MCAAP Resource Packet on RSV Prevention in Infants and Nirsevimab

Watch and share this video on how Nirsevimab works by the American Society for Microbiology: https://youtu.be/f7isAsM2ydI?si=NdyRAWUOy292NtRH

To read the August 25, 2023, edition of the MMWR regarding infant RSV prevention. https://www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7234a4-H.pdf

Information about the Universal Vaccine Purchasing Program and the Massachusetts Vaccine Purchase Trust Fund:

https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter111/Section24N#:~:text=The%20council%20shall%20recommend%20the,as%20determined%20by%20the%20council.

CDC Page on RSV Prevention (updated frequently): https://www.cdc.gov/vaccines/vpd/rsv/index.html
CDC's Nirsevimab "Immunization Information Sheet" can be found at:
https://www.cdc.gov/vaccines/vpd/rsv/downloads/Immunization-Information-Statement.pdf

AAP: All you want to know about Nirsevimab and medically attended RSV disease prevention (updated very frequently) https://www.aap.org/en/patient-care/respiratory-syncytial-virus-rsv-prevention/

AAP: Nirsevimab Readiness Practice Checklist includes coding/billing, ordering, office workflows, and messaging to families and the community. Invaluable https://downloads.aap.org/AAP/PDF/Nirsevimab_Readiness_Practice_Checklist_FINAL.pdf

AAP: Nirsevimab Implementation Guide includes recall processes, scheduling in vaccine clinics and well child visits, documentation, eligibility and scheduling, inventory management and more: https://downloads.aap.org/AAP/PDF/Nirsevimab_Implementation_Guide_FINAL.pdf



DEDICATED TO THE HEALTH OF ALL CHILDREN®

Massachusetts Chapter of the American Academy of Pediatrics FAQs About RSV Preventive Antibodies for Infants:

- 1. What is Nirsevimab? Nirsevimab is a monoclonal antibody product that is a passive immunization. While not technically a "vaccine" in a traditional sense (active immunization), it is being used in a manner similar to routine childhood vaccines and may be referred to as a vaccine by some entities. Nirsevimab confers long-lasting protection from RSV, with protection expected to last at least 5 months (about the length of a typical RSV season). Nirsevimab is part of the Vaccines for Children program.
- 2. **Should we call Nirsevimab a vaccine?** Legally, Nirsevimab is being included in most regulations regarding vaccines. Many clinicians are choosing terms "Nirsevimab immunization", "RSV immunization, or "RSV preventive antibodies" with patients. Just be consistent and factual.
- 3. Who can administer Nirsevimab? Any team member who is currently administering vaccines in your practice setting may administer Nirsevimab. In Massachusetts, that includes medical assistants if they have been trained to administer vaccines.
- 4. What do I need to document for Nirsevimab administration? Document just as you would a routine childhood vaccine to comply with federal law: Vaccine name and manufacturer, Lot number, date of administration, name/address/title of the administering HCP, the Immunization Information Statement (IIS) edition date from the lower righthand corner on the second page and the date the IIS was given to the caregiver. Federal law does not require a caregiver to sign a consent form in order to receive a vaccination; providing them with the appropriate VIS(s) and answering their questions is sufficient under federal law. Practices and hospitals may develop their own policies in addition to federally-compliant procedures.
- 5. Is Nirsevimab/Beyfortus part of the MA Universal Child Vaccine Purchase Program? Yes, it is. That means that any VFC provider in Massachusetts may order this product at no cost. It also means that non-VFC providers may not be ensured that private payers will cover the purchase cost of Nirsevimab and they will need to ask payers what their policy will be on payment outside VFC
- 6. Do you have any tools to help me figure out how many doses of Nirsevimab I should order? Please get in touch with your Sanofi representative, who can provide you with a ordering tool to model how many doses to order. You may consider placing a small order initially as you gauge interest in the immunization among your patients as you will be able to place additional orders later in the season.
- 7. **How long can we keep Nirsevimab and will Sanofi accept product returns?** Nirsevimab has a long shelf life with expiration dates up to 18 months after distribution. At this time it is not assured that the product can be returned for refund or restitution. See MPDPH's 2024 Guidelines for Compliance with Federal and State Vaccine Administration Requirements. You may be able to use product in up to two RSV seasons. Order carefully.
- 8. How do I plan for use of paluzivimab (Synagis) in the 2024-25 RSV season?
 - It is not expected that palivizumab will be used this season due to the availability of nirsevimab.
 - If nirsevimab is administered, palivizumab should not be administered later that season.
 - If palivizumab was administered initially for the season and <5 doses were administered, the infant should receive 1 dose of nirsevimab. No further palivizumab should be administered.



- If palivizumab was administered in season 1 and the child is eligible for RSV prophylaxis in season 2, the child should receive nirsevimab in season 2, if available. If nirsevimab is not available, palivizumab should be administered as previously recommended.
- 9. **How do I report suspected adverse reactions to Nirsevimab?** Report side effects that happen after getting nirsevimab (with NO coadministered vaccines) to the <u>MedWatch website</u> or by calling 1-800-FDA-1088. Report side effects that happen after getting nirsevimab WITH coadministered vaccines (the same day) to the <u>VAERS</u> website or by calling 1-800-822-7967.
- 10. If an infant has been diagnosed with RSV this season, should they still receive nirsevimab? Unlike palivizumab (Synagis), Nirsevimab recommendations are the same regardless of prior RSV infection or RSV-associated hospitalization.

A Few Words About Maternal RSV Vaccine:

- 1. What does the American College of Obstetricians say about the maternal RSV vaccine? "ACOG unequivocally supports ACIP's recommendation for the use of the maternal RSV vaccine in pregnancy during 32 through 36 weeks gestation using seasonal administration. The national and global burden of RSV disease demonstrates how critical it is to prevent this virus in infants. ACOG believes the maternal RSV vaccine is efficacious and it is necessary that parents have this option to protect their newborns from RSV after birth. ACOG is currently making updates to its clinical guidance that will be released in the coming days."
- 2. If an infant's mother has received maternal RSV vaccine, should the infant receive nirsevimab? The CDC does not recommend nirsevimab for most infants born to a mother who received maternal RSV vaccine, except for infants where less than 14 days have elapsed between vaccination and birth.
- **3. Are there any videos on how maternal RSV vaccine works?** ACOG has some good videos about maternal RSV vaccine (ABRYSVO) during pregnancy: https://www.acog.org/womens-health/videos/get-your-recommended-rsv-vaccine-during-pregnancy





Nirsevimab CPT Codes for Product Billing

From https://www.aap.org/en/patient-care/respiratory-syncytial-virus-rsv-prevention/nirsevimab-coding-payment/

- CPT codes 90380–90381 were approved by the American Medical Association's (AMA's) Current Procedural Terminology (CPT) Editorial Panel in May 2023, released on June 30, 2023.
- Report codes 90380–90381 based on the dose administered: 0.5mL or 1.0 mL.
- 90380: Respiratory syncytial virus, monoclonal antibody, seasonal dose; 0.5 mL (50 mg) dosage, for intramuscular use
- 90381: Respiratory syncytial virus, monoclonal antibody, seasonal dose; 1 mL (100 mg) dosage, for intramuscular use

Follow state specifications for reporting the immunization when the immunoglobulin product is provided through the Vaccines for Children program. For example, report 90380 SL to indicate state-supplied product. From https://www.aap.org/en/patient-care/respiratory-syncytial-virus-rsv-prevention/nirsevimab-coding--payment/

Administration CPT Codes and ICD-10 Codes

Administration Code

As of 10-6-2023 CPT released 2 new **codes** specific for reporting the administration and counseling of monoclonal antibodies for RSV. Report the administration of nirsevimab with code **96380** Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection, with counseling by physician or other qualified health care professional or **96381** Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection. Code selection is based on if a physician or QHP provided counseling on the same date as the administration of nirsevimab. If counseling was not performed on the date of administration **96381** is the correct code to report.

Do not report immunization administration codes **90461–90462** or **90471–90472** for the injection of nirsevimab, as these codes are limited to the administration of vaccine and toxoid products. During the transition to the new codes, payer policies may require reporting **96372** therapeutic, prophylactic, or diagnostic injection instead of **96380** and **96381**. The AAP is working with payers to update their payment systems and payment policies. See examples of reporting administration of nirsevimab along with other services in the coding vignettes below.

Diagnosis Codes

Administration of nirsevimab is not reported with Z23 Encounter for immunization. Z23 is specific to immunization related to vaccines. While nirsevimab is categorized as a monoclonal antibody by CPT, ICD10 CM's index guides us to code Z29.11 Encounter for prophylactic immunotherapy for respiratory syncytial virus (RSV). Using the appropriate diagnosis code is not only important for billing and claims payment, but it is also necessary for data collection and quality metrics.



Coding Vignettes

Outpatient Setting:

Vignette 1: A 6-month-old previously healthy patient presents with a 2-day history of cough and runny nose and today started with a fever of 100.1, and after an exam is diagnosed with a URI. Mother would like to know what else she could do to protect her baby from getting sick since the fall season is starting. Mother is counseled for 20 minutes about the recommendations for flu, COVID vaccines, and nirsevimab. All her questions were answered, and we will discuss more when the baby returns next week for a well-child check.

CPT Codes Used:

99213 Office or other outpatient visit for the E/M of an established patient, requiring straightforward medical decision-making.

99401 Preventive medicine counseling provided to an individual; approximately 15 minutes

Coding Tips: Modifier 25 is required to report codes 99213 and 99401 together.

Preventive medicine counseling codes are **not** reportable with well visit codes 99381-99385 and 99391-99395

Vignette 2: A 2-month-old established patient born prior to the start of the RSV season is seen in the office for a well exam. The patient is up to date with vaccines and will be receiving the recommended 2-month vaccines. In addition, the provider counsels the mother about nirsevimab. All of mother's questions were answered, and she would like to proceed with the recommendations.

CPT Codes used:

99391 Periodic comprehensive preventive medicine reevaluation and management of an established patient; infant (age younger than 1 year)

Appropriate Coding for Tdap, IPV, PCV, Hib, Rotavirus, Hep B combination vaccines administered

90380 Respiratory syncytial virus, monoclonal antibody, seasonal dose; 0.5 mL dosage, for IM use, with counseling by a qualified health professional with their own NPI.

Vaccine/Monoclonal Antibody Administration:

90460 IM through 18 yrs, any route of administration, with counseling by physician or other qualified health care professional; first or only component of each vaccine or toxoid administered = 3 units OR

90461 IM administration through 18 yrs, any route of administration, with counseling by physician or other qualified health care professional; each additional vaccine or toxoid component administered = 4 units AND

96380 Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection, with counseling by physician or other qualified health care professional = 1 unit or 96372 = 1 unit based on payer policy



Vignette 3: A 7-month-old established patient presents for a scheduled nirsevimab injection. Counseling was provided by the physician at the well-child visit 2 weeks ago, Mother had additional questions that were answered by the RN. Mother agrees to proceed with the administration of nirsevimab.

CPT codes used:

90381 Respiratory syncytial virus, monoclonal antibody, seasonal dose; 1 mL dosage, for IM use

96380 Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection, with counseling by physician or other qualified health care professional = 1 unit or 96372 = 1 unit based on payer policy

Coding Tip: Additional counseling provided by RN and subsequent administration of nirsevimab *does not* support reporting an additional E/M code such as 99211. To report any E/M, a condition must be evaluated and managed; for coding purposes, counseling does not equate to the management of a condition.

Vignette 4: An 18-month-old established patient with a history of severe immune compromise presents for a well-child visit. A preventive service is provided, including age-appropriate developmental screening. The physician also counsels on RSV prevention and discusses the risks and benefits of receiving nirsevimab. All of the family's questions are answered and documented. The patient receives nirsevimab 200 mg (2 separate injections of 100 mg each) via intramuscular injection.

CPT codes:

99392 Periodic comprehensive preventive medicine reevaluation and management of an established patient; early childhood (age 1 through 4 years)

96110 Developmental screening (e.g., developmental milestone survey, speech and language delay screen), with scoring and documentation, per standardized instrument

90381 Respiratory syncytial virus, monoclonal antibody, seasonal dose; 1 mL dosage, for IM use = 2 units

96380 Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection, with counseling by physician or other qualified health care professional = 1 unit or **96372** = 1 unit based on payer policy

Nursery Setting:

Vignette: A 2-day-old patient weighing 3 kg was born during the RSV season. Counseling on RSV prevention was provided by the hospitalist, including the risks and benefits of receiving nirsevimab. All of the family's questions are answered and documented, and the newborn receives nirsevimab 0.5 mL prior to hospital discharge

CPT Codes Used:

90380 Respiratory syncytial virus, monoclonal antibody, seasonal dose; 0.5 mL dosage, for IM use

Coding Tips: Inpatient counseling for nirsevimab and any other medications or vaccines is bundled into any E/M provided on that date of service. Since the vignette shows no other billable services, a claim should not be filed by the hospitalist for counseling for nirsevimab.



Practical Considerations of Nirsevimab Timing

Here are some tools that help you identify the time to administer Nirsevimab to healthy newborns and infants in your practice:

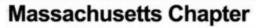
Month of birth Recommended timing of nirsevimab immunization

October–March Within 1 week of birth

April–September Beginning in October, for example at a 2, 4, or 6 month well child visit

Looking Back and Forward to Infants Born in 2024 and 2025

Month of Birth	Eligible this season?	When Eligible?	Closest WCC or vax visit?
January 2024	No, unless high risk		
February 2024	Unlikely unless given before October.	October 2024	
March 2024	Only if given in October	October 2024	Vax visit in October
April 2024	Yes	October 2024	6-month WCC in 10/24 or vax visit before 8 months of age
May 2024	Yes	October 2024	6-month WCC in 11/24 or vax visit before 8 months of age
June 2024	Yes	October 2024	4-month WCC in 10/24 or vax visit before 8 months of age
July 2024	Yes	October 2024	4-month WCC in 11/24 or vax visit before 8 months of age
August 2024	Yes	October 2024	2-month WCC in 10/24 or vax visit before 8 mos old and 4/1
September 2024	Yes	October 2024	1-month WCC in 10/24 or vax visit before 8 months
October 2024	Yes	At birth or soon after	In first 2-4 weeks if possible
November 2024	Yes	At birth or soon after	In first 2-4 weeks if possible
December 2024	Yes	At birth or soon after	In first 2-4 weeks if possible
January 2025	Yes	At birth or soon after	In first 2-4 weeks if possible
February 2025	Yes	At birth or soon after	In first 2-4 weeks if possible
March 2025	Yes	At birth or soon after	In first 2-4 weeks if possible
April 2025	Yes	October 2025	6-month WCC in 10/25 or vax visit before 8 months of age
May 2025	Yes	October 2026	6-month WCC in 11/25 or vax visit before 8 months of age
June 2025	Yes	October 2025	4-month WCC in 10/25 or vax visit before 8 months of age
July 2025	Yes	October 2025	4-month WCC in 11/25 or vax visit before 8 months of age
August 2025	Yes	October 2025	2-month WCC in 10/25 or vax visit before 8 mos old a 4/1
September 2025	Yes	October 2025	1-month WCC in 10/25 or vax visit before 4/1/26
October 2025	Yes	At birth or soon after	In first 2-4 weeks if possible
November 2025	Yes	At birth or soon after	In first 2-4 weeks if possible
December 2025	Yes	At birth or soon after	In first 2-4 weeks if possible



INCORPORATED IN MASSACHUSETTS



It is likely that practices will start getting Nirsevimab in October. There is little expectation of repeated shortages although birth doses will be prioritized.

Nirsevimab Scheduling Questions:

I have a healthy patient who was 7 months old in October. They present to the clinic in November, at 8 months of age. Can they receive nirsevimab at this visit? From AAP.org: No. CDC recommends that only those healthy infants younger than 8 months of age at the time of administration receive nirsevimab.

Should I administer nirsevimab to an infant who is born at the very end of the RSV season? From AAP.org: Yes. Optimal timing for administration is within 1 week after birth during the RSV season. Administering nirsevimab through the end of the season is important because the risk of severe disease is highest during the first few months of life.

What does "shortly before or during" the RSV season mean? When should I start administering nirsevimab? From AAP.org: In most of the continental US, "shortly before or during the season" means that administration of nirsevimab should begin on October 1 and conclude on March 31. In tropical climates (southern Florida, Hawaii, Guam, Puerto Rico, US Virgin Islands and US-affiliated Pacific Islands) and Alaska, RSV circulation patterns may differ. Because timing of the onset, peak and decline of RSV activity may vary, providers can adjust administration schedules based on local RSV activity in the community. The Centers for Disease Control and Prevention (CDC) monitors RSV activity in the United States in collaboration with state and county health departments and commercial and clinical laboratories. These data are available from the National Respiratory and Enteric Virus Surveillance System. Information about local epidemiology can be determined by contacting your local, state, tribal, or territorial health department or other local health authority. Optimal timing for nirsevimab administration is shortly before the RSV season begins, however, it may be given to eligible infants and toddlers who have not yet received a dose at any time during the season.

Per <u>CDC</u>, healthcare providers may choose to give nirsevimab before the start of RSV season if they feel that the child may not return for a visit when nirsevimab would be recommended. For example, a clinician may choose to give nirsevimab to an infant who presented for care in September who has not yet received a dose of nirsevimab and may be unlikely to return for a visit in October or November. Nirsevimab has been shown to protect against severe RSV disease for at least 5 months, and the ideal timing of administration may differ depending on the clinical situation.





View from Massachusetts: General

- Ordering of RSV products will open in the MIIS on September 3:
 - Beyfortus 50 mg
 - Beyfortus 100 mg
 - Abrysvo
- Massachusetts is on allocation from the CDC for all RSV products this respiratory season.
 - Due to allocation constraints, sites will NOT be able to order their full season need at the **opening** of MIIS ordering.
 - Sites will be able to receive all doses necessary throughout the duration of respiratory season.
 - It is best practice for sites to order monthly in smaller increments rather in sporadic large orders.



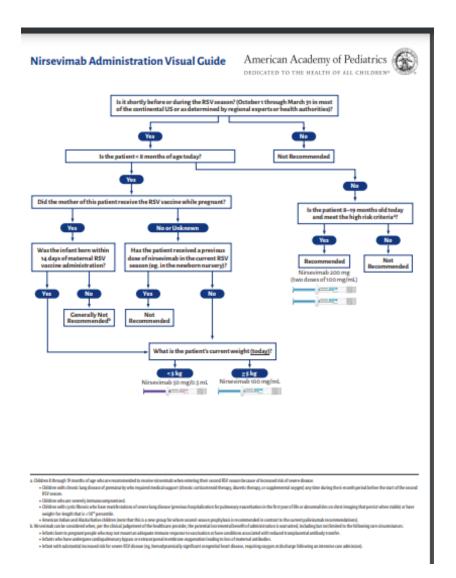
View from Massachusetts: Nirsevimab/Beyfortus

- Practice sites that have Beyfortus doses still inventory from last season should use those dose first before replenishing stock with newly ordered additional doses.
- Beyfortus 50 mg doses will be prioritized to enrolled Birthing Hospitals and additional dose distribution will be considered when the autumn supply allocation is clear.
- Beyfortus 100 mg dose orders will be capped at 50 doses per order to begin the respiratory season.
- State-supplied Beyfortus is available universally for all eligible infants and the defined high-risk toddlers.

Massachusetts Chapter

INCORPORATED IN MASSACHUSETTS





https://downloads.aap.org/AAP/PDF/Nirsevemab-Visual-Guide.pdf

Massachusetts Chapter

INCORPORATED IN MASSACHUSETTS



Immunization Administration Tips
At the time of administration, affirm the 7 rights to reduce errors:

- z. Right time (age, in RSV season)
- 3. Right immunization (correct medication)
- 4. The right dosage (based on weight)
- 5. The right route, needle length, and technique

Intramuscular (IM) injection Use a 22–25 gauge needle. Choose the injection site and needle length that is appropriate to the person's age and body mass.				
Age	Needle length	Injection site		
Newborns (1st 28 days)	%*a	Anterolateral thigh muscle		
Infants (1–12 months)	1"	Anterolateral thigh muscle		
Toddlers (1-2 years)	1-1)4"	Anterolateral thigh muscle ^c		
loudiers (1–2 years)	% ^b −1*	Deltoid muscle of arm		

- 6. Right site
- 7. The right documentation

Co-administration and Suggested Injection Volumes
In accordance with the CDC's Ceneral Best Practice Guidelines for Immunization, simultaneous administration of nirsevimab with age-appropriate vaccines is recommended. CDC does not address the issue of maximum volumes that can be injected into each muscle group in different age groups. CDC is in the process of creating a job aid for healthcare providers to help address the issue and offers the suggested volumes as follows:

- Deltoid muscle of arm: Average 0.5 mL (range 0.5-z mL)
 Anterolateral thigh muscle (Vastus Lateralis): Average 1-4 mL (range 1-5 mL)

Infants and toddlers would fall at the lower end of the range, whereas adolescents and adults would generally fall on the higher end of the

- range. Strategies healthcare providers can use to decrease the number/injection volume include:

 Healthcare providers should always use professional judgement when administering injections. Muscle size can vary greatly from one patient
 - · Include an age-appropriate combination vaccine in the facility's inventory (Pentacel, Pediarix, Vaxelis).
 - Use an alternate route (other than IM) if possible. IPV (single component, NOT a combination vaccine), MMR (toddlers and infant travelers only),
 Varicella-containing vaccines (toddlers only), and PPSV23 (high-risk toddlers only) can be administered subcutaneously.
 - Take advantage of recommended age ranges some of the routinely recommended vaccines have. For example, the 3rd dose of HepB can be
 given as late as 18 months of age.

NOTE: Always refer to the package insert included with each biologic for complete vaccine administration information. CDC's Advisory Committee on Immu vaccine should be reviewed as well. Access the ACP recommendations at www.immunize.org/acig.

Massachusetts Chapter

INCORPORATED IN MASSACHUSETTS

American Academy of Pediatrics DEDICATED TO THE HEALTH OF ALL CHILDREN®

a. If skin is stretched tightly and subcutaneous tissues are not bunched.

b. Alternate needle lengths may be used if the skin is stretched tightly and subcutaneous tissues are not bunched, as follows: a) a 3% needle in toddlers, children, and patients weighing less than 130 lbs (less than 60 kg) for IM injection in the deltoid muscle only, or b) a 1" needle for administration in the thigh muscle for adults of any weight.

Massachusetts Department of Public Health notifications regarding Nirsevimab:

1. 10/26/23: To: Physicians, Certified Nurse Practitioners (CNPs), Certified Nurse Midwives (CNMs), and Physician Assistants (PAs)

The purpose of this communication is to inform and remind all primary care providers, including Physicians, Certified Nurse Practitioners (CNPs), Certified Nurse Midwives (CNMs), and Physician Assistants (PAs) about certifications approved by the Department of Public Health (DPH) in addition to those named in M.G.L. c. 112, §265, that permit medical assistants who meet the certification requirements to administer immunizations under the direction of a primary care provider (PCP) acting within their designated scope of practice.

As described in <u>Circular Letter DCP 17-8-102</u> - <u>https://www.mass.gov/doc/august-10-2017-circular-letter-immunization-administration-by-medical-assistants-0/download</u>, a PCP may delegate the administration of immunizations to a medical assistant who:

- (1) has graduated from a post-secondary medical assisting education program accredited by the Commission on Accreditation of Allied Health Education Programs, or the Accrediting Bureau of Health Education Schools;
- (2) is employed in the clinical practice of a licensed primary care provider; and
- (3) performs basic administrative, clerical, and clinical duties upon the specific authorization and under the direct supervision of a licensed primary care provider.

Please note: The guidance linked in this communication is still current and valid. Also, in light of numerous questions the Department has received regarding the administration of the recently licensed RSV monoclonal antibody (nirsevimab), this communication is intended to clarify that the definition of "immunizations" as noted in this Circular Letter is inclusive of both active immunizations (vaccines) and passive immunizations (antibody preparations like nirsevimab).

* Nirsevimab (Beyfortus) is available to providers without charge by the Commonwealth's Childhood Vaccine Program.

