

Respiratory Vaccines Update

Webinar 4

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 - No late evaluations will be accepted. Please complete the survey ASAP.
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Webinar

- If you have a question during or after the webinar, please ask your question in the chat.
 - I will do my best to answer all questions before the end of the webinar.
- If you have a question after the webinar, please email Allie Staton.
 - Email: allie@immunizear.org

Objectives

- Interpret current guidelines for respiratory vaccines.
- Recommend appropriate respiratory vaccines to patients and community members.
- Discuss current respiratory vaccine guidelines and recommendations.

Topics

- Review current guidance for COVID-19 vaccines for patients ages 65 years and older
- Discuss current RSV vaccine recommendations for patients ages 60 years and older
- Review RSV vaccine recommendations for pregnant patients

IMPORTANT NOTE...

As providers, it is our responsibility to make sure we are up to date on current recommendations and best practices.

Insurance companies are not responsible for "stopping us" from doing something that is wrong.

DON'T FORGET!

A strong recommendation from a healthcare provider is important!

Patients are more likely to choose to vaccinate if their healthcare providers make a **strong** recommendation for vaccination.

COVID-19

Immunization Products

COVID-19 Vaccine Products

Pfizer	Moderna	Novavax
mRNA	mRNA	Protein Subunit
6 months and older	6 months and older	12 years and older
<u>Products</u>	<u>Products</u>	<u>Products</u>
2023 – 2024 season	2023 – 2024 season	2023 – 2024 season
6 months thru 4 years	6 months thru 11 years	• 12 years and older
• 5 years thru 11 years	• 12 years and older	
• 12 years and older		

COVID-19

Vaccine Recommendation
Update

Patients ages 65 years and older

Summary of recent changes (last updated March 1, 2024):

All people ages 65 years and older should receive 1 additional dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech). For detailed guidance, see <u>Table 1</u> and <u>Table 2</u>.

Special situation for people ages 65 years and older: People ages 65 years and older should receive 1 additional dose of any updated (2023–2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech) at least 4 months following the previous dose of updated (2023–2024 Formula) COVID-19 vaccine. For initial vaccination with Novavax COVID-19 Vaccine, the 2-dose series should be completed before administration of the additional dose.

COVID-19 Vaccine Recommendations

Healthy Teens and Adults: Ages 12 years and older

Last Updated: March 4, 2024



Ages: 12 years and older								
	COVID-19 Vaccine History		2023 – 2024 Updated Vaccines				ADDITIONAL DOSES	
Pfizer			Pfizer: 0.3 mL				Patio	ents ages 65 years and older
Cap: Gray Age: 12 years and older	Unvaccinated		OR Moderna: 0.5 mL				Wait	Pfizer: 0.3 mL OR
Moderna Cap: Dark Blue			OR Novavax: 0.5 mL	Wait 3 – 8 weeks	Novavax 0.5 mL		4 months	Moderna: 0.5 mL OR Novavax: 0.5 mL
Label: Blue Age: 12 years and							Desi	ents ages 65 years and older
Novavax Cap: Blue Label: Blue Age: 12 years and older	1 or more doses any mRNA (Pfizer or Moderna)	Wait 8 weeks	Pfizer: 0.3 mL OR Moderna: 0.5 mL OR Novavax: 0.5 mL				Wait 4 months	Pfizer: 0.3 mL OR Moderna: 0.5 mL OR Novavax: 0.5 mL
	1 or more doses Novavax, J&J, including in combination with any mRNA vaccine dose(s) Wait 8 weeks Moderna: 0.5 mL OR Novavax: 0.5 mL			Wait 4 months	Pfizer: 0.3 mL OR Moderna: 0.5 mL OR Novavax: 0.5 mL			

Heterologous COVID-19 vaccine products **may** be used for updated vaccines in this age group.

Mixing and matching COVID-19 vaccines is authorized.

Exception: Unvaccinated patients who choose to receive Novavax should complete a 2-dose series with Novavax.

COVID-19 Vaccine Recommendations



Last Updated: December 20, 2023



Ages: 12 years a	nd older								
	COVID-19 Vaccine History		2023 – 2024 Updated Vaccines						
Pfizer Cap: Gray			Pfizer: 0.3 mL	Wait 3 weeks	Pfizer: 0.3 mL	Wait 4 weeks	Pfizer: 0.3 mL		
Age: 12 years and older			OR			'		Additional doses may	
	Unvaccinated		Moderna: 0.5 mL	Wait 4 weeks	Moderna: 0.5 mL	Wait 4 weeks	Moderna: 0.5 mL	be administered at least 2 months after last dose of COVID-19	
Moderna			OR					vaccine.	
Cap: Dark Blue Label: Blue			Novavax: 0.5 mL	Wait 3 weeks	Novavax: 0.5 mL				
Age: 12 years and older									
older	1 dose any Pfizer	Wait 3 weeks	Pfizer: 0.3 mL	Wait 4 weeks	Pfizer: 0.3 mL		Additional doses may be administered at least 2 months after last dose of COVID-19 vaccine.		
	2 doses any Pfizer	Wait 4 weeks	Pfizer: 0.3 mL				Additional doses may be administered at least 2 months after last dose of COVID-19 vaccine.		
Novavax									
Cap: Blue Label: Blue Age: 12 years and	1 dose any Moderna	Wait 4 weeks	Moderna: 0.5 mL	Wait 4 weeks	Moderna: 0.5 mL		Additional doses may be administered at least 2 months after last dose of COVID-19 vaccine.		
older	2 doses any Moderna	Wait 4 weeks	Moderna: 0.5 mL				Additional doses may be administered at least 2 months after last dose of COVID-19 vaccine.		
			Pfizer: 0.3 mL						
			OR			be administered at least 2 months after last			
	3 or more doses any mRNA		Moderna: 0.5 mL						
(Pfizer or Moderna)		8 weeks	OR				dose of COVID-19 vaccine.		
			Novavax: 0.5 mL						
			Pfizer: 0.3 mL						
			OR						
	1 or more doses Novavax, J&J, including in combination with any mRNA vaccine dose(s)	Wait 8 weeks	Moderna: 0.5 mL			Additional doses may be administered at least 2 months after lo dose of COVID-19 vaccine.			
			OR						
			Novavax: 0.5 mL						

^{*}Heterologous mRNA products may be used for updated vaccines for this age group, except when completing the first 3 doses for mRNA vaccines (Pfizer or Moderna) or first 2 doses of Novavax.

• See interchangeability guidance on CDC website. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#Interchangeability Mixing and matching COVID-19 vaccines is authorized after dose 3 (for mRNA vaccines) or dose 2 (for Novavax).

Pfizer Additional Doses: Pfizer Gray Cap (0.3 mL)

Moderna Additional Doses: Moderna Blue Cap/Dark Blue Label (0.5 mL)

Novavax Additional Doses: Novavax Blue Cap/Blue Label (0.5 mL)

A 67 year old patient comes into your clinic/pharmacy. Patient has diabetes. This patient is not considered moderately to severely immunocompromised.

They heard on the news that people over 65 should get another dose of a COVID-19 vaccine. They want to know if they can get theirs today. Your clinic only carries Moderna.

COVID-19 vaccine history:

1/1/21 - Pfizer

2/1/21 - Pfizer

10/1/21 - Moderna

10/1/22 – Moderna

10/1/23 - Pfizer

A 67 year old patient comes into your clinic/pharmacy. Patient has diabetes. This patient is not considered moderately to severely immunocompromised.

They heard on the news that people over 65 should get another dose of a COVID-19 vaccine. They want to know if they can get theirs today.

Your clinic only carries Moderna.

COVID-19 vaccine history:

1/1/21 - Pfizer

2/1/21 – Pfizer

10/1/21 – Moderna

10/1/22 - Moderna

10/1/23 - Pfizer

For you to make a recommendation... What are you looking for in their vaccine history?

A 67 year old patient comes into your clinic/pharmacy. Patient has diabetes. This patient is not considered moderately to severely immunocompromised.

They heard on the news that people over 65 should get another dose of a COVID-19 vaccine. They want to know if they can get theirs today.

Your clinic only carries Moderna.

COVID-19 vaccine history:

1/1/21 - Pfizer

2/1/21 - Pfizer

10/1/21 – Moderna

10/1/22 – Moderna

10/1/23 - Pfizer

For you to make a recommendation... What are you looking for in their vaccine history?

Date of last vaccine.

 Has it been at least 4 months since their last COVID-19 vaccine?

A 67 year old patient comes into your clinic/pharmacy. Patient has diabetes. This patient is not considered moderately to severely immunocompromised.

They heard on the news that people over 65 should get another dose of a COVID-19 vaccine. They want to know if they can get theirs today.

Your clinic only carries Moderna.

Can this patient receive a dose of a COVID-19 vaccine today?

COVID-19 vaccine history:

1/1/21 – Pfizer

2/1/21 – Pfizer

10/1/21 – Moderna

10/1/22 – Moderna

10/1/23 – Pfizer

A 67 year old patient comes into your clinic/pharmacy. Patient has diabetes. This patient is not considered moderately to severely immunocompromised.

They heard on the news that people over 65 should get another dose of a COVID-19 vaccine. They want to know if they can get theirs today.

Your clinic only carries Moderna.

COVID-19 vaccine history:

1/1/21 - Pfizer

2/1/21 - Pfizer

10/1/21 – Moderna

10/1/22 - Moderna

10/1/23 - Pfizer

Can this patient receive a dose of a COVID-19 vaccine today?

YES. Administer appropriate formulation and dose of whichever 2023 – 2024 COVID-19 vaccine you have in stock.

This patient will be up to date on all recommended COVID-19 vaccines.

COVID-19 VACCINE RESOURCES

Updated COVID-19 vaccine charts available here:

https://www.immunizear.org/covid-19-provider-resources



CDC COVID-19 Vaccine Interim Clinical Considerations:

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html



CDC COVID-19 Vaccines Infographic (Healthy)

https://www.cdc.gov/vaccines/covid-19/downloads/COVID19-vaccination-recommendations-most-people.pdf



CDC COVID-19 Vaccines Infographic (Immunocompromised)

https://www.cdc.gov/vaccines/covid-19/downloads/COVID19-vaccination-recommendations-immunocompromised.pdf



RSV

Immunization Products

	Abrysvo (RSVpreF) <i>Pfizer</i>	Arexvy (RSVpreF3) <i>GSK</i>	Beyfortus (nirsevimab) Sanofi and AstraZeneca		
FDA approved for: Ages 60 and older			X		
ACIP/CDC recommended for: Ages 60 and older			X		
FDA approved for: Use in pregnancy		X	X		
ACIP/CDC recommended for: Use in pregnancy		X	X		
FDA approved for: Use in infants	X	X			
ACIP/CDC recommended for: Use in infants	X	X			

Abrysvo & Arexvy MMWR (older adults)

What is already known about this topic?

- RSV causes substantial morbidity and mortality in older adults.
- In May 2023, FDA approved the first two vaccines for prevention of RSV lower respiratory tract disease (LRTD) for use in adults aged 60 years and older.

What is added by this report?

- For both vaccine products, Abrysvo and Arexvy, vaccination with a single RSV vaccine dose demonstrated moderate to high efficacy in preventing symptomatic RSV-associated LRTD among adults aged 60 years and older.
- On June 21, 2023, the Advisory Committee on Immunization Practices (ACIP) recommended that all persons aged 60 years and older may receive a single dose of RSV vaccine, using shared clinical decision making.

What are the implications for public health practice?

- RSV vaccination might prevent substantial morbidity in older adults at risk for severe RSV disease.
- Post-marketing surveillance for safety and effectiveness will direct future guidance.

Abrysvo MMWR (pregnancy)

What is already known about this topic?

- Nirsevimab is recommend in infants to prevent respiratory syncytial virus (RSV)-associated lower respiratory tract infection (LRTI).
- In August 2023, the FDA approved Pfizer RSV vaccine for pregnant persons at 32-36 weeks' gestation to prevent RSV-associated LRTI in infants <6 months.

What is added by this report?

• On September 22, 2023, CDC's Advisory Committee on Immunization Practices (ACIP) recommended RSV vaccine for pregnant persons at 32-26 weeks' gestation using seasonal administration (meaning September thru January in most of the United States) to prevent RSV-associated LRTI in infants aged <6 months.

What are the implications for public health practice?

• CDC recommends protecting all infants against RSV-associated LRTI through use of either the maternal RSV vaccine or through infant receipt of nirsevimab.

RSV

Immunizations for Older Adults

RSV (adults)

Two RSV vaccines approved for adults ages 60 years and older.

	Abrysvo (RSVpreF) <i>Pfizer</i>	Arexvy (RSVpreF3) GSK
FDA-approved use	 Patients ages 60 years and older Pregnant patients 32 – 36 weeks gestational age 	Patients ages 60 years and older
ACIP/CDC Recommendations	 Administer one dose to patients ages 60 years and older, using shared clinical decision making Administer one dose to pregnant patients during weeks 32 – 36 weeks of pregnancy during September through January. 	 Administer one dose to patients 60 years and older, using shared clinical decision making

NOTE: These vaccines are NOT approved or authorized for use in older adults under the age of 60 years.

Vaccines for Older Adults

New <u>RSV vaccines</u> are available for adults 60 and older. <u>CDC recommends</u> that adults 60 and older may receive a single dose of RSV vaccine, using shared clinical decision-making. The decision to vaccinate an individual patient should be based on a discussion between the healthcare provider and the patient. It may be informed by the patient's risk of severe RSV disease and their characteristics, values, and preferences; the healthcare provider's clinical discretion; and the characteristics of the vaccine.

Healthcare providers should be aware of underlying conditions that may increase the risk of severe RSV illness, and who might be most likely to benefit from these new vaccines. Adults 60 and older who are at increased risk include those with certain chronic medical conditions such as chronic lung or heart disease, immune compromise, those who are elderly or frail, or those living in nursing homes.

RSV vaccine is recommended as a single dose. Studies are ongoing to determine whether (and if so, when) revaccination may be needed over time. For adults 60 and older who have not already received an RSV vaccine and decide with their healthcare provider to get one, CDC encourages healthcare providers to maximize the benefit of RSV vaccination by giving them their RSV vaccine in late summer or early fall, just prior to the RSV season.

Timing of RSV vaccination and number of doses

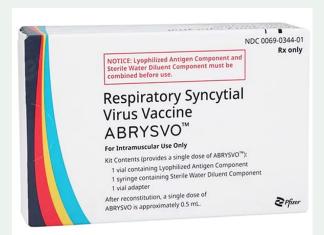
For patients who have not already received an RSV vaccine and decide to get one, CDC encourages healthcare providers to maximize the benefit of RSV vaccination by giving them their RSV vaccine in late summer or early fall. Although typical RSV seasonality was disrupted by the COVID-19 pandemic, the 2023-2024 RSV season more closely resembled pre-pandemic RSV seasonal trends, so RSV seasonality is likely to be more predictable in the future. The benefit of vaccines can be maximized if administered just before the RSV season usually begins.

The RSV vaccine is not currently an annual vaccine, meaning people do not need to get a dose every RSV season. Currently, CDC recommends only a single dose of RSV vaccine for adults ages 60 and older, using shared clinical decision-making. Additional surveillance and evaluation activities are ongoing to determine whether older adults might benefit from receiving additional RSV vaccines in the future. So far, RSV vaccines appear to provide some protection for at least two RSV seasons.

Abrysvo & Arexvy

Similarities:

- Both have similar efficacy
 - "Moderately to highly" effective in preventing symptomatic RSV-associated LRTD among patients 60 years and older
 - Studies not powered to show decrease in RSVassociated hospitalizations or deaths
- Both require reconstitution
- Both stored at refrigerated temperature
- Both good for 4 hours after reconstitution
- Both administered intramuscularly
- Both approved for one dose for patients ages 60 and older





Differences:

- Different mechanisms for reconstitution
- Arexvy has an adjuvant, Abrysvo does not
- Abrysvo has an indication for pregnancy

RSV Vaccines (adults ages 60 years and older)

- Abrysvo and Arexvy approved for patients 60 years and older.
- Currently, only one dose is recommended.
 - Providers are encouraged to administer in late summer or early fall to maximize benefits during peak RSV season.
 - RSV season is typically October thru March.
 - This is NOT a yearly recommendation. It is currently a "one and done" recommendation.
- Coadministration with other vaccines is acceptable.
 - Efficacy of coadministration is not expected to be an issue.
 - Studies are ongoing.
 - Patients may experience more side effects when Abrysvo or Arexvy are administered with other vaccines.
 - Counsel appropriately.
 - Use your clinical judgment when deciding to coadminister.
 - Will the patient return for other vaccines?

A 55 year old patient with COPD comes into your clinic/pharmacy and asks for an RSV vaccine. The date is March 26th.

What do you recommend for this patient?

- Is this patient eligible for an RSV vaccine?
- Will this patient benefit from an RSV vaccine?
- How should you encourage vaccination?
- How can you approach this to build confidence and develop trust?

A 55 year old patient with COPD comes into your clinic/pharmacy and asks for an RSV vaccine. The date is March 26th.

What do you recommend for this patient?

- Is this patient eligible for an RSV vaccine?
 - No. This patient is not age 60 or older.
- Will this patient benefit from an RSV vaccine?
 - We do not know the answer to this yet. We don't have the data to support this.
- How should you encourage vaccination?
 - Let them know its great they asked about it and you're glad they want to take care of their health. Vaccinations are a great way to help prevent and lower the risk of severe disease.
- How can you approach this to build confidence and develop trust?
 - By being honest with this patient, your patient will trust your recommendation.

A 60 year old patient with no chronic disease states comes into your clinic/pharmacy and asks for an RSV vaccine. The date is March 26th.

What do you recommend for this patient?

- Is this patient eligible for an RSV vaccine?
- Will this patient benefit from an RSV vaccine?
- How should you encourage vaccination?
- How can you approach this to build confidence and develop trust?

A 60 year old patient with no chronic disease states comes into your clinic/pharmacy and asks for an RSV vaccine. The date is March 26th.

What do you recommend for this patient?

- Is this patient eligible for an RSV vaccine?
 - Yes. This patient is age 60, so they are eligible.
- Will this patient benefit from an RSV vaccine?
 - This patient will likely benefit from vaccination. However, it is recommended for clinicians to consider waiting until late summer or early fall for patients to have the most protection from RSV.
- How should you encourage vaccination?
 - Let them know its great they asked about it and you're glad they want to take care of their health. Vaccinations are a great way to help prevent and lower the risk of severe disease.
- How can you approach this to build confidence and develop trust?
 - The recommendation for patients ages 60 and older to receive an RSV vaccine is based on shared clinical decision making. Let the patient know you are happy to do whatever they prefer. You are there to take care of them the best that you can, but ultimately, the decision is up to them.

RSV

Immunizations to Protect Infants

RSV Immunizations (to protect infants)

There are two immunizations recommended to prevent RSV lower respiratory tract infection in infants.

1. Abrysvo (RSVpreF): maternal vaccination

Administered to pregnant patient during 32 – 36 weeks gestation (during the months of September through January)

2. Beyfortus (nirsevimab): long-lasting monoclonal antibody

Administered to infant after birth

<u>Either</u> maternal vaccination *or* monoclonal antibody is recommended, in most situations for newborns.

Administration of both is not needed for most infants.

RSV

Immunizations for Pregnant Patients

NO LONGER RECOMMENDED FOR THIS SEASON.

RSV (pregnancy)

One RSV vaccine approved for pregnant patients.

	Abrysvo (RSVpreF) Pfizer
FDA-approved use	Pregnant patients 32 – 36 weeks gestational age
ACIP/CDC Recommendations	 Administer one dose to pregnant patients during weeks 32 – 36 weeks of pregnancy during September through January It is not currently recommended to administer Abrysvo to pregnant patients after January

NO LONGER RECOMMENDED FOR THIS SEASON.

Thank you!

Questions?

References

- RSV Vaccines in Older Adults MMWR
 - https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm
- Use of Pfizer RSV vaccine during pregnancy MMWR
 - https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm
- Use of nirsevimab for prevention of RSV in infants and young children MMWR
 - https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm
- Abrysvo Package Insert
 - https://www.fda.gov/media/168889/download
- Arexvy Package Insert
 - https://www.fda.gov/media/167805/download
- Beyfortus (nirsevimab) Package Insert
 - https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf
- American Academy of Pediatrics Resources:
 - https://www.aap.org/en/patient-care/respiratory-syncytial-virus-rsv-prevention/nirsevimab-administration/
 - https://www.aap.org/en/patient-care/respiratorysyncytial-virus-rsv-prevention/
 - https://www.aap.org/en/patient-care/respiratorysyncytial-virus-rsv-prevention/nirsevimab-administration/
 - https://www.aap.org/en/patient-care/respiratory-syncytial-virusrsv-prevention/nirsevimab-frequently-askedquestions/?_ga=2.232011547.541786410.1696354732-1748098428.1612884933

References

Pfizer:

- https://www.fda.gov/vaccines-blood-biologics/coronavirus-covid-19-cber-regulated-biologics/pfizer-biontech-covid-19-vaccine
- https://www.fda.gov/media/151707/download

Moderna:

- https://www.fda.gov/vaccines-blood-biologics/coronavirus-covid-19-cber-regulated-biologics/moderna-covid-19-vaccine
- https://www.fda.gov/vaccines-blood-biologics/spikevax