

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



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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 [2023 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) this season as Nirsevimab (Beyfortus) is introduced?** *(see update at end of packet for discussion of use during the supply chain shortage)*
- 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 [MedWatch website](#) or by calling 1-800-FDA-1088. Report side effects that happen after getting nirsevimab WITH coadministered vaccines (the same day) to the [VAERS 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?** The ACIP recommendation for **maternal** RSV vaccine (ABRYSVO) is new (9/22/23) so fewer scientists have made videos on this so far, but here are two overviews of the vaccine. <https://www.contagionlive.com/view/the-changing-rsv-prevention-landscape> (mostly after 3:00) and <https://www.contagionlive.com/view/fda-advisory-committee-affirms-safety-and-efficacy-of-pfizer-rsvpref-vaccine> (after 2:00).
4. **Will the CDC provide a Vaccine Information Sheet (VIS) for Nirsevimab?** <https://www.cdc.gov/vaccines/vpd/rsv/downloads/Immunization-Information-Statement.pdf>
5. **Do we need to document a parent’s refusal to consent to Nirsevimab?** You should follow your practice’s standard protocol for vaccine refusal. If you do document vaccine refusal for any immunization, you may use a form found here: https://downloads.aap.org/DOPCSP/SOID_RTV_form_01-2019_English.pdf



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.

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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 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 2023 and 2024

Month of Birth	Eligible this season?	When Eligible?	Closest WCC or vax visit?
January 2023	No, unless high risk		
February 2023	Maybe. Some will be 8 months after introduction	October 2023	Vax visit or 9-month WCC in 11/23
March 2023	Yes	October 2023	Vax visit
April 2023	Yes	October 2023	6-month WCC in 10/23 or vax visit
May 2023	Yes	October 2023	6-month WCC in 11/23 or vax visit
June 2023	Yes	October 2023	4-month WCC in 10/23 or vax visit
July 2023	Yes	October 2023	4-month WCC in 11/23 or vax visit
August 2023	Yes	October 2023	2-month WCC in 10/23 or vax visit
September 2023	Yes	October 2023	1-month WCC in 10/23 or vax visit
October 2023	Yes	At birth or soon after	In first 2-4 weeks if possible
November 2023	Yes	At birth or soon after	In first 2-4 weeks if possible
December 2023	Yes	At birth or soon after	In first 2-4 weeks if possible
January 2024	Yes	At birth or soon after	In first 2-4 weeks if possible
February 2024	Yes	At birth or soon after	In first 2-4 weeks if possible
March 2024	Yes	At birth or soon after	In first 2-4 weeks if possible
April 2024	Yes	October 2024	6-month WCC in 10/24 or vax visit
May 2024	Yes	October 2024	6-month WCC in 11/24 or vax visit
June 2024	Yes	October 2024	4-month WCC in 10/24 or vax visit
July 2024	Yes	October 2024	4-month WCC in 11/24 or vax visit
August 2024	Yes	October 2024	2-month WCC in 10/24 or vax visit
September 2024	Yes	October 2024	1-month WCC in 10/24 or vax visit
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

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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.*

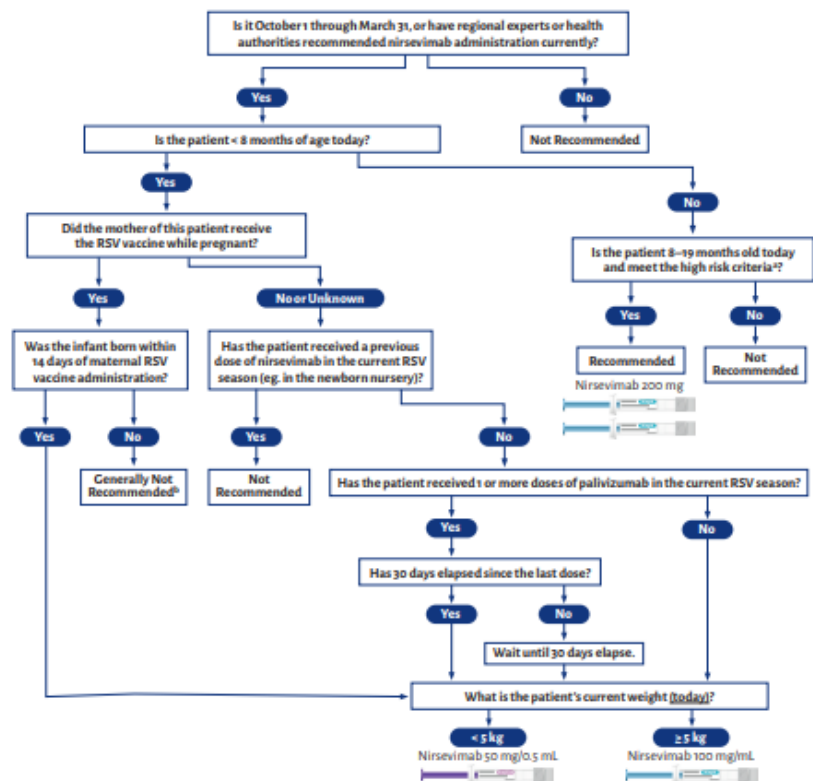
What does "shortly before or during" the RSV season mean? When should I start administering nirsevimab? *From AAP.org: In most of the continental US, "shortly before or during the season" means that administration of nirsevimab should begin on October 1 and conclude on March 31. In tropical climates (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 **CDC**, 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.*



Nirsevimab Administration Visual Guide

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- a. Children 8 through 19 months of age who are recommended to receive nirsevimab when entering their second RSV season because of increased risk of severe disease.
- Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season.
 - Children who are severely immunocompromised.
 - Children with cystic fibrosis who have manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable) or have weight-for-length that is < 5th percentile.
 - American Indian and Alaska Native children (note that this is a new group for whom second-season prophylaxis is recommended in contrast to the current palivizumab recommendations).
- b. Nirsevimab can be considered when, per the clinical judgement of the healthcare provider, the potential incremental benefit of administration is warranted, including but not limited to the following rare circumstances:
- Infants born to pregnant people who may not mount an adequate immune response to vaccination or have conditions associated with reduced transplacental antibody transfer.
 - Infants who have undergone cardiopulmonary bypass or extracorporeal membrane oxygenation leading to loss of maternal antibodies.
 - Infants with substantial increased risk for severe RSV disease (eg, hemodynamically significant congenital heart disease, intensive care admission and requiring oxygen at discharge).

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

1. Right patient
2. 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
6. [Right site](#)

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 (1 st 28 days)	5/8" ^c	Anterolateral thigh muscle
Infants (1–12 months)	1"	Anterolateral thigh muscle
Toddlers (1–2 years)	1–1 1/4"	Anterolateral thigh muscle ^e
	5/8" ^d –1"	Deltoid muscle of arm

7. The right documentation

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

d. Alternate needle lengths may be used if the skin is stretched tightly and subcutaneous tissues are not bunched, as follows: a) a 5/8" 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.

e. Preferred site

NOTE: Always refer to the package insert included with each biologic for complete vaccine administration information. CDC's Advisory Committee on Immunization Practices (ACIP) recommendations for the particular vaccine should be reviewed as well. Access the ACIP recommendations at www.immunize.org/acip.



CDC updates on Nirsevimab limited availability (10/23/23):

<https://emergency.cdc.gov/han/2023/han00499.asp>

Excerpt: In the context of limited supply during the 2023–2024 RSV season, CDC recommends prioritizing available nirsevimab 100mg doses for infants at the highest risk for severe RSV disease: young infants (age <6 months) and infants with underlying conditions that place them at highest risk for severe RSV disease. Recommendations for using 50mg doses remain unchanged at this time. Avoid using two 50mg doses for infants weighing ≥5 kilograms (≥11 pounds) to preserve supply of 50mg doses for infants weighing <5 kilograms (<11 pounds). Providers should be aware that some insurers may not cover the cost of two 50mg doses for an individual infant.

CDC further recommends that providers suspend using nirsevimab in [palivizumab-eligible children](#) aged 8–19 months for the 2023–2024 RSV season. These children should receive palivizumab per [American Academy of Pediatrics \(AAP\) recommendations](#). Nirsevimab should continue to be offered to American Indian and Alaska Native children aged 8–19 months who are not palivizumab-eligible and who live in remote regions, where transporting children with severe RSV for escalation of medical care is more challenging or in communities with known high rates of RSV among older infants and toddlers. Prenatal care providers should discuss potential nirsevimab supply concerns when counseling pregnant people about RSVpreF vaccine (Abrysvo, Pfizer) as maternal vaccination is effective and will reduce the number of infants requiring nirsevimab during the RSV season.

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 [Circular Letter DCP 17-8-102](#) - <https://www.mass.gov/doc/august-10-2017-circular-letter-immunization-administration-by-medical-assistants-0/download>, 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.

