Flu Clinic this year?
 - Parents can choose to receive the flu vaccine with their child if they register ahead of the appointment.