SDIC
San Diego Immunization Coalition

San Diego Immunization Coalition Presents

21st Annual Kick the Flu+2 Summit

Inhale **Immunize** **Innovate**

Event Guide and Resources

COUNTY OF SAN DIEGO HEALTH AND HUMAN SERVICES AGENCY | LIVE WELL SAN DIEGO

CALIFORNIA IMMUNIZATION COALITION

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21st Annual Kick the Flu+2 Summit

DISCOVER THE LATEST FLU, COVID-19, & RSV VACCINE UPDATES, DATA TRENDS, & STRATEGIES TO PROTECT OUR COMMUNITIES.

September *10, 2025*

8:30 AM - 1:00 PM

COUNTY OPERATIONS CENTER - CHAMBERS
5520 OVERLAND AVE., SAN DIEGO, CA 92123

CAN'T JOIN US IN PERSON? JOIN US ONLINE: https://bit.ly/4kIsE51!

Register Today!

CEU's Provided
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County of San Diego | Live Well San Diego

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California Immunization Coalition

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21st Annual *Kick the Flu*+2 Summit

Inhale Immunize Innovate

Meet Our Immunization Champion Speakers!

Dr. Pia Pannaraj, MD, MPH

Pediatric Infectious Disease Specialist at UCSD & President of California Immunization Coalition

Lourdes Martinez, Ph.D.

San Diego State University Professor, "Exploring Influenza Vaccine Acceptance in the U.S.-Mexico Border Region"

Hankyul Kim, PharmD

County of San Diego, Pharmacy Manager, "Vaccines on Wheels: Redefining Access Through Mobile Pharmacies"

Danelle Wallace, MPH

Senior Epidemiologist with the Epidemiology & Immunization Services Branch of the County of San Diego Health & Human Services Agency

NURSE CE CREDIT

Provider approved by
California Board of Registered Nursing Provider CEP17194 for
2 contact hours

CHES® - CECH

Category 1 continuing education contact hours (CECH) granted by the Institute for Public Health: Multiple Event Provider approved by the National Commission for Health Education Credentialing, Inc.
Provider Number 101840

September *10, 2025*

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Meet Our Poster Presenters!

Dr. K. Michael Peddecord, DrPH

San Diego State University, Emeritus Professor

"Can Medical Group Quality Recognition Improve Immunization Coverage?"

Sahitya Kothapalli, BDS, MPH

California Department of Public Health, Office of Binational Border Health, BIDS Epidemiologist

"Examining the relationship between COVID-19 and annual influenza vaccine uptake, and trusted sources of health information, amongst farmworkers in San Diego and Imperial counties, California, 2023"

Tracy Enright, MSPH

County of San Diego, Epidemiologist II

"San Diego County Pediatric Influenza Vaccination Coverage Trends"

Brenda Aguirre, DNP, RN, PHN

County of San Diego, Public Health Nurse

"Strategic Support for COVID-19 and Influenza Vaccine Uptake: Leveraging a Vaccine Provider Toolkit and Principles of Academic Detailing to Empower Community Providers"

SDIC
San Diego Immunization Coalition

21st Annual *Kick the Flu*+2 Summit

Inhale *Immunize* Innovate

Meet Our Panel Speakers!

Seema Shah, MD, MPH
County of San Diego

Kenneth Hempstead, MD, FAAP
Kaiser Permanente

Marsha Spitzer, MD, FAAP
Family Health Centers of San Diego

Pia Pannaraj, MD, MPH
UCSD & Rady Children's Hospital

Sujana Gunta, MD, MS, FAAP
Vista Community Clinic

San Diego Immunization Coalition Presents

21st Annual Kick the Flu +2 Summit

Inhale Immunize Innovate

2025 Kick the Flu +2 Fall Summit
Presented by the San Diego Immunization Coalition

Wednesday, September 10, 2025 | 8:30 AM – 1:00 PM | County Operations Center Chambers

Time (PM)	Topic	Presenter
8:30 – 9:00	**Posters, Networking, and Exhibits**	*View Poster Submissions, Network, Enjoy Refreshments, Visit the Exhibits*
9:00 – 9:15	**Formal Welcome and Announcements (15 min)**	**SDIC Co-Chairs:** **Gaile Crean, MPH** Immunization Coordinator Kaiser Permanente **Heidi DeGuzman, BSN** UCSD Program Director South Region PHC
9:15 – 9:25	**Public Health Officer Greeting (10 min)**	**Sayone Thilhalolipavan, MD, MPH** Public Health Officer Public Health Services County of San Diego Health & Human Services Agency
9:25 – 9:50	**What's New with the Flu +2? (25 min)**	**Pia Pannaraj, MD, MPH** Pediatric Infectious Disease Specialist, UCSD Rady Children's Hospital President of California Immunization Coalition
9:50 – 10:10	**2024 – 2025 San Diego County Respiratory Virus Surveillance Summary (20 min)**	**Danelle Wallace, MPH** Senior Epidemiologist Epidemiology and Immunization Services Branch Public Health Services
10:10 – 10:20	**State Influenza Vaccine Program Award Presentation (10 min)**	**Araceli Montera, MPH** Community Health Program Specialist Epidemiology and Immunization Services Branch Public Health Services
10:20 – 10:40	**BREAK (20 min)**	*View Poster Submissions, Network, Enjoy Refreshments, Visit the Exhibits*
10:40 – 10:50	**California Immunization Coalition Greeting and Award Presentation (10 min)**	**Catherine Flores-Martin** Executive Director California Immunization Coalition
10:50 – 11:10	**Exploring Influenza Vaccine Acceptance in the U.S.-Mexico Border Region (20 min)**	**Lourdes Martinez, PhD** Professor, School of Communication, San Diego State Associate Director, Center for Human Dynamics in the Mobile Age
11:10 – 11:30	**Vaccines on Wheels: Redefining Access Through Mobile Pharmacies (20 min)**	**Hankyul Kim, PharmD** Pharmacy Manager Medical Care Services, Pharmacy County of San Diego Health & Human Services Agency
11:30 – 12:20	**Vaccinating Against Mistrust: The Role of Providers in Restoring Confidence Panel Q&A (50 min)**	**Sujana Gunta, MD, MS, FAAP –** Vista Community Clinic **Kenneth Hempstead, MD, FAAP** - Kaiser Permanente **Pia Pannaraj, MD, MPH** – UCSD/Rady Children's Hospital **Seema Shah, MD, MPH –** County of San Diego **Marsha Spitzer, MD, FAAP** – Family Health Centers of San Diego
12:20 – 12:30	**SDIC Partner Announcements (10 min)**	**San Diego Immunization Coalition Partners**
12:30– 12:35	**Announcements and Closing Remarks (5 min)**	**SDIC Co-Chairs:** **Gaile Crean, MPH** **Heidi DeGuzman, BSN**
12:35 – 1:00	**Posters, Networking, and Exhibits**	*View Poster Submissions, Network, Visit the Exhibits*

2025 SDIC General Meeting Series
Next Meeting: October 2025

The mission of SDIC is to increase immunization rates and improve the health of the residents of San Diego County by raising awareness and providing education about vaccine-preventable diseases.

SDIZCOALITION.ORG

Immunization Resources

- American Academy of Family Physician Immunization Schedule
- American Academy of Pediatrics Immunization Schedule
- American College of Obstetricians and Gynecologists Immunization, Infectious Disease, and Public Health Preparedness Program
- Association of Immunization Managers
- California Department of Public Health Immunization Branch
- California Immunization Coalition
- County of San Diego Immunization Unit
  - Getting Your Vaccines
  - Request Community Vaccination Events
  - Respiratory Viruses
- SDIC website
  - SDIC social media: Facebook and Instagram
- Subscribe to the Respiratory Virus Surveillance Report to receive email notifications about current COVID-19, flu, and RSV surveillance in San Diego County
- Vaccine Integrity Project

Exhibitor Resources

- Albertsons/Vons/Pavillions
- CSL Seqirus
- Epidemiology & Immunizations Services Branch
  - Programs Outreach & Promotion
  - Childhood Lead Poisoning Prevention Program
  - Perinatal Hepatitis B
- Moderna
- MotherToBaby
- Rotary District 5340
- Sanofi
- UCSD PIA Lab - Pediatric Immunization Advancement
- UCSD Moores Cancer Center
- 211 San Diego

SDIC Upcoming Events

BOOSTING PROTECTION IN LONG-TERM CARE THROUGH RESPIRATORY VACCINATIONS

2025 VIRTUAL SUMMIT

Join us for a virtual webinar on the importance of vaccinations and infection prevention strategies in skilled nursing, long-term care, and congregate care facilities, as well as other programs serving older adults.

Register Here

https://bit.ly/40UZcSm

SAVE THE DATE!

10.22.25

Immunization SKILLS INSTITUTE

The innovative course will train medical personnel (e.g., medical assistants, pharmacists, nurses) on current, effective, and caring immunization techniques. **Provider #CEP579 is approved by the California Board of Registered Nursing (BRN) to provide 2 continuing education contact hours** offered for this training.

TOPICS COVERED

- Best practices
- Needle selection
- Injection sites
- Routes of administration & after care
- Vaccine storage & handling
- Immunization preparation
- Vaccine preparation
- Immunization documentation

Wednesday, October 29, 2025

8:00 AM - 12:30 PM

5530 Overland Ave #124
San Diego, CA 92123

Register Here

izinfo.hhsa@sdcounty.ca.gov SDIZcoallition.org @SDIZ_coallition SDIC

Moderna

INTRODUCING mNEXSPIKE®

An Enhanced COVID-19 Vaccine for Patients at Risk[1–8]

mNEXSPIKE®
COVID-19 Vaccine, mRNA

Next-generation mNEXSPIKE is different from the comparator vaccine[1,4–6,9]

mNEXSPIKE encodes immunodominant epitopes of the COVID-19 spike protein, thus incorporating a smaller mRNA molecule compared to Spikevax, which encodes for the entire spike protein[1,4]

LOWER DOSE
1/5
that of Spikevax (10 µg vs 50 µg)[1,6]

SMALLER VOLUME
0.2 mL
vs 0.5 mL dose for Spikevax[1,6]

mNEXSPIKE demonstrated an increased rVE against COVID-19 vs Spikevax® (COVID-19 Vaccine, mRNA) in a phase 3 noninferiority trial[1]

- **11,366 participants aged ≥12 years** received either **mNEXSPIKE (n=5679)** or **Spikevax (n=5687)**
- **Primary efficacy objective: noninferior vaccine efficacy against COVID-19** starting 14 days after mNEXSPIKE compared with that after Spikevax

Higher antibody responses and seroresponse rates leading to a **greater immune response** compared with Spikevax

Clinical study of mNEXSPIKE was not designed to evaluate superiority.

PRIMARY EFFICACY ANALYSIS POPULATION

9.3%
increase in rVE against COVID-19* vs Spikevax†
(99.4% CI: -6.6, 22.8)

In a subgroup analysis of adults aged 65 years and older, mNEXSPIKE demonstrated increased rVE vs Spikevax[1]

	≥65 Years of Age	
COVID-19 events through January 31, 2024—per-protocol set for efficacy	mNEXSPIKE (10 µg) n=1630	Spikevax (50 µg) n=1635
COVID-19 cases	149	172
Incidence rate per 100 person-months	1.3	1.5

rVE analyses by subgroups were descriptive without *P*-values.

SUBGROUP ANALYSIS IN ADULTS AGED 65 YEARS AND OLDER

13.5%
increase in rVE against COVID-19* vs Spikevax
(95% CI: -7.7, 30.6)

*Presence of at least 1 symptom from a list of COVID-19 symptoms and a positive NP swab for SARS-CoV-2 by RT-PCR. Listed symptoms were fever (temperature ≥38 °C/≥100.4 °F) or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle aches or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, and diarrhea. †Success criteria was defined as lower bound of 2-sided 99.4% (alpha-adjusted) CI of rVE >-10% (2-sided alpha spending function: 0.0028).

mNEXSPIKE rVE across individuals with comorbidities was studied in a post hoc analysis[7,8]

		mNEXSPIKE (10 µg)	Spikevax (50 µg)
	rVE based on HR (95% CI)	Participants with COVID-19, % [n/N]	
≥1 comorbidities in all participants 12 years of age and older	**17.5%** (3.0, 29.8)	10.2% (267/2617)	12.4% (329/2658)
And ≥50 years of age with ≥1 comorbidities	**23.0%** (6.1, 36.9)	9.6% (169/1755)	12.4% (228/1833)
And ≥65 years of age with ≥1 comorbidities	**28.6%** (4.6, 46.6)	8.5% (78/913)	11.8% (110/929)

Analysis Limitation:
This endpoint was not powered for statistical analysis and should be considered descriptive only. Therefore, results require cautious interpretation and could represent chance findings. These data are not included in the mNEXSPIKE prescribing information.

mNEXSPIKE demonstrated a safety profile comparable with Spikevax[1]

Most commonly (≥10%) reported adverse reactions within 7 days‡ after administration of mNEXSPIKE vs Spikevax:

12-17 years of age	Pain at the injection site (68.8% vs 78.8%), headache (54.5% vs 58.0%), fatigue (47.3% vs 50.7%), myalgia (39.2% vs 36.0%), axillary swelling or tenderness (34.6% vs 27.1%), chills (31.6% vs 31.9%), arthralgia (23.9% vs 23.6%), and nausea/vomiting (16.1% vs 17.6%)
18-64 years of age	Pain at the injection site (74.8% vs 81.7%), fatigue (54.3% vs 52.5%), headache (47.8% vs 44.3%), myalgia (41.6% vs 41.1%), arthralgia (32.4% vs 30.6%), chills (24.3% vs 21.3%), axillary swelling or tenderness (21.7% vs 21.0%), and nausea/vomiting (13.8% vs 11.9%)
65 years of age and older	Pain at the injection site (54.6% vs 67.7%), fatigue (43.0% vs 41.0%), headache (33.1% vs 29.3%), myalgia (30.5% vs 28.5%), arthralgia (25.6% vs 22.4%), chills (16.5% vs 12.8%), and axillary swelling or tenderness (10.7% vs 10.0%)

mNEXSPIKE showed generally fewer local adverse reactions for patients 65 years of age and older

‡7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).

Recommend mNEXSPIKE, an enhanced COVID-19 vaccine for patients at risk[1–8]

mNEXSPIKE Storage and Handling[1]

- Store frozen between -40 °C to -15 °C (-40 °F to 5 °F).
- During storage and after thawing, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- After thawing, mNEXSPIKE may be stored refrigerated between 2 °C to 8 °C (36 °F to 46 °F) for up to 90 days or up to the expiration date printed on the carton, whichever comes first.
- After thawing, mNEXSPIKE may be stored between 8 °C to 25 °C (46 °F to 77 °F) for up to 24 hours.
- Do not refreeze once thawed. Thawed syringes can be handled in room light conditions.

INDICATION

mNEXSPIKE is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

mNEXSPIKE is approved for use in individuals who have been previously vaccinated with any COVID-19 vaccine and are:

- 65 years of age and older, or
- 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

IMPORTANT SAFETY INFORMATION

Contraindications

Do not administer mNEXSPIKE to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of mNEXSPIKE or to individuals who had a severe allergic reaction following a previous dose of SPIKEVAX (COVID-19 Vaccine, mRNA) or any Moderna COVID-19 vaccine authorized for emergency use.

Warnings and Precautions

- **Management of Acute Allergic Reactions:** Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of mNEXSPIKE.
- **Myocarditis and Pericarditis:** Postmarketing data with authorized or approved mRNA COVID-19 vaccines have demonstrated increased risks of myocarditis and pericarditis, with onset of symptoms typically in the first week following vaccination. The observed risk has been highest in males 12 years through 24 years of age.
- **Syncope (fainting):** May occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.
- **Altered Immunocompetence:** Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished immune response to mNEXSPIKE.
- **Limitations of Vaccine Effectiveness:** mNEXSPIKE may not protect all vaccine recipients.

Adverse Reactions

The most commonly reported (≥10%) adverse reactions were pain at the injection site, fatigue, headache, myalgia, chills, arthralgia, axillary swelling or tenderness, and nausea/vomiting.

Reporting Adverse Events and Vaccine Administration Errors

The vaccination provider is responsible for mandatory reporting of certain adverse events to the Vaccine Adverse Event Reporting System (VAERS) online at https://vaers.hhs.gov or by calling 1-800-822-7967.
For Colorado and Connecticut price disclosure, please visit https://modernadirect.com/wac-disclosure.

Please click for mNEXSPIKE Full Prescribing Information.

Scan or click to learn more about mNEXSPIKE

COVID-19, coronavirus disease 2019; HR, hazard ratio; mRNA, messenger RNA; NP, nasopharyngeal; RT-PCR, reverse transcription polymerase chain reaction; rVE, relative vaccine efficacy; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

References: 1. mNEXSPIKE Prescribing Information. Moderna; 2025. **2.** Allen JC, et al. *Vaccine*. 2020;38(52):8264-8272. **3.** Andrew MK, et al. *Clin Interv Aging*. 2021;16:731-738. **4.** Chalkias S, et al. *J Infect Dis*. 2025;231(4):e754-e763. **5.** Montgomerie I, et al. *iScience*. 2023;26(4):106256. **6.** Spikevax Prescribing Information. Moderna; 2025. **7.** Chalkias S. Efficacy, immunogenicity, and safety of a next-generation mRNA-1283 COVID-19 vaccine compared with the mRNA-1273 vaccine: results from NextCOVE, a phase 3, randomized, observer-blind, active-controlled trial. 2025. Supplementary appendix. **8.** CDC. Accessed May 9, 2025. https://www.cdc.gov/covid/risk-factors/index.html **9.** Chaudhary N, et al. *Nat Rev Drug Discov*. 2021;20(11):817-838.

mNEXSPIKE® by moderna
COVID-19 Vaccine, mRNA

Moderna 2025-2026 Respiratory Vaccine Portfolio[1–3]*

Available **exclusively** as **ready-to-use pre-filled syringes**

Moderna vaccines are ready to use once thawed to room temperature.

Expected Product Information[1–6]

	STORAGE AND HANDLING	BILLING CODES
mNEXSPIKE® COVID-19 Vaccine, mRNA 	**Frozen Storage:** -40 °F to 5 °F (-40 °C to -15 °C) **Thawing From Frozen:** • **Refrigeration:** 36 °F to 46 °F (2 °C to 8 °C) • **Room Temperature:** 59 °F to 77 °F (15 °C to 25 °C) **Storage After Thawing:** • **Refrigeration:** 36 °F to 46 °F (2 °C to 8 °C) for **up to 90 days** or up to the expiration date printed on the carton, whichever comes first • **Room Temperature:** 46 °F to 77 °F (8 °C to 25 °C) for **up to 24 hours** at room temperature	**NDC (paperboard tray carton of 10 PFS):** 80777-0400-60 **NDC (pre-filled syringe):** 80777-0400-17 **CVX:** To be provided following FDA approval of the 2025–2026 Formula **MVX:** MOD **CPT®†:** • 91323 • 90480 **ICD-10-CM:** Z23
spikevax® COVID-19 Vaccine, mRNA 6 months–11 years of age‡: 0.25 mL dose 12 years of age and older§: 0.5 mL dose 	**Frozen Storage:** -58 °F to 5 °F (-50 °C to -15 °C) **Thawing From Frozen:** • **Refrigeration:** 36 °F to 46 °F (2 °C to 8 °C) • **Room Temperature:** 59 °F to 77 °F (15 °C to 25 °C) **Storage After Thawing:** • **Refrigeration:** 36 °F to 46 °F (2 °C to 8 °C) for **up to 60 days** or up to the expiration date printed on the carton, whichever comes first • **Room Temperature:** 46 °F to 77 °F (8 °C to 25 °C) for **up to 12 hours** at room temperature	**NDC (paperboard tray carton of 10 PFS):** • 0.25 mL dose: 80777-0113-80 • 0.5 mL dose: 80777-0112-96 **NDC (pre-filled syringe):** • 0.25 mL dose: 80777-0113-09 • 0.5 mL dose: 80777-0112-01 **CVX:** • 0.25 mL dose: 311 • 0.5 mL dose: 312 **MVX:** MOD **CPT†:** • 0.25 mL dose: 91321 • 0.5 mL dose: 91322 • 90480 **ICD-10-CM:** Z23
mRESVIA® (Respiratory Syncytial Virus Vaccine) 	**Frozen Storage:** -40 °F to 5 °F (-40 °C to -15 °C) **Thawing From Frozen:** • **Refrigeration:** 36 °F to 46 °F (2 °C to 8 °C) • **Room Temperature:** 59 °F to 77 °F (15 °C to 25 °C) **Storage After Thawing:** • **Refrigeration:** 36 °F to 46 °F (2 °C to 8 °C) for **up to 90 days** or up to the expiration date printed on the carton, whichever comes first • **Room Temperature:** 46 °F to 77 °F (8 °C to 25 °C) for **up to 24 hours** at room temperature	**NDC (paperboard tray carton of 10 PFS):** 80777-0345-61 **NDC (pre-filled syringe):** 80777-0345-01 **CVX:** 326 **MVX:** MOD **CPT†:** • 90683 • 90471 **ICD-10-CM:** Z23

*Spikevax (COVID-19 Vaccine, mRNA) 2025–2026 Formula and mNEXSPIKE (COVID-19 Vaccine, mRNA) 2025–2026 Formula have not been FDA authorized or approved and will require authorization or approval prior to sale. Information is subject to change. †CPT is a registered trademark of the American Medical Association (AMA). ‡For individuals 6 months–11 years of age at high risk for severe COVID-19.[2] §For individuals 65 years of age and older and those 12–64 years of age at high risk for severe COVID-19.[2]

mNEXSPIKE® INDICATION (2024–2025 Formula)

mNEXSPIKE® (COVID-19 Vaccine, mRNA) is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

mNEXSPIKE is approved for use in individuals who have been previously vaccinated with any COVID-19 vaccine and are:

- 65 years of age and older, or
- 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

mNEXSPIKE IMPORTANT SAFETY INFORMATION

Contraindications

Do not administer mNEXSPIKE® to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of mNEXSPIKE or to individuals who had a severe allergic reaction following a previous dose of SPIKEVAX (COVID-19 Vaccine, mRNA) or any Moderna COVID-19 vaccine authorized for emergency use.

SPIKEVAX® INDICATION (2024–2025 Formula)

SPIKEVAX® (COVID-19 Vaccine, mRNA) is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

SPIKEVAX is approved for use in individuals who are:

- 65 years of age and older, or
- 6 months through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

SPIKEVAX IMPORTANT SAFETY INFORMATION

Contraindications

Do not administer SPIKEVAX® to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of SPIKEVAX or to individuals who had a severe allergic reaction (e.g., anaphylaxis) following a previous dose of a Moderna COVID-19 vaccine.

mRESVIA® INDICATION

mRESVIA® (Respiratory Syncytial Virus Vaccine) is a vaccine indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older and individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV.

mRESVIA IMPORTANT SAFETY INFORMATION

Contraindications

Do not administer mRESVIA® to individuals with a history of severe allergic reaction (e.g., anaphylaxis) to any component of mRESVIA.

Please see continued IMPORTANT SAFETY INFORMATION throughout, and scan or click the QR codes on page 2 for mNEXSPIKE Full Prescribing Information, SPIKEVAX Full Prescribing Information, and mRESVIA Full Prescribing Information.

mNEXSPIKE IMPORTANT SAFETY INFORMATION (CONT.)

Warnings and Precautions

- **Management of Acute Allergic Reactions:** Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of mNEXSPIKE.
- **Myocarditis and Pericarditis:** Postmarketing data with authorized or approved mRNA COVID-19 vaccines have demonstrated increased risks of myocarditis and pericarditis, with onset of symptoms typically in the first week following vaccination. The observed risk has been highest in males 12 years through 24 years of age.
- **Syncope (fainting):** May occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.
- **Altered Immunocompetence:** Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished immune response to mNEXSPIKE.
- **Limitations of Vaccine Effectiveness:** mNEXSPIKE may not protect all vaccine recipients.

Adverse Reactions

The most commonly reported (≥10%) adverse reactions were pain at the injection site, fatigue, headache, myalgia, chills, arthralgia, axillary swelling or tenderness, and nausea/vomiting.

Reporting Adverse Events and Vaccine Administration Errors

The vaccination provider is responsible for mandatory reporting of certain adverse events to the Vaccine Adverse Event Reporting System (VAERS) online at https://vaers.hhs.gov or by calling 1-800-822-7967.

Please scan or click the QR code or ask your representative for mNEXSPIKE Full Prescribing Information.

SPIKEVAX IMPORTANT SAFETY INFORMATION (CONT.)

Warnings and Precautions

- **Management of Acute Allergic Reactions:** Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of SPIKEVAX.
- **Myocarditis and Pericarditis:** Postmarketing data with authorized or approved mRNA COVID-19 vaccines have demonstrated increased risks of myocarditis and pericarditis, with onset of symptoms typically in the first week following vaccination. The observed risk has been highest in males 12 years through 24 years of age.
- **Syncope (fainting):** May occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.
- **Altered Immunocompetence:** Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished immune response to SPIKEVAX.
- **Limitations of Vaccine Effectiveness:** SPIKEVAX may not protect all vaccine recipients.

Adverse Reactions

The most commonly reported (>10%) adverse reactions in participants 6 - 36 months of age: irritability/crying, pain at the injection site, sleepiness, loss of appetite, fever, erythema, swelling at the injection site, and axillary (or groin) swelling/tenderness.

The most commonly reported (>10%) adverse reactions in participants 37 months - 11 years of age were: pain at the injection site, fatigue, headache, myalgia, chills, nausea/vomiting, axillary (or groin) swelling/tenderness, fever, erythema, swelling at the injection site, and arthralgia.

The most commonly reported (≥10%) adverse reactions in participants 12 years and older were: pain at the injection site, headache, fatigue, myalgia, arthralgia, chills, and axillary swelling/tenderness, nausea/vomiting, and swelling at the injection site.

Reporting Adverse Events and Vaccine Administration Errors

To report suspected adverse reactions, contact ModernaTX, Inc. at 1-866-663-3762 or VAERS at 1-800-822-7967 or https://vaers.hhs.gov.

Please scan or click the QR code or ask your representative for SPIKEVAX Full Prescribing Information.

mRESVIA IMPORTANT SAFETY INFORMATION (CONT.)

Warnings and Precautions

- **Management of Acute Allergic Reactions:** Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of mRESVIA.
- **Syncope:** Syncope (fainting) may occur in association with administration of injectable vaccines, including mRESVIA. Procedures should be in place to avoid injury from fainting.
- **Altered Immunocompetence:** Immunocompromised individuals, including those receiving immunosuppressive therapy, may have a diminished immune response to mRESVIA.

Adverse Reactions

In a clinical trial conducted in participants 60 years of age and older, the most commonly reported (≥10%) adverse reactions were injection-site pain (55.9%), fatigue (30.8%), headache (26.7%), myalgia (25.6%), arthralgia (21.7%), axillary (underarm) swelling or tenderness (15.2%) and chills (11.6%).

In a clinical trial conducted in participants 18 through 59 years of age at increased risk for LRTD caused by RSV, the most commonly reported (≥10%) adverse reactions were injection site pain (73.9%), fatigue (36.9%), headache (33.3%), myalgia (28.9%), arthralgia (22.7%), chills (19.9%), axillary (underarm) swelling or tenderness (17.1%), and nausea/vomiting (10.8%).

To report suspected adverse reactions, contact ModernaTX, Inc. at 1-866-663-3762 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

Please scan or click the QR code or ask your representative for mRESVIA Full Prescribing Information.

Colorado & Connecticut prescribers and pharmacists may view WAC information at modernadirect.com/wac-disclosure.

COVID-19, coronavirus disease 2019; CPT, Current Procedural Terminology; CVX, vaccine administered; ICD-10-CM, International Classification of Disease, Tenth Revision, Clinical Modification; FDA, US Food and Drug Administration; mRNA, messenger RNA; MVX, Manufacturer of Vaccine; NDC, National Drug Code; PFS, pre-filled syringe; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

References: 1. mNEXSPIKE Prescribing Information. Moderna; 2025. **2.** Spikevax Prescribing Information. Moderna; 2025. **3.** mRESVIA Prescribing Information. Moderna; 2025. **4.** CDC. Accessed August 4, 2025. https://www.cdc.gov/iis/code-sets/fall-season-respiratory-codes.html **5.** CMS. Accessed August 4, 2025. https://www.cms.gov/medicare/payment/covid-19/coding-covid-19-vaccine-shots **6.** ICD10Data.com. 2024 ICD-10-CM diagnosis code Z23. Accessed July 31, 2025. https://www.icd10data.com/ICD10CM/Codes/Z00-Z99/Z20-Z29/Z23-/Z23

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UNDERSTANDING RECENT GUIDANCE

Individuals Who Should Receive COVID-19 Vaccination

What is the FDA's regulatory framework for COVID-19 vaccination?[1]

On May 20, 2025, the FDA published an updated policy position in the *New England Journal of Medicine* on an evidence-based approach to COVID-19 vaccination.

The following patient populations are at elevated risk for severe outcomes from COVID-19 infection[1]:

Adults aged ≥65 years

~61 million (nearly **1 in 4** adults in the US)[2]

Individuals aged ≥6 months who have ≥1 underlying condition that puts them at high risk for severe COVID-19 outcomes

~100–200 million Americans[1,3]

What underlying conditions increase the risk of severe COVID-19?

CDC 2025 List of Underlying Medical Conditions That Increase a Person's Risk of Severe COVID-19[1]

- **Asthma**
- **Cancer**
  - Hematologic malignancies
- **Cerebrovascular disease**
- **Chronic kidney disease***
  - People receiving dialysis
- **Chronic lung diseases** limited to the following:
  - Bronchiectasis
  - **COPD** (chronic obstructive pulmonary disease)
  - Interstitial lung disease
  - Pulmonary embolism
  - Pulmonary hypertension
- Chronic liver diseases limited to the following:
  - Cirrhosis
  - Nonalcoholic fatty liver disease
  - Alcoholic liver disease
  - Autoimmune hepatitis
- Cystic fibrosis
- **Diabetes mellitus, type 1**
- **Diabetes mellitus, type 2***
- Gestational diabetes
- Disabilities,† including Down's syndrome
- **Heart conditions** (such as heart failure, coronary artery disease, or cardiomyopathies)
- HIV (human immunodeficiency virus)
- Mental health conditions limited to the following:
  - Mood disorders, including depression
  - Schizophrenia spectrum disorders
- Neurologic conditions limited to dementia† and Parkinson's disease
- **Obesity** (BMI ≥30 kg/m^2 or ≥95th percentile in children)
- Physical inactivity
- Pregnancy and recent pregnancy‡
- Primary immunodeficiencies
- Heart conditions (such as heart failure, coronary artery disease, or cardiomyopathies)
- Smoking, current and former
- Solid-organ or blood stem-cell transplantation
- Tuberculosis
- Use of corticosteroids or other immunosuppressive medications

*Indicates presence of evidence for pregnant and nonpregnant women.[1]

†Underlying conditions for which there is evidence in pediatric patients.[1]

‡As of May 27, 2025, the US Secretary of Health and Human Services, Robert F. Kennedy Jr., announced that the COVID-19 vaccine will no longer be recommended for healthy pregnant women.[4]

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UNDERSTANDING RECENT FEDERAL GUIDANCE

COVID-19 Vaccination in Children and Adolescents

What is the updated CDC recommendation on vaccinating children and adolescents against COVID-19?

As of May 28, 2025, the CDC recommends shared clinical decision making for vaccinating individuals ages 6 months–17 years who are NOT moderately or severely immunocompromised.[5]

Shared clinical decision-making vaccinations are individually based and informed by a decision process between the healthcare provider and the patient or parent/guardian. Where the parent presents with a desire for their child to be vaccinated, children 6 months and older may receive COVID-19 vaccination, informed by the clinical judgment of a healthcare provider and personal preference and circumstances.

Where can I find more information?

FDA Policy Position: An Evidence-Based Approach to COVID-19 Vaccination

CDC 2025 Child and Adolescent Immunization Schedule

BMI, body mass index; CDC, Centers for Disease Control and Prevention; COVID-19, coronavirus disease 2019; FDA, US Food and Drug Administration.

References: 1. Prasad V, et al. *N Engl J Med*. Published online May 20, 2025. doi:10.1056/NEJMsb2506929 **2.** U.S. Census Bureau. Accessed May 12, 2025. https://www.census.gov/data/tables/time-series/demo/popest/2020s-national-detail.html. **3.** Adams ML, et al. *Emerg Infect Dis*. 2020;26(8):1831-1833. **4.** Schwartz JL. *N Engl J Med*. Published online June 18, 2025. doi:10.1056/NEJMp2507766. **5.** CDC. Accessed June 4, 2025. https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/child/0-18yrs-child-combined-schedule.pdf

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mRESVIA®
(Respiratory Syncytial Virus Vaccine)

Ready to Protect More Patients Against RSV[1]

CDC recommends a single dose of RSV vaccine for older adults to help prevent serious RSV infection and hospitalization[2,3]:

- **All adults aged ≥75 years**
- **Adults aged 50–74 years at increased risk for severe RSV disease***

Older adults, especially those with **certain chronic medical conditions**, are at increased risk for severe infection, hospitalization, and death[2–4]:

Congestive heart failure (CHF)

Chronic obstructive pulmonary disease (COPD)

Diabetes

Asthma

Advanced liver or kidney disease

Protect older adults against RSV infection with mRESVIA—**the only CDC-recommended RSV vaccine available in a ready-to-use pre-filled syringe**.[1–6]

mRESVIA is ready to use once thawed to room temperature.[1†]

Indication

mRESVIA (Respiratory Syncytial Virus Vaccine) is a vaccine indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older and individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV.

Important Safety Information

Contraindications

Do not administer mRESVIA to individuals with a history of severe allergic reaction (e.g., anaphylaxis) to any component of mRESVIA.

Warnings and Precautions

- **Management of Acute Allergic Reactions:** Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of mRESVIA.
- **Syncope:** Syncope (fainting) may occur in association with administration of injectable vaccines, including mRESVIA. Procedures should be in place to avoid injury from fainting.
- **Altered Immunocompetence:** Immunocompromised individuals, including those receiving immunosuppressive therapy, may have a diminished immune response to mRESVIA.

Please see additional IMPORTANT SAFETY INFORMATION throughout, and click here for Full Prescribing Information.

Tired of Reconstituting?

Ready-to-use mRESVIA Can Help Streamline RSV Vaccination[1]

Available in a Convenient Pre-filled Syringe[1]

- **Pre-filled syringe presentation without the need for reconstitution.**
- **Option to thaw at refrigeration or room temperature. mRESVIA is ready to use once thawed to room temperature.†**

Talking Points to Help You Confidently Initiate Conversations With Patients

- As we age, adults are at higher risk for severe consequences from RSV infection[2–4]*
- Severe RSV infection can include lung infection, pneumonia, and worsening of serious conditions, such as asthma, COPD, or CHF; RSV infection in older adults may even lead to hospitalization or death[4]
- Based on your age and/or medical history, I recommend you receive your RSV vaccine today—it's easy to schedule[1–3]

Scan or click the QR code to learn more about mRESVIA.

Important Safety Information (Cont.)

Adverse Reactions

In a clinical trial conducted in participants 60 years of age and older, the most commonly reported (≥10%) adverse reactions were injection-site pain (55.9%), fatigue (30.8%), headache (26.7%), myalgia (25.6%), arthralgia (21.7%), axillary (underarm) swelling or tenderness (15.2%) and chills (11.6%).

In a clinical trial conducted in participants 18 through 59 years of age at increased risk for LRTD caused by RSV, the most commonly reported (≥10%) adverse reactions were injection site pain (73.9%), fatigue (36.9%), headache (33.3%), myalgia (28.9%), arthralgia (22.7%), chills (19.9%), axillary (underarm) swelling or tenderness (17.1%), and nausea/vomiting (10.8%).

To report suspected adverse reactions, contact ModernaTX, Inc. at 1-866-663-3762 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

For Colorado and Connecticut price disclosure, please visit https://modernadirect.com/wac-disclosure.

*Comorbidities that increase risk of severe RSV disease include, but are not limited to, chronic kidney disease, severe obesity, chronic obstructive pulmonary disease, asthma, congestive heart failure, chronic liver disease, and diabetes.[3]

†Stored frozen between -40 °C to -15 °C (-40 °F to 5 °F), with the option to thaw at refrigeration or room temperature. A carton of 2 pre-filled syringes can be thawed at refrigeration 2 °C to 8 °C (36 °F to 46 °F) for 100 minutes or at room temperature 15 °C to 25 °C (59 °F to 77 °F) for 40 minutes. A carton of 10 pre-filled syringes can be thawed at refrigeration 2 °C to 8 °C (36 °F to 46 °F) for 160 minutes or at room temperature 15 °C to 25 °C (59 °F to 77 °F) for 80 minutes.[1]

CDC, Centers for Disease Control and Prevention; RSV, respiratory syncytial virus.

References: 1. mRESVIA Prescribing Information. Moderna; 2025. **2.** CDC. Accessed July 24, 2025. https://www.cdc.gov/rsv/hcp/vaccine-clinical-guidance/adults.html **3.** CDC. Accessed July 24, 2025. https://www.cdc.gov/rsv/hcp/clinical-overview/index.html **4.** CDC. Accessed July 24, 2025. https://www.cdc.gov/rsv/older-adults/ **5.** AREXVY Prescribing Information. GlaxoSmithKline Biologics SA. **6.** ABRYSVO Prescribing Information. Pfizer Inc.

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mRESVIA®
(Respiratory Syncytial Virus Vaccine)

mRESVIA®
(Respiratory Syncytial Virus Vaccine)

Now Indicated for Individuals 18-59 Years of Age Who Are at Increased Risk for LRTD Caused by RSV[1]

READY TO PROTECT MORE PATIENTS against RSV[1]

The only CDC-recommended ready-to-use RSV vaccine in a pre-filled syringe[1–4]

mRESVIA is ready to use once thawed to room temperature.[1]*

mRESVIA Provides Exceptional Convenience[1]

- Pre-filled syringe presentation
- No reconstitution required
- Flexible storage and handling options†

*Stored frozen between -40 °C to -15 °C (-40 °F to 5 °F), with the option to thaw at refrigeration or room temperature. A carton of 2 pre-filled syringes can be thawed at refrigeration 2 °C to 8 °C (36 °F to 46 °F) for 100 minutes or at room temperature 15 °C to 25 °C (59 °F to 77 °F) for 40 minutes. A carton of 10 pre-filled syringes can be thawed at refrigeration 2 °C to 8 °C (36 °F to 46 °F) for 160 minutes or at room temperature 15 °C to 25 °C (59 °F to 77 °F) for 80 minutes.[1] †Please see mRESVIA Full Prescribing Information for details on how to store mRESVIA.

Indication

mRESVIA (Respiratory Syncytial Virus Vaccine) is a vaccine indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older and individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV.

Important Safety Information

Contraindications

Do not administer mRESVIA to individuals with a history of severe allergic reaction (e.g., anaphylaxis) to any component of mRESVIA.

Please see additional IMPORTANT SAFETY INFORMATION throughout, and scan the QR code on the back for Full Prescribing Information.

mRESVIA®
(Respiratory Syncytial Virus Vaccine)

Order Today

Order mRESVIA Via:

- Moderna Direct
- Authorized Distributor

Scan the QR code for additional information about ordering mRESVIA.

Important Safety Information (Cont.)

Warnings and Precautions

- **Management of Acute Allergic Reactions:** Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of mRESVIA.
- **Syncope:** Syncope (fainting) may occur in association with administration of injectable vaccines, including mRESVIA. Procedures should be in place to avoid injury from fainting.
- **Altered Immunocompetence:** Immunocompromised individuals, including those receiving immunosuppressive therapy, may have a diminished immune response to mRESVIA.

Adverse Reactions

In a clinical trial conducted in participants 60 years of age and older, the most commonly reported (≥10%) adverse reactions were injection-site pain (55.9%), fatigue (30.8%), headache (26.7%), myalgia (25.6%), arthralgia (21.7%), axillary (underarm) swelling or tenderness (15.2%) and chills (11.6%).

Scan the QR code for Full Prescribing Information.

In a clinical trial conducted in participants 18 through 59 years of age at increased risk for LRTD caused by RSV, the most commonly reported (≥10%) adverse reactions were injection site pain (73.9%), fatigue (36.9%), headache (33.3%), myalgia (28.9%), arthralgia (22.7%), chills (19.9%), axillary (underarm) swelling or tenderness (17.1%), and nausea/vomiting (10.8%).

To report suspected adverse reactions, contact ModernaTX, Inc. at 1-866-663-3762 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

For Colorado and Connecticut price disclosure, please visit https://modernadirect.com/wac-disclosure.

CDC, Centers for Disease Control and Prevention; LRTD, lower respiratory tract disease; RSV, respiratory syncytial virus.

References: 1. mRESVIA Prescribing Information. Moderna; 2025. **2.** CDC. Accessed July 24, 2025. https://www.cdc.gov/rsv/hcp/vaccine-clinical-guidance/adults.html **3.** AREXVY Prescribing Information. GlaxoSmithKline Biologics; 2025. **4.** ABRYSVO Prescribing Information. Pfizer Inc; 2025.

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MotherToBaby

Do You Know If You Are Protected Against Measles?

Having measles during pregnancy can increase the chance of serious problems for mom and baby. The MMR (measles, mumps, rubella) vaccine provides the best protection against measles.

Have you ever had an MMR vaccine?

YES

I'M NOT SURE

NO

Check your vaccine records for the MMR vaccine.

Can't find your vaccine records?

- Ask your parents/guardians if they have your records.
- Ask your healthcare provider to check your medical records.
- Contact the state or jurisdiction where you grew up to request your vaccine records.

I found my vaccine records and I have had at least 1 dose of MMR vaccine.

I can't find my records **OR** I have found them, but I have not had an MMR vaccine.

Great!
For most adults, having 1 or more doses* of the MMR vaccine in their lifetime is sufficient.

Talk to your healthcare provider about getting the MMR vaccine.
Repeating the vaccine isn't harmful.

When can I get up to date on the MMR Vaccine?

I am NOT PREGNANT

- Getting an MMR vaccine before pregnancy helps protect you against measles now and during any future pregnancy.
- Some adults need to get 2 doses,* at least 28 days apart.
- SMFM recommends waiting at least 4 weeks after getting an MMR vaccine before getting pregnant.

I am PREGNANT

- The MMR vaccine is generally not recommended during pregnancy.
- You can lower your chances of getting measles during pregnancy by avoiding outbreak areas and contact with sick people, and washing your hands often.
- Taking vitamin A does not prevent measles. High doses of vitamin A during pregnancy can cause birth defects.

I am POSTPARTUM or BREASTFEEDING

- If you never got an MMR vaccine, then after pregnancy is a great time to get vaccinated.
- You can get it at the hospital after delivery before you go home. When everyone around your baby is vaccinated against measles, it helps protect your baby against infection.
- The MMR vaccine **can** be given while breastfeeding.

*If you are a student at college or other post-high school education institution, an international traveler, living with HIV, a healthcare worker, or live with someone who is severely immunocompromised, you might need 2 doses. Talk with your healthcare provider about your MMR vaccine recommendations. In case of a measles outbreak in your area, follow local recommendations.

MotherToBaby®

Society for Maternal-Fetal Medicine

Additional Resources:

mothertobaby.org

highriskpregnancyinfo.org

cdc.gov

COVID-19 mRNA Vaccine (Moderna/Spikevax® and Pfizer/Comirnaty®)

This sheet is about exposure to a COVID-19 mRNA vaccine in pregnancy and while breastfeeding. This information is based on published research studies. It should not take the place of medical care and advice from your healthcare provider.

What is COVID-19?

COVID-19 (short for Coronavirus Disease 2019) is an illness caused by the SARS-CoV-2 virus. The virus easily spreads from person to person through respiratory droplets that come from our mouths and noses when we breathe, talk, cough, or sneeze. For more information on COVID-19, please see the MotherToBaby fact sheet at https://mothertobaby.org/fact-sheets/covid-19/.

What is a COVID-19 mRNA vaccine?

A COVID-19 messenger RNA (mRNA) vaccine helps protect against the virus that causes COVID-19. It is often called a "COVID vaccine." Brand names of COVID-19 mRNA vaccines in the United States are Moderna/Spikevax® and Pfizer/Comirnaty®. COVID-19 mRNA vaccines do not contain live virus that could cause COVID-19. While no vaccine is 100% effective at preventing COVID-19, it can greatly lower the chance of getting very sick from the virus.

For more information on another type of COVID-19 vaccine, please see the MotherToBaby fact sheet at https://mothertobaby.org/fact-sheets/covid-19-protein-subunit-vaccine/.

Are COVID-19 mRNA vaccines recommended for women who are pregnant?

Medical organizations including the American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) recommend that women who are planning a pregnancy, pregnant, or recently pregnant stay up to date with the latest COVID-19 vaccines. A COVID-19 mRNA vaccine can be given at any time in pregnancy.

Having a COVID-19 infection while pregnant increases the chance of severe illness and pregnancy complications. Studies have shown that women who are up to date with COVID-19 vaccines in pregnancy are less likely to get very sick or have pregnancy complications from a COVID-19 infection than women who are not up to date.

Can getting a COVID-19 mRNA vaccine make it harder for me to get pregnant or affect fertility treatments?

Some women have reported changes in their menstrual cycle (period) after getting a COVID-19 mRNA vaccine, such as having a slightly longer or heavier period or starting their next period sooner than expected. Studies have found that if these changes happen, they are temporary and do not affect the woman's fertility (ability to get pregnant).

Studies of women undergoing in-vitro fertilization (IVF) have found no effect of COVID-19 mRNA vaccines on the function of the ovaries (the organ that releases the egg), number of oocytes (immature eggs), hormone levels, or success rates of embryo implantation. Most studies have not found differences in pregnancy rates between recently vaccinated and unvaccinated women undergoing fertility treatments. There is no recommendation to postpone fertility treatment after getting a COVID-19 mRNA vaccine or to avoid getting the vaccine during or after treatment.

I just got a COVID-19 mRNA vaccine. How long do I need to wait before I get pregnant?

There is no recommendation to wait before trying to get pregnant after getting a COVID-19 mRNA vaccine.

Does getting a COVID-19 mRNA vaccine increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Studies have not found a higher chance of miscarriage after getting a COVID-19 mRNA vaccine anytime in pregnancy.

Does getting a COVID-19 mRNA vaccine increase the chance of birth defects?

Birth defects can happen in any pregnancy for different reasons. Out of all babies born each year, about 3 out of 100 (3%) will have a birth defect. We look at published data to try to understand if an exposure, like a COVID-19 mRNA vaccine, might increase the chance of birth defects in a pregnancy. Studies have not found a higher chance of birth defects after getting a COVID-19 mRNA vaccine anytime in pregnancy.

Fever is a possible side effect of getting a COVID-19 mRNA vaccine. A high fever in the first trimester can increase the chance of certain birth defects. Acetaminophen is usually recommended to reduce fever during pregnancy. For more information about fever and pregnancy, see the MotherToBaby fact sheet about fever/hyperthermia at https://mothertobaby.org/fact-sheets/hyperthermia-pregnancy/.

Does getting a COVID-19 mRNA vaccine in pregnancy increase the chance of other pregnancy-related problems?

Studies have not found an increased chance of pregnancy-related problems or newborn complications such as stillbirth, preterm delivery (birth before week 37), babies born smaller than expected, low Apgar scores, admission to a neonatal intensive care unit (NICU), or neonatal death when a COVID-19 mRNA vaccine is given anytime during pregnancy.

Having a COVID-19 infection during pregnancy does increase the chance of pregnancy-related problems, such as preterm delivery.

Does getting a COVID-19 mRNA vaccine in pregnancy affect future behavior or learning for the child?

Studies comparing thousands of children whose mothers received COVID-19 mRNA vaccines during pregnancy to children whose mothers did not get the vaccine in pregnancy found no differences in development at 12-18 months of age.

Does getting a COVID-19 mRNA vaccine during pregnancy protect the baby from COVID-19 after delivery?

When a woman gets a COVID-19 mRNA vaccine during pregnancy, antibodies can pass to the fetus and may provide protection for the baby after delivery. Infants born to women who are vaccinated against COVID-19 during pregnancy are less likely to be hospitalized and die from a COVID-19 infection for up to 6 months after delivery.

Breastfeeding and COVID-19 mRNA vaccines:

Small studies have found that mRNA from COVID-19 mRNA vaccines is unlikely to enter the breast milk. If any small amounts of vaccine ingredients did enter the breast milk, they would most likely be destroyed in the baby's stomach. Studies have not reported serious adverse reactions to COVID-19 mRNA vaccines in women who are breastfeeding or their infants. Less than 10% of women reported changes in milk supply (more or less milk) after getting a COVID-19 mRNA vaccine, but their supply returned to normal within a day or two.

Organizations including the Academy of Breastfeeding Medicine (ABM) and the American Academy of Pediatrics (AAP) agree that women who are breastfeeding can receive a COVID-19 mRNA vaccine. There is no recommendation to postpone breastfeeding or discard breast milk after getting a COVID-19 mRNA vaccine.

Antibodies that protect against the virus that causes COVID-19 have been found in the breast milk of women who have received an mRNA vaccine. More research is needed to know how these antibodies might protect a breastfeeding child against the virus. Talk to your healthcare provider about all of your breastfeeding questions.

If a man gets a COVID-19 mRNA vaccine, could it affect fertility or increase the chance of birth defects?

Studies have found no differences in sperm production before and after getting a COVID-19 mRNA vaccine. In general, exposures that fathers or sperm donors have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/.

If you have received a dose of a COVID-19 mRNA vaccine in the last 2 months while pregnant, you might be a good match for our COVID-19 mRNA vaccine study. Help us help other pregnant people. If you are interested in learning more about this study, please call 1-877-311-8972 or visit: https://mothertobaby.org/join-study/.

Please click here for references.

Questions? Call 866.626.6847 | Text 855.999.3525 | Email or Chat at MotherToBaby.org.

Respiratory Syncytial Virus (RSV) Vaccine (Abrysvo®)

This sheet is about exposure to the respiratory syncytial virus (RSV) vaccine in pregnancy and while breastfeeding. This information is based on available published literature. It should not take the place of medical care and advice from your healthcare provider.

What is respiratory syncytial virus?

Respiratory syncytial virus (RSV) is a virus that can cause an infection of the respiratory (breathing) tract. RSV spreads easily from person to person through droplets when an infected person coughs or sneezes. It can also spread through direct contact with surfaces that have the virus on them. Most cases of RSV are mild and cause only cold-like symptoms. However, sometimes having RSV can lead to an infection in the lungs, such as pneumonia (also called lower respiratory tract disease). Serious symptoms like fever, severe cough, wheezing, rapid breathing, and cyanosis (blue skin caused by not having enough oxygen in the body) might require hospitalization or the use of a ventilator to help the person breathe. Infants, babies that are born preterm (before 37 weeks), and people with weakened immune systems have a higher chance of developing severe RSV infection.

What is the RSV vaccine?

The RSV vaccine causes a person to make antibodies against RSV. When a woman gets the RSV vaccine at the recommended time during pregnancy (32-36 weeks), the antibodies she makes can pass to the developing baby. It takes about 2 weeks after getting the vaccine in pregnancy for antibodies to fully pass to the developing baby. These antibodies can help protect the baby from severe RSV infection for about 6 months after they are born.

The only RSV vaccine approved for use in pregnancy in the United States (US) is called Abrysvo® (other available RSV vaccines are approved for use in older adults but not for use in pregnancy). Abrysvo® is a protein subunit vaccine. It does not contain live virus that can cause RSV. The Centers for Disease Control and Prevention (CDC) recommend the Abrysvo® RSV vaccine for women who are 32-36 weeks pregnant who have not received an RSV vaccine in a previous pregnancy. The RSV vaccine is only recommended for use during RSV season. In most regions of the continental US, RSV season is from September to January. However, the timing and severity of RSV seasons can be different from year to year.

If a pregnant woman has already received an RSV vaccine during any previous pregnancy, she does not need to get an RSV vaccine again in her current pregnancy. Instead, she should talk to her healthcare provider about protecting her baby against RSV with nirsevimab (infant antibody). CDC has information about the maternal RSV vaccine and nirsevimab here: https://www.cdc.gov/rsv/vaccines/protect-infants.html.

Does getting the RSV vaccine make it harder to get pregnant?

Studies have not been done to see if getting the RSV vaccine can make it harder to get pregnant.

I just got the RSV vaccine. How long do I need to wait before I get pregnant?

The Abrysvo® RSV vaccine is only recommended for women who are already pregnant (32-36 weeks) and for older adults. In the rare event that someone gets the RSV vaccine and is planning a pregnancy, there is no recommendation to wait to get pregnant.

Does getting the RSV vaccine increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Studies have not been done to see if the RSV vaccine increases the chance for miscarriage. The RSV vaccine is recommended for use during the third trimester of pregnancy, which is past the time when a miscarriage can happen.

Does getting the RSV vaccine increase the chance of birth defects?

Birth defects can happen in any pregnancy for different reasons. Out of all babies born each year, about 3 out of 100

(3%) will have a birth defect. We look at research studies to try to understand if an exposure, like the RSV vaccine, might increase the chance of birth defects in a pregnancy. Studies on women who received the Abrysvo® RSV vaccine during pregnancy have not found a higher chance of birth defects.

Does getting the RSV vaccine in pregnancy increase the chance of other pregnancy-related problems?

A clinical trial looking at over 3,600 women who received the Abrysvo® RSV vaccine between 24 and 36 weeks of pregnancy found no increased chance of pregnancy-related problems, such as low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth). However, slightly more preterm deliveries were seen in those who received the vaccine. In most cases, the preterm deliveries happened a month or more after getting the vaccine. A newer study looking at over 2,900 pregnant women who received the Abrysvo® RSV vaccine did not find an increased chance of preterm delivery. The recommendation to get the vaccine closer to the end of pregnancy (at 32-36 weeks) allows time for antibodies to pass to the baby before delivery but lowers the chance (if there is one) of delivering early from the vaccine, since the vaccine is given closer to full term.

Does getting the RSV vaccine in pregnancy affect future behavior or learning for the child?

Studies have not been done to see if getting the RSV vaccine can cause behavior or learning issues for the child.

Breastfeeding and the RSV vaccine:

The Abrysvo® RSV vaccine is only recommended for women who are pregnant (32-36 weeks) and for older adults. Studies have not been done on the RSV vaccine in women who are breastfeeding. The Advisory Committee on Immunization Practices (ACIP) and CDC state that subunit vaccines, like Abrysvo®, pose no risk for women who are breastfeeding or their infants (see https://www.cdc.gov/breastfeeding/breastfeeding-special-circumstances/vaccinations-medications-drugs/vaccinations.html). Be sure to talk to your healthcare provider about all your breastfeeding questions.

If a man gets the RSV vaccine, could it affect fertility or increase the chance of birth defects?

Studies have not been done to see if the RSV vaccine could affect a man's fertility (ability to get a a woman pregnant) or increase the chance of birth defects. In general, exposures that men have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/.

Please click here for references.

Seasonal Influenza Vaccine (Flu Shot)

This sheet is about exposure to the flu shot in pregnancy and while breastfeeding. This information is based on research studies. It should not take the place of medical care and advice from your healthcare provider.

What is influenza?

Influenza is commonly called the "flu." It is an infection of the respiratory (breathing) tract. Symptoms of the flu are fever, headache, chills, muscle aches, cough, congestion (stuffy nose), runny nose, sore throat, and feeling tired (fatigue). The flu sometimes causes vomiting and diarrhea. The typical flu season lasts from October through May of each year, with most cases of flu happening between December and February. The types (strains) of viruses that cause seasonal influenza can change from year to year.

Why is the flu a concern during pregnancy?

Even in healthy people, the body can have a harder time fighting infections during pregnancy. The flu can cause serious problems in women who are pregnant, such as respiratory distress (severe breathing problems) and even death. Being very sick from the flu can also increase the chance of pregnancy complications, such as preterm delivery (birth before week 37). While having the flu during pregnancy does not appear to increase the chance of birth defects, some symptoms of the flu, such as a high fever, could affect the fetus. For more information, see the MotherToBaby fact sheet on Seasonal Influenza (the Flu) at https://mothertobaby.org/fact-sheets/seasonal-influenza-the-flu-pregnancy/.

What is the seasonal influenza vaccine (flu shot)?

The seasonal influenza vaccine lowers the chance of getting the flu or getting very sick from the flu. The vaccine is updated every year to protect against the flu strains that are expected to be common that season. It is necessary to get the influenza vaccine (flu shot) each year in order to stay protected against the flu strains that are currently active.

The injected seasonal influenza vaccine is commonly known as the "flu shot". The flu shot is an inactivated vaccine, which means it does not contain live flu virus. The flu shot cannot cause you to get the flu. Major medical groups recommend that women who are pregnant (whether in their first, second, or third trimester) get the flu shot.

A nasal spray flu vaccine might also be available, but it is not recommended for use during pregnancy. Unlike the flu shot, the nasal spray vaccine contains a live, but weakened, flu virus (live attenuated influenza vaccine).

I got the nasal spray flu vaccine before I knew I was pregnant. Should I be concerned?

The nasal spray flu vaccine is a live attenuated vaccine (contains live but weakened flu virus). In general, it is suggested that women avoid live vaccines during pregnancy. However, accidentally getting the nasal spray vaccine while pregnant is not expected to increase the chance of birth defects or pregnancy complications. Talk with your healthcare provider in the unlikely case that you have any symptoms of the flu after receiving the nasal spray vaccine.

One of my family members just got the nasal spray flu vaccine. Can I be around them while I am pregnant?

People who are pregnant can be in close contact with others who have gotten the nasal spray flu vaccine.

When should I get the flu shot?

The flu shot usually becomes available in September and is offered throughout flu season. Protection begins about 2 weeks after you get the flu shot and lasts at least six to eight months. It is necessary to receive the seasonal flu shot each year to be protected during flu season.

In general, September and October are good times to get the flu shot each year. Getting it in July or August can be considered for people who are in the third trimester of pregnancy during those months. Talk with your healthcare provider about the best time for you to get the flu shot.

I am pregnant and my due date is only a couple weeks away. Do I still need to get the flu shot?

It is important to protect yourself from getting sick both during your pregnancy and after your baby is born. Getting the flu shot lowers the chance of getting sick and passing influenza to your baby. Getting vaccinated during pregnancy can also pass antibodies (protection) to the baby to help protect them from getting the flu during their first 6 months of life. This is important because infants cannot receive their own flu vaccine until 6 months of age.

I just got the flu shot. How long should I wait before trying to get pregnant?

There is no recommended waiting period before trying to get pregnant. The flu shot can be given at any time before or during pregnancy.

Can getting the flu shot make it harder for me to get pregnant?

Studies have not been done to see if getting the flu shot can make it harder to get pregnant.

Does getting a flu shot increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Studies have shown that getting the flu shot during pregnancy does not increase the chance of miscarriage.

Does getting the flu shot increase the chance of birth defects?

Birth defects can happen in any pregnancy for different reasons. Out of all babies born each year, about 3 out of 100 (3%) will have a birth defect. We look at published data to try to understand if an exposure, like the flu shot, might increase the chance of birth defects in a pregnancy. In the United States (U.S.), the flu shot has been given in pregnancy since the 1960s. Studies of thousands of people in the U.S. and around the world who have received the flu shot just before or during pregnancy have not found an increased chance of birth defects.

Does getting the flu shot in pregnancy increase the chance of other pregnancy-related problems?

Studies have not found a higher chance for other pregnancy-related problems, such as preterm delivery (birth before week 37) or low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth) after getting the flu shot during pregnancy.

Does getting the flu shot in pregnancy affect future behavior or learning for the child?

Studies have not found an increased chance of behavior or learning issues for the child after getting the flu shot during pregnancy.

Breastfeeding after getting the flu vaccine:

Major medical groups state that women who are breastfeeding can receive the flu shot or nasal spray influenza vaccine. Be sure to talk to your healthcare provider about all your breastfeeding questions.

If a man gets the flu shot, could it affect his fertility or increase the chance of birth defects?

There is no evidence that getting the flu shot or nasal spray influenza vaccine would affect a man's fertility (ability to get partner pregnant) or increase the chance of birth defects. When everyone who is around the baby after delivery is vaccinated against the flu, it helps protect the baby from being exposed to the flu virus. In general, exposures that fathers or sperm donors have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/.

Please click here for references.

Tetanus, Diphtheria and Pertussis (Tdap) Vaccine

This sheet is about exposure to the Tetanus, Diphtheria and Pertussis (Tdap) vaccine in pregnancy and while breastfeeding. This information is based on available published literature. It should not take the place of medical care and advice from your healthcare provider.

What are tetanus, diphtheria, and pertussis?

Tetanus, diphtheria, and pertussis are diseases caused by bacteria.

Tetanus causes tightening of the muscles and painful muscle spasms. Even with good medical care, 10-20% of people with tetanus die from tetanus. The tetanus bacteria come from soil and animal waste. The bacteria get into the body through an open cut or sore.

Diphtheria often starts with a fever and sore throat. A thin layer (called a membrane) can form over the back of the throat and airways, making it hard to breathe. Without treatment, diphtheria is often deadly. People get the illness from other people with diphtheria through droplets when they cough or sneeze. The use of vaccines has made diphtheria uncommon in the United States, Canada, and many other countries.

Pertussis is sometimes called whooping cough. Symptoms usually start similar to those of the common cold. Severe coughing can develop over several weeks. Fast, heavy coughing can cause a high-pitched whooping sound when breathing in. People get pertussis from other people with pertussis through droplets when they cough or sneeze. In people not vaccinated, the chance of getting pertussis in a household with an infected person is 80%. Pertussis is most serious in infants. In an outbreak in 2010 in California, 10 infants died. Serious disease and the need for hospital care can happen in up to 5% of teens and adults that get pertussis.

Do these diseases cause problems in pregnancy?

Tetanus and diphtheria can be deadly to a pregnant woman and can cause the loss of the pregnancy. They could also cause preterm delivery (birth before week 37).

Pertussis infection during pregnancy has not been well studied. There were no pregnancy complications seen in 1 case series of 32 pregnant women who had pertussis late in pregnancy. Severe disease could be a risk to the health of the mother and baby. There are a few reports of problems for the baby, but it is not known if those problems were due to pertussis during the pregnancy or for other reasons. Pertussis infection can be severe for babies under age 6 months; especially in babies born premature (birth before week 37) and babies who also have other health problems.

What is the Tdap vaccine?

The Tdap vaccine protects people from getting tetanus, diphtheria, and pertussis. Childhood vaccination for these diseases does not provide lifelong protection. Some brand names of Tdap are Adacel®, Boostrix® and Daptacel®.

The Tdap vaccine is noninfectious, meaning you cannot get the diseases from the vaccine. People get the vaccine by an injection. Like any vaccine, it does not provide 100% protection against the diseases.

Why should pregnant women get the Tdap vaccine during late pregnancy?

In the past, pregnant women did not regularly get the Tdap vaccine because pertussis used to be rare in adults. However, this is no longer the case and outbreaks have been happening across the United States. It is recommended that pregnant women get the vaccine during the third trimester of pregnancy (between weeks 27-36). However, it can be given anytime during pregnancy, if needed earlier.

After getting the vaccine, the body starts to make antibodies against the bacteria that can cause these diseases. Some of these antibodies can cross the placenta (the organ that grows in the uterus during pregnancy) and reach the fetus. Receiving the vaccine in the third trimester of pregnancy can help the baby get as many antibodies as possible. After delivery, these antibodies provide some protection against pertussis until the baby can receive their own vaccines. If

all household members and caregivers get the vaccine, it can lower the chance for the baby to get pertussis.

I had Tdap in my last pregnancy. Do I need it again?

It has been recommended to get the Tdap vaccine in the third trimester of every pregnancy. Discuss current recommendations with your healthcare team.

I just got the Tdap vaccine. How long should I wait until I get pregnant?

There is no recommended waiting period after getting the Tdap shot. In addition, women can get the vaccine at any time during pregnancy.

Does taking the Tdap vaccine increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. The Tdap vaccine is not associated with an increased chance of miscarriage.

Does the Tdap vaccine increase the chance of birth defects?

Every pregnancy starts out with a 3-5% chance of having a birth defect. This is called the background risk. Noninfectious vaccines, like Tdap, do not increase the chance for birth defects. The tetanus and diphtheria vaccine have a long history of use during pregnancy without increased risk.

Does the Tdap vaccine increase the chance of other pregnancy-related problems?

The Tdap vaccine has not been associated with a higher chance for other pregnancy-related problems, such as preterm delivery (having the baby before 37 weeks), low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth), preeclampsia (high blood pressure and problems with organs, such as the kidneys, which can lead to seizures), or stillbirth.

Does the Tdap vaccine in pregnancy affect future behavior or learning for the child?

Studies have not been done to see if Tdap vaccines in pregnancy can increase the chance of behavior or learning issues for the child.

Breastfeeding and the Tdap vaccine:

Noninfectious vaccines like Tdap are compatible with breastfeeding. If you get the vaccine while breastfeeding, it can help prevent you from getting sick and passing the illness to your baby. Be sure to talk to your healthcare provider about all your breastfeeding questions.

If a man gets a Tdap vaccine, could it affect his fertility or increase the chance of birth defects?

There is no proof that vaccines will affect sperm, and vaccines given to men do not reach the developing baby. Vaccination of others in the home will help protect the newborn from illness. In general, exposures that fathers or sperm donors have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/.

MotherToBaby is currently conducting a study to learn more about the pertussis vaccine in pregnancy. If you are pregnant and have received the pertussis vaccine (TDAP / DTAP), and you are interested in learning more about this study, please contact MotherToBaby Pregnancy Studies at 877-311-8972 or visit https://mothertobaby.org/join-study/

Please click here for references.

Sanofi

Beyfortus® (nirsevimab-alip) 50 mg 100 mg Injection

ACIP and AAP recommended[1,2]*

A single-dose, pre-filled syringe that offers convenient administration[3]

How Beyfortus® is supplied

Beyfortus injection is a sterile, preservative-free, clear-to-opalescent, colorless-to-yellow solution supplied as follows:

- **Five 50 mg/0.5 mL** single-dose, pre-filled syringes in a carton: **NDC 49281-575-15**
- **Five 100 mg/1 mL** single-dose, pre-filled syringes in a carton: **NDC 49281-574-15**

Each Beyfortus pre-filled syringe is for one-time use only. Only 5-pack cartons will be marketed in the US at this time.

Recommended Dosage of Beyfortus for the First RSV Season

Carton of 5 x 50 mg/0.5 mL
140 x 108 mm (5.5" x 4.25")

Carton of 5 x 100 mg/1 mL
140 x 108 mm (5.5" x 4.25")

Speak with your Sanofi representative to learn more about how to order your Beyfortus supply for the 2024-2025 RSV season.

- For children undergoing cardiac surgery with cardiopulmonary bypass, an additional dose of Beyfortus is recommended as soon as the child is stable after surgery; please consult the Prescribing Information for complete information on dosing in these circumstances[3]
- Second season: children up to 24 months of age, regardless of body weight, who remain vulnerable[3]:
  – 1 x 200 mg dose administered as 2 intramuscular injections (2 x 100 mg)

AAP, American Academy of Pediatrics; **ACIP**, Advisory Committee on Immunization Practices; **CDC**, Centers for Disease Control and Prevention.

*ACIP and AAP recommend 1 dose of Beyfortus for all infants aged <8 months born during or entering their first RSV season (50 mg for infants weighing <5 kg and 100 mg for infants weighing ≥5 kg). ACIP and AAP recommend 1 dose of Beyfortus (200 mg administered as 2 intramuscular injections [2 x 100 mg]) for children aged 8-19 months who are at increased risk of severe RSV disease and entering their second RSV season. Refer to the most current CDC immunization schedule for additional immunization considerations.

INDICATION

Beyfortus is indicated for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in:

- Neonates and infants born during or entering their first RSV season.
- Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

IMPORTANT SAFETY INFORMATION

Contraindication

Beyfortus is contraindicated in infants and children with a history of serious hypersensitivity reactions, including anaphylaxis, to nirsevimab-alip or to any of the excipients.

Please see additional Important Safety Information on the following page and accompanying full Prescribing Information.

Beyfortus® (nirsevimab-alip) | 50 mg 100 mg Injection

Important details on administration and storage of Beyfortus®

Beyfortus is the **first and only long-acting antibody** indicated for the **prevention of RSV lower respiratory tract disease** in term and preterm infants.[3]

Beyfortus can be administered concomitantly with other childhood vaccines[3]

- There is limited experience of Beyfortus coadministration with vaccines
- In clinical trials, when Beyfortus was given with routine childhood vaccines, the safety and reactogenicity profile of the coadministered regimen was similar to the childhood vaccines given alone
- Beyfortus should not be mixed with any vaccine in the same syringe or vial. When administered concomitantly with injectable vaccines, they should be given with separate syringes and at different injection sites

How should Beyfortus be administered?[3]

- Beyfortus is for intramuscular injection only, preferably in the anterolateral aspect of the thigh
- The entire contents of the syringe should be administered intramuscularly
- **The gluteal muscle should not be used routinely** as an injection site because of the risk of damage to the sciatic nerve

How should Beyfortus be stored?[3]

- Store in a **refrigerator** 36° F to 46° F (2° C to 8° C)
- Beyfortus may be **kept at room temperature** 68° F to 77° F (20° C to 25° C) for a maximum of 8 hours. After removal from the refrigerator, Beyfortus must be used within 8 hours or discarded
- **Do not** freeze
- **Do not** shake or expose to direct heat
- Store in original carton to **protect from light** until time of use

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions

- **Hypersensitivity Reactions Including Anaphylaxis:** Serious hypersensitivity reactions have been reported following Beyfortus administration. These reactions included urticaria, dyspnea, cyanosis, and/or hypotonia. Anaphylaxis has been observed with human immunoglobulin G1 (IgG1) monoclonal antibodies. If signs and symptoms of anaphylaxis or other clinically significant hypersensitivity reactions occur, initiate appropriate treatment.
- **Use in Individuals with Clinically Significant Bleeding Disorders:** As with other IM injections, Beyfortus should be given with caution to infants and children with thrombocytopenia, any coagulation disorder or to individuals on anticoagulation therapy.

Most common adverse reactions with Beyfortus were rash (0.9%) and injection site reactions (0.3%).

Please see additional Important Safety Information on the previous page and accompanying full Prescribing Information.

References: 1. Jones JM, Fleming-Dutra KE, Prill MM, et al. Use of nirsevimab for the prevention of respiratory syncytial virus disease among infants and young children: recommendations of the Advisory Committee on Immunization Practices – United States, 2023. *MMWR Morb Mortal Wkly Rep.* 2023;72(34):920-925. **2.** ACIP and AAP recommendations for nirsevimab. American Academy of Pediatrics. August 15, 2023. Accessed October 7, 2023. https://publications.aap.org/redbook/resources/25379/ACIP-and-AAP-Recommendations-for-Nirsevimab **3.** Beyfortus (nirsevimab-alip). Prescribing Information. Sanofi.

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NEW FLUBLOK DATA:
ONE OF THE LARGEST FLU VACCINE STUDIES EVALUATING THE SAFETY PROFILE IN PREGNANT WOMEN[1-3]

SANOFI HIGHER-DOSE FLU VACCINES CAN PROVIDE

THE POWER TO HELP PROTECT BEYOND FLU[1,4-7]

ACIP RECOMMENDED**

Flublok and Fluzone High-Dose are vaccines indicated for active immunization for the prevention of disease caused by influenza A virus subtypes and type B virus contained in (or in the case of Flublok, represented by antigens contained in) the vaccine. Flublok is approved for use in persons 18 years of age and older. Fluzone High-Dose is approved for use in persons 65 years of age and older.

Flublok® Influenza Vaccine | FOR AGES 18+

FLUBLOK IS THE FIRST AND ONLY RECOMBINANT VACCINE PROVEN TO HELP PREVENT INFLUENZA AND DEMONSTRATED TO REDUCE ITS COMPLICATIONS[1,5*]

- Combines recombinant technology with **3x the antigen content of standard-dose flu vaccines**[1,5,9†]
- **Proven to prevent more flu cases than a standard-dose vaccine** in a randomized controlled trial of patients aged 50+[1*]
- **Approved for over 10 years,** studied across 7 flu seasons, and evaluated in the **largest real-world randomized flu effectiveness study to date**[1,5,10-12]
- **An established safety profile** comparable to that of a standard-dose vaccine in adults aged 50-64[5‡]
- Outcomes from **one of the largest safety studies of a flu vaccine in pregnant women** evaluated the safety profile of Flublok[1-3]

*In a clinical study of approximately 9000 people conducted during the 2014-2015 flu season, Flublok Quadrivalent (influenza vaccine) was proven 30% more effective at preventing the flu in people aged 50+ vs Fluarix Quadrivalent (standard-dose vaccine). The efficacy of Flublok (quadrivalent) is relevant to Flublok (trivalent) because both vaccines are manufactured using the same process and have overlapping compositions.[1]

†Flublok contains 45 micrograms (mcg) of hemagglutinin (HA) per strain compared with 15 mcg of HA per strain in a standard-dose flu vaccine.[1,5,8]

‡The safety experience of Flublok (quadrivalent formulation) is relevant to Flublok (trivalent formulation) because both vaccines are manufactured using the same process and have overlapping compositions.[1]

Fluzone® High-Dose Influenza Vaccine | FOR AGES 65+

FLUZONE HIGH-DOSE IS THE FIRST AND ONLY FLU VACCINE TO DELIVER SUPERIOR FLU PROTECTION VS STANDARD DOSE[4,13§]

- **Contains 4x the antigen** and reduced laboratory-confirmed flu cases by 24% vs a standard-dose flu vaccine[3,13§¶]
- **The ONLY ACIP-recommended vaccine for patients 65+** to prove superiority in a randomized controlled trial versus a standard-dose vaccine[4,8,13§]
- **The #1-administered flu vaccine** for people aged 65+[11‖]
- **More than a decade of real-world evidence** in preventing flu and its complications and a **safety profile comparable to standard-dose vaccines** in people aged 65+[4,7,14#]

ACIP=Advisory Committee on Immunization Practices; CI=confidence interval.

§In a clinical study conducted in 2011-2012 and 2012-2013 in approximately 32,000 adults aged 65+, the trivalent formulation of Fluzone High-Dose was proven 24% more effective at preventing the flu than standard-dose Fluzone (influenza vaccine). The prespecified statistical superiority criterion for the primary endpoint (lower limit of 2-sided 95% CI of the vaccine efficacy of Fluzone High-Dose relative to Fluzone >9.1%) was met.[4,13]

¶Fluzone High-Dose contains 60 micrograms (mcg) of hemagglutinin (HA) per strain vs 15 mcg of HA per strain in a standard-dose influenza vaccine.[13]

‖Internal calculations by Sanofi based on IQVIA database of total flu vaccines administered from 7/23 to 4/24 in people aged 65+. Not inclusive of all Federal payors. Study details and information maintained by Sanofi.[11]

#Analysis included studies conducted over 12 influenza seasons (2009-2010 to 2019-2020, and 2021-2022).[7]

**Flublok and Fluzone High-Dose are among the flu vaccines preferentially recommended by the CDC over standard-dose flu vaccines for people 65+. If none of the preferentially recommended vaccines are available, then any other age-appropriate influenza vaccine should be used.[8]

YOU CAN HELP PROTECT YOUR ELIGIBLE PATIENTS BEYOND FLU

IMPORTANT SAFETY INFORMATION FOR FLUBLOK (INFLUENZA VACCINE) AND FLUZONE HIGH-DOSE (INFLUENZA VACCINE)

Do not administer Flublok or Fluzone High-Dose to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine (including egg protein for Fluzone High-Dose). Fluzone High-Dose should not be administered to anyone who has had a severe allergic reaction after previous dose of any influenza vaccine.

Please see additional Important Safety Information on next page. Please see the full Prescribing Information for Flublok and Fluzone High-Dose.

INDICATIONS

Flublok and Fluzone High-Dose are vaccines indicated for active immunization for the prevention of disease caused by influenza A virus subtypes and type B virus contained in (or in the case of Flublok, represented by antigens contained in) the vaccine. Flublok is approved for use in persons 18 years of age and older. Fluzone High-Dose is approved for use in persons 65 years of age and older.

IMPORTANT SAFETY INFORMATION FOR FLUBLOK (INFLUENZA VACCINE) AND FLUZONE HIGH-DOSE (INFLUENZA VACCINE)

Do not administer Flublok or Fluzone High-Dose to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine (including egg protein for Fluzone High-Dose). Fluzone High-Dose should not be administered to anyone who has had a severe allergic reaction after previous dose of any influenza vaccine.

Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of the vaccine.

If Guillain-Barré syndrome has occurred within 6 weeks following previous influenza vaccination, the decision to give Flublok or Fluzone High-Dose should be based on careful consideration of the potential benefits and risks.

If Flublok or Fluzone High-Dose are administered to immunocompromised persons, including those receiving immunosuppressive therapy, the expected immune response may not be attained.

Vaccination with Flublok or Fluzone High-Dose may not protect all recipients.

Syncope (fainting) has been reported following vaccination with Flublok and Fluzone High-Dose. Procedures should be in place to avoid injury from fainting.

For Flublok, in adults 18 through 64 years of age, the most common injection site adverse reaction was pain; the most common solicited systemic adverse reactions were headache, fatigue, and myalgia. In adults 65 years of age and older, the most common injection-site adverse reaction was pain; the most common solicited systemic adverse reactions were fatigue and headache.

For Fluzone High-Dose, in adults 65 years of age and older, the most common injection-site reaction was pain; the most common solicited systemic adverse reactions were myalgia, malaise, and headache. For Flublok and Fluzone High-Dose, other adverse reactions may occur.

Please see the full Prescribing Information for Flublok and Fluzone High-Dose.

References: 1. Flublok. Prescribing Information. Protein Sciences Corporation. **2.** Fluarix. Prescribing Information. GlaxoSmithKline. **3.** Flucelvax. Prescribing Information. Seqirus Inc. **4.** Fluzone High-Dose. Prescribing Information. Sanofi Pasteur Inc. **5.** Dunkle LM, Izikson R, Patriarca P, et al; PSC12 Study Team. Efficacy of recombinant influenza vaccine in adults 50 years of age or older. *N Engl J Med.* 2017;376(25):2427-2436. doi:10.1056/NEJMoa1608862 **6.** Zimmerman RK, Nowalk MP, Dauer K, et al. Vaccine effectiveness of recombinant and standard dose influenza vaccines against influenza-related hospitalization using a retrospective test-negative design. *Vaccine.* 2023;41:5134-5140. doi:10.1016/j.vaccine.2023.06.056 **7.** Lee JKH, Lam GKL, Yin JK, Loiacono MM, Samson SI. High-dose influenza vaccine in older adults by age and seasonal characteristics: systematic review and meta-analysis update. *Vaccine X.* 2023;14:100327. doi:10.1016/j.jvacx.2023.100327 **8.** Grohskopf LA, Ferdinands JM, Blanton LH, et al. Prevention and control of seasonal influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices - United States, 2024-25 influenza season. *MMWR Recomm Rep.* 2024;73(5):1-25. doi:10.15585/mmwr.rr7305a1 **9.** Arunachalam AB, Post P, Rudin D. Unique features of a recombinant haemagglutinin influenza vaccine that influence vaccine performance. *NPJ Vaccines.* 2021;6:144. doi:10.1038/s41541-021-00403-7 **10.** Hsiao A, Yee A, Fireman B, Hansen J, Lewis N, Klein NP. Recombinant or standard dose influenza vaccine in adults under 65 years of age. *N Engl J Med.* 2023;389:2245-2255. doi:10.1056/NEJMoa2302099 **11.** Sanofi Pasteur Inc. Data on file. **12.** Cox MM, Izikson R, Post P, Dunkle L. Safety, efficacy, and immunogenicity of Flublok in the prevention of seasonal influenza in adults. *Ther Adv Vaccines.* 2015;3(4):97-108. doi:10.1177/2051013615595595 **13.** DiazGranados CA, Dunning AJ, Kimmel M, et al. Efficacy of high-dose versus standard-dose influenza vaccine in older adults. *N Engl J Med.* 2014;371(7):635-645. doi:10.1056/NEJMoa1315727 **14.** Falsey AR, Treanor JJ, Tornieporth N, Capellan J, Gorse GJ. Randomized, double-blind controlled phase 3 trial comparing the immunogenicity of high-dose and standard-dose influenza vaccine in adults 65 years of age and older. *J Infect Dis.* 2009;200(2):172-180. doi:10.1086/599790

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Flublok® Influenza Vaccine | Fluzone® High-Dose Influenza Vaccine

Is your baby ready for RSV season?

What is RSV?

Respiratory Syncytial Virus (RSV) is a highly contagious virus that can lead to respiratory infection in babies.

- It is most common during the **winter virus season**, although this can vary by local area.
- RSV **spreads easily** through actions such as kissing or by snuggling with a favorite toy.
- Most of the time, RSV will cause a **mild, cold-like illness.** However, the **infection may spread to the lungs** and symptoms can worsen. It can also cause severe illness such as **bronchiolitis** or **pneumonia.**
- RSV is **unpredictable;** it's hard to know if a baby will have a mild or serious infection—**even if they're born healthy and at full term**.
- Although severe RSV is rare, RSV is the **leading cause of hospitalizations in babies under 1.**

What is Beyfortus?

Beyfortus is recommended for newborns and babies born during or entering their first RSV season.

- Beyfortus provides **fast-acting protection** against serious lung infection caused by RSV, which may require medical care. Medical care can include trips to the **doctor, urgent care, ER, or hospital.** Beyfortus may not protect all children.
- Beyfortus is a **preventative antibody – not a vaccine**. Preventative antibodies act like bodyguards while your baby's immune system develops.
- The **most common side effects** of Beyfortus include rash and pain, swelling, or hardness at the site of your baby's injection.

Indication: Beyfortus is a prescription medicine used to help prevent a serious lung disease caused by Respiratory Syncytial Virus (RSV) in:

- Newborns and babies under 1 year of age born during or entering their first RSV season.
- Children up to 24 months of age who remain at risk of severe RSV disease through their second RSV season.

Ask the doctor about Beyfortus. Before RSV season.

IMPORTANT SAFETY INFORMATION

Your child should not take Beyfortus if your child has a history of serious allergic reactions to nirsevimab-alip or any of the ingredients in Beyfortus.

Please see full Important Safety Information on the back, and the accompanying full Prescribing Information, including the Patient Information.

Beyfortus® (nirsevimab-alip) 50 mg 100 mg Injection

IMPORTANT SAFETY INFORMATION

Your child should not take Beyfortus if your child has a history of serious allergic reactions to nirsevimab-alip or any of the ingredients in Beyfortus.

Before your child receives Beyfortus, tell your healthcare provider about all of your child's medical conditions, including if your child:

- has ever had a reaction to Beyfortus.
- has bleeding or bruising problems. If your child has a problem with bleeding or bruises easily, an injection could cause a problem.

Tell your healthcare provider about all the medicines your child takes, including prescription and over-the counter medicines, vitamins, and herbal supplements. Your infant should not receive a medicine called palivizumab if they have already received Beyfortus in the same RSV season.

Serious allergic reactions have happened with Beyfortus.
Get medical help right away if your child has any of the following signs or symptoms of a serious allergic reaction:

- swelling of the face, mouth, or tongue
- difficulty swallowing or breathing
- unresponsiveness
- bluish color of skin, lips, or under fingernails
- muscle weakness
- severe rash, hives, or itching

The most common side effects of Beyfortus include rash and pain, swelling, or hardness at the site of your child's injection. These are not all the possible side effects of Beyfortus. Call your healthcare provider if you have questions about side effects.

Please see accompanying full Prescribing Information, including the Patient Information.

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LEARN MORE AT WWW.BEYFORTUS.COM

MAT-US-2406195-v1.0-07/2024

Beyfortus® (nirsevimab-alip) 50 mg 100 mg Injection

Tu bebé está listo para la temporada de VRS?

¿Qué es el VRS?

El virus respiratorio sincitial (VRS) es un virus altamente contagioso que puede provocar infecciones respiratorias en los bebés.

- Es más común durante la **temporada de virus de invierno** aunque esto puede variar según el área local.
- El VRS **se propaga fácilmente** a través de acciones como los besos o abrazarse a un juguete favorito.
- La mayoría de las veces, el VRS causará una **enfermedad leve similar a un resfriado**. Sin embargo, la **infección puede extenderse a los pulmones y los** síntomas pueden empeorar. También puede causar enfermedades graves como **bronquiolitis o neumonía**.
- El VRS es **impredecible;** es difícil saber si un bebé tendrá una infección leve o grave, **incluso si nace sano y a término**.
- Aunque el VRS grave no es común, el VRS es la **causa principal de hospitalización en bebés menores de 1 año**.

¿Qué es Beyfortus?

Se recomienda Beyfortus para los recién nacidos y los bebés nacidos durante o a inicios de su primera temporada del VRS.

- Beyfortus ofrece **una protección de acción rápida** contra la infección pulmonar grave causada por el VRS, que puede requerir atención médica. La atención médica puede incluir visitas al **médico, a un centro de atención de urgencia, a la sala de emergencias o al hospital.** Es posible que Beyfortus no proteja a todos los niños.
- Beyfortus es un **anticuerpo preventivo, no una vacuna**. Los anticuerpos preventivos actúan como guardaespaldas mientras se desarrolla el sistema inmunitario de tu bebé.
- Los **efectos secundarios más comunes** de Beyfortus incluyen erupción cutánea y dolor, hinchazón o endurecimiento en el lugar de la inyección del bebé.

Indicación: Beyfortus es un medicamento recetado que se usa para ayudar a prevenir una enfermedad pulmonar grave causada por el virus respiratorio sincitial (VRS) en:

- Recién nacidos y bebés menores de 1 año nacidos durante o a inicios de su primera temporada del VRS.
- Niños de hasta 24 meses que siguen teniendo riesgo de sufrir una enfermedad grave por el VRS durante su segunda temporada del VRS.

Pregúntale al médico acerca de Beyfortus antes de la temporada del VRS.

INFORMACIÓN DE SEGURIDAD IMPORTANTE

Tu hijo/a no debe recibir Beyfortus si tiene un historial de reacciones alérgicas graves a nirsevimab-alip o a cualquiera de los ingredientes de Beyfortus.

Consulta la información de seguridad importante completa en el reverso y la información de prescripción completa adjunta, incluida la información para el paciente.

Beyfortus® (nirsevimab-alip) 50 mg 100 mg Inyección

INFORMACIÓN DE SEGURIDAD IMPORTANTE

Tu hijo/a no debe recibir Beyfortus si tiene un historial de reacciones alérgicas graves a nirsevimab-alip o a cualquiera de los ingredientes de Beyfortus.

Antes de que tu hijo/a reciba Beyfortus, infórmale a tu proveedor de atención médica sobre todas las afecciones médicas de tu hijo/a, incluso si ha presentado lo siguiente:

- si alguna vez ha tenido una reacción a Beyfortus.
- si tiene problemas de hemorragia o hematomas. Si tu hijo/a tiene un problema de hemorragia o sufre hematomas fácilmente, la inyección puede provocar problemas.

Infórmale a tu proveedor de atención médica sobre todos los medicamentos que toma tu hijo/a, incluidos los medicamentos de venta libre y de venta con receta, las vitaminas y los suplementos a base de hierbas. Tu hijo/a lactante no debe recibir el medicamento llamado palivizumab si ya recibió Beyfortus en la misma temporada del VRS.

Se han producido reacciones alérgicas graves con Beyfortus.
Busca ayuda médica de inmediato si tu hijo/a tiene cualquiera de los siguientes signos o síntomas de reacción alérgica grave:

- hinchazón de la cara, la boca o la lengua
- dificultades para tragar o respirar
- sin capacidad de respuesta
- piel, labios o parte interior de las uñas de color azul
- debilidad muscular
- erupciones cutáneas, urticaria o prurito graves

Los efectos secundarios más comunes de Beyfortus son erupciones cutáneas y dolor, hinchazón o endurecimiento del punto de inyección de tu hijo/a. Estos no son todos los posibles efectos secundarios de Beyfortus. Llama a tu proveedor de atención médica si tienes preguntas sobre los efectos secundarios.

Consulta la información de prescripción completa, incluida la información del paciente que se adjunta.

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MÁS INFORMACIÓN EN WWW.BEYFORTUS.COM

MAT-US-2407035-v2.0-09/2024

Beyfortus® (nirsevimab-alip) 50 mg 100 mg Inyección

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RSV Health Systems Toolkit

Approved as of January 3, 2025

RSV, respiratory syncytial virus.

Beyfortus® (nirsevimab-alip) 50 mg and 100 mg Injection Indication and Important Safety Information

INDICATION

Beyfortus is indicated for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in:

- Neonates and infants born during or entering their first RSV season.
- Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

IMPORTANT SAFETY INFORMATION

Contraindication

Beyfortus is contraindicated in infants and children with a history of serious hypersensitivity reactions, including anaphylaxis, to nirsevimab-alip or to any of the excipients.

Warnings and Precautions

- **Hypersensitivity Reactions Including Anaphylaxis:** Serious hypersensitivity reactions have been reported following Beyfortus administration. These reactions included urticaria, dyspnea, cyanosis, and/or hypotonia. Anaphylaxis has been observed with human immunoglobu lin G1 (lgG1) monoclonal antibodies. If signs and symptoms of anaphylaxis or other clinically significant hypersensitivity reactions occur, initiate appropriate treatment.
- **Use in Individuals with Clinically Significant Bleeding Disorders:** As with other IM injections, Beyfortus should be given with caution to infants and children with thrombocytopenia, any coagulation disorder or to individuals on anticoagulation therapy.

Most common adverse reactions with Beyfortus were rash (0.9%) and injection site reactions (0.3%).

Please see full Prescribing Information for more details.

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Table of Contents

Background

This document was created specifically to provide a comprehensive overview of the materials and are intended to provide education about Beyfortus® (nirsevimab-alip) 50 mg and 100 mg Injection.

Using these materials can help to standardize care across sites of care and help protect all eligible infants from the risks of RSV disease.

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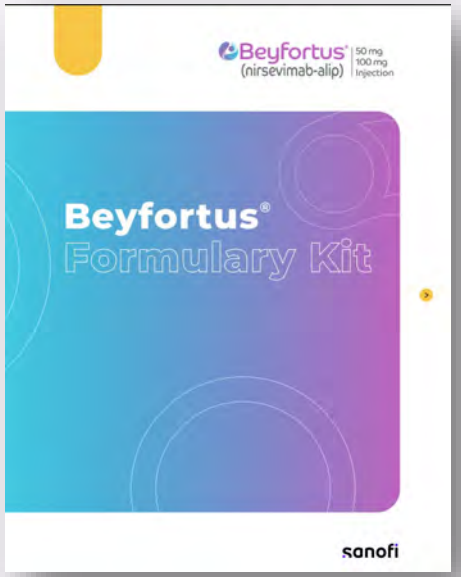
Provider & Care Team Education

Provider & Care Team Education — Implementation

- Formulary Kit
- Implementation Starter Kit
- Shelf Talkers
- Implementation Office Poster
- Quick Reference Guides
- Implementation FAQ Guide
- RSV Prevalence Flashcard
- Health Systems Implementation Roadmap

Provider & Care Team Education — Implementation



Formulary Kit

A kit to support P&T formulary decision-making, including a Product Monograph, Coding and Billing Guide, and ACIP Recommendations

MAT-US-2306484-v6.0-09/2024

Implementation Starter Kit

A starter kit to understand the basics on operationalizing implementation of Beyfortus® (nirsevimab-alip) 50 and 100 mg Injection (eg, recommendations, dosing regimen, storage/handling, available resources)

Digital: MAT-US-2308727-v3.0-09/2024
Print: MAT-US-2306999-v3.0-09/2024

Shelf Talkers

Two printed Shelf Talkers that can be placed where Beyfortus is being stored to provide quick identification of dosage options. The Shelf Talkers should be placed at eye level

MAT-US-2306998-v3.0-09/2024

Implementation Office Poster

A poster that displays the Beyfortus weight-based doses for quick reference. The poster should be hung at eye level at the hospital or clinic

MAT-US-2307000-v3.0-09/2024

The Implementation Kit is available digitally. Printed practice materials are available for order. Please contact a local rep to order materials, such as Shelf Talkers and dosing poster.

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ACIP, Advisory Committee on Immunization Practices.

Please see Important Safety Information on slide 2 and full Prescribing Information.

Provider & Care Team Education — Implementation

ACIP Quick Reference Guide

A guide to help understand ACIP recommendations for Beyfortus® (nirsevimab-alip) 50 and 100 mg Injection

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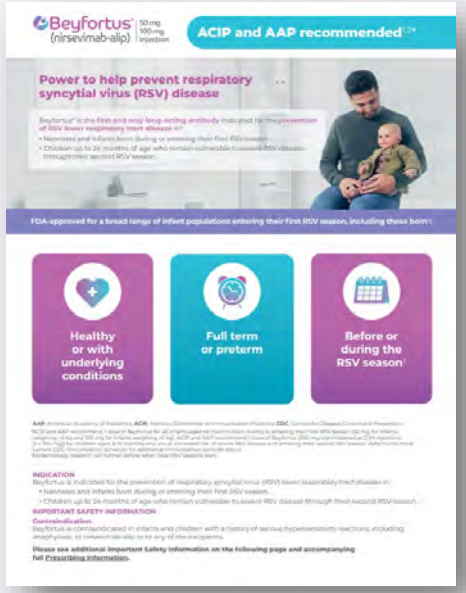
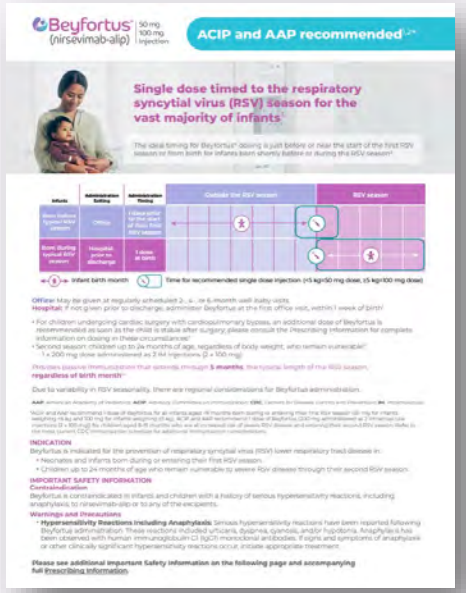


Efficacy & Safety Quick Reference Guide

A guide to help understand Beyfortus efficacy and safety clinical trial results

MAT-US-2307613-v3.0-09/2024



Implementation Quick Reference Guide

A guide to help understand when to administer Beyfortus for infants born outside of RSV season and those born during RSV season

MAT-US-2307611-v3.0-09/2024

Supply & Practical Considerations Quick Reference Guide

A guide to help understand the Beyfortus product specs and dosages

MAT-US-2307612-v3.0-09/2024

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Please see Important Safety Information on slide 2 and full Prescribing Information.

Provider & Care Team Education — Implementation

Implementation FAQ Guide

A guide of FAQs to use during Beyfortus® (nirsevimab-alip) 50 and 100 mg Injection implementation, collected based on real-world experience during the first full season with Beyfortus. The content is organized by types of relevant questions

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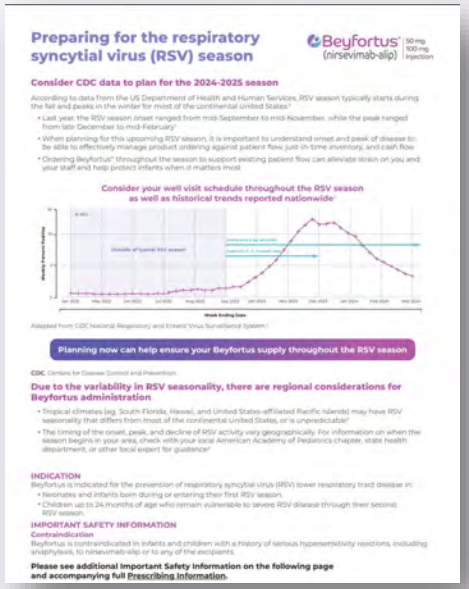

RSV Prevalence Flashcard

A flashcard outlining RSV seasonality patterns in the US and the importance of administration timing in advance of and throughout the RSV season

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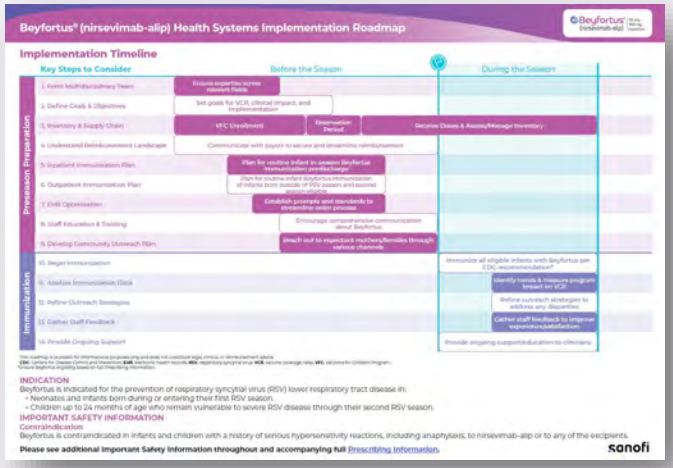


Health System Implementation Road Map

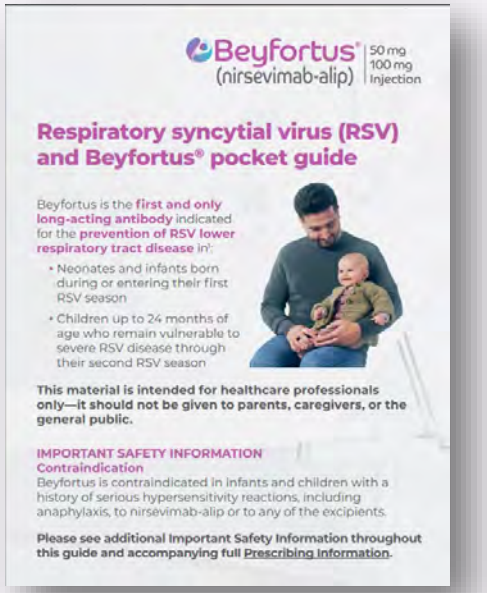
A digital PDF to understand the steps to implementing Beyfortus across all sites of care (ie, hospital or clinic)

MAT-US-2405989-v2.0-07/2024

Provider & Care Team Education — How to Help Counsel Patients

- Staff Pocket Guide

Provider & Care Team Education — How to Help Counsel Patients



Staff Pocket Guide

A pocket guide for you and your staff to reference for key FAQs about Beyfortus® (nirsevimab-alip) 50 and 100 mg Injection. This can serve as a refresher prior to counseling patients

MAT-US-2406722-v2.0-09/2024

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Please see Important Safety Information on slide 2 and full Prescribing Information.

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Parent Engagement

Parent Engagement — Beyfortus® (nirsevimab-alip) 50 mg and 100 mg Injection Education

- Parent Educational Brochure (English & Spanish)
- Beyfortus Flip Chart (English & Spanish)
- Parent One-Pager (English & Spanish)

Parent Engagement — Beyfortus® (nirsevimab-alip) 50 mg and 100 mg Injection Education

Parent Educational Brochure - English

A print and digital educational piece to provide to parents during their visit to become more informed about Beyfortus® (nirsevimab-alip) 50 and 100 mg Injection

Digital: MAT-US-2303307-v2.0-03/2024
Print: MAT-US-2310579-v3.0-09/2024

Parent Educational Brochure - Spanish

A print and digital educational piece to provide to Spanish-speaking parents during their visit to become more informed about Beyfortus

Digital: MAT-US-2310663-v2.0-03/2024
Print: MAT-US-2310660-v2.0-09/2024

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Please see Important Safety Information on slide 2 and full English and Spanish Prescribing Information.

Parent Engagement — Beyfortus® (nirsevimab-alip) 50 mg and 100 mg Injection Education

Beyfortus Flip Chart - English

A printed flip chart to help guide parents on Beyfortus® (nirsevimab-alip) 50 and 100 mg Injection

MAT-US-2307329-v2.0-03/2024

Beyfortus Flip Chart - Spanish

A printed flip chart to help guide Spanish-speaking parents on Beyfortus

Printed materials are available for order. Please contact a local rep to order materials.

MAT-US-2409426-v1.0-10/2024

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Please see Important Safety Information on slide 2 and full English and Spanish Prescribing Information.

Parent Engagement — Beyfortus® (nirsevimab-alip) 50 mg and 100 mg Injection Education

Parent One-Pager - English

A take-home one-pager for parents and caregivers to reference for education on RSV and Beyfortus® (nirsevimab-alip) 50 and 100 mg Injection

MAT-US-2406195-v1.0-07/2024

Parent One-Pager - Spanish

A take-home one-pager for Spanish-speaking parents and caregivers to reference for education on RSV and Beyfortus

MAT-US-2407035-v2.0-09/2024

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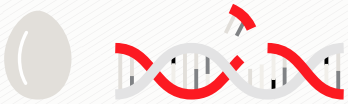
Please see Important Safety Information on slide 2 and full English and Spanish Prescribing Information.

MAT-US-2412151-v2.0-01/2025


Seqirus

HOW A FLU VACCINE IS MADE **MATTERS**

EGG ADAPTATION



When human flu viruses mutate to grow in eggs during traditional flu vaccine production, which may cause strain mismatch[1,2]

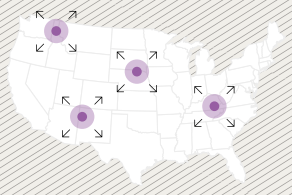
STRAIN MISMATCH

When the vaccine strains do not match the circulating flu strains[1-3]

▶ For more information, visit: thinkoutsidetheshell.com

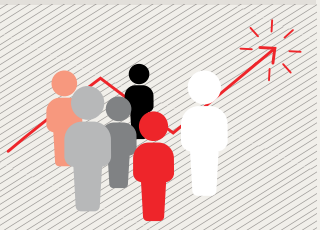
U.S. GOVERNMENT HAS OUTLINED ITS 4 POLICY OBJECTIVES TO MODERNIZE INFLUENZA VACCINES[4]

01 **Reduce** U.S. reliance on egg-based production



02 **Expand** domestic capacity of alternative methods that allow for more agile and rapid responses to emerging influenza viruses

03 **Advance** the development of new, broadly protective vaccine candidates that provide more effective and longer lasting immunity



04 **Support** the promotion of increased influenza immunization across recommended populations

VALUE OF CELL-BASED TECHNOLOGY

FOR SEASONAL FLU

- Produced in mammalian cells to **avoid egg adaptation**[1,5,6]
- Provides an **exact antigenic match** to the WHO-selected flu strains[1,5,6]
- May have the potential to **increase vaccine effectiveness**[1,5,6]

FOR U.S. PANDEMIC FLU PREPAREDNESS

- **Not dependent on an egg supply.** Might be easier to scale up if egg supply is limited[5]
- Might permit **faster** start-up of the vaccine manufacturing process[5]
- Established manufacturing process in the **U.S.A**

CSL Seqirus

A GLOBAL VACCINE LEADER DEVELOPING VACCINES FOR >100 YEARS

Committed to Innovation and Pandemic Preparedness

CSL SEQIRUS MANUFACTURES THE FIRST AND ONLY CELL CULTURE-BASED INFLUENZA VACCINE IN THE U.S.

Waltham, MA, U.S.
R&D facility supporting CSL's growing portfolio, including seasonal and pandemic influenza vaccines

INVESTING
$800M+

Tullamarine, Melbourne, Aus.
New state-of the art manufacturing facility, on track to be operational in 2026, using innovative technology to produce seasonal and pandemic cell-based influenza vaccines

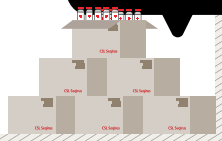
Holly Springs, NC, U.S.
Largest cell-based influenza vaccine manufacturing facility in the world, built through a public-private partnership established in 2009 with Biomedical Advanced Research and Development Authority (BARDA). ▶ Holly Springs video

CSL SEQIRUS IS POSITIONED TO DELIVER CELL CULTURE-BASED PANDEMIC INFLUENZA VACCINES TO THE U.S. GOVERNMENT IN THE EVENT OF A PANDEMIC

- Recognized by the U.S. Government as having a **pandemic ready designation**
- Multi-year agreement with BARDA for flu **pandemic preparedness**

- Highly scalable method of production, positioned to deliver **150M vaccine doses** within **six months** of a pandemic declaration
- Dedicated **team of experts** with deep and broad knowledge of influenza pandemic preparedness and response

150M DOSES
IN SIX MONTHS



▶ For additional information on seasonal flu vaccines, contact your local CSL Seqirus representative or visit flu360.com

▶ For additional information on pandemic response, visit Pandemic Response | CSL

References:
1. Rajaram S, et al. Ther Adv Vaccines Immunother. 2020;8:2515135520908121.
2. Paules CI, et al. N Engl J Med. 2018;378(1):7-9.
3. Zost SJ, et al. Proc Natl Acad Sci USA. 2017;114(47):12578-12583.
4. National Influenza Vaccine Modernization Strategy (NIVMS) 2020-2030.
5. CDC. Cell-based flu vaccines. Accessed Aug 19, 2024. https://www.cdc.gov/flu/prevent/cell-based.htm.
6. Rockman S, et al. Vaccines (Basel). 2022;11(1):52.

Seqirus USA Inc., 25 Deforest Avenue, Summit, NJ 07901, USA

CSL Seqirus

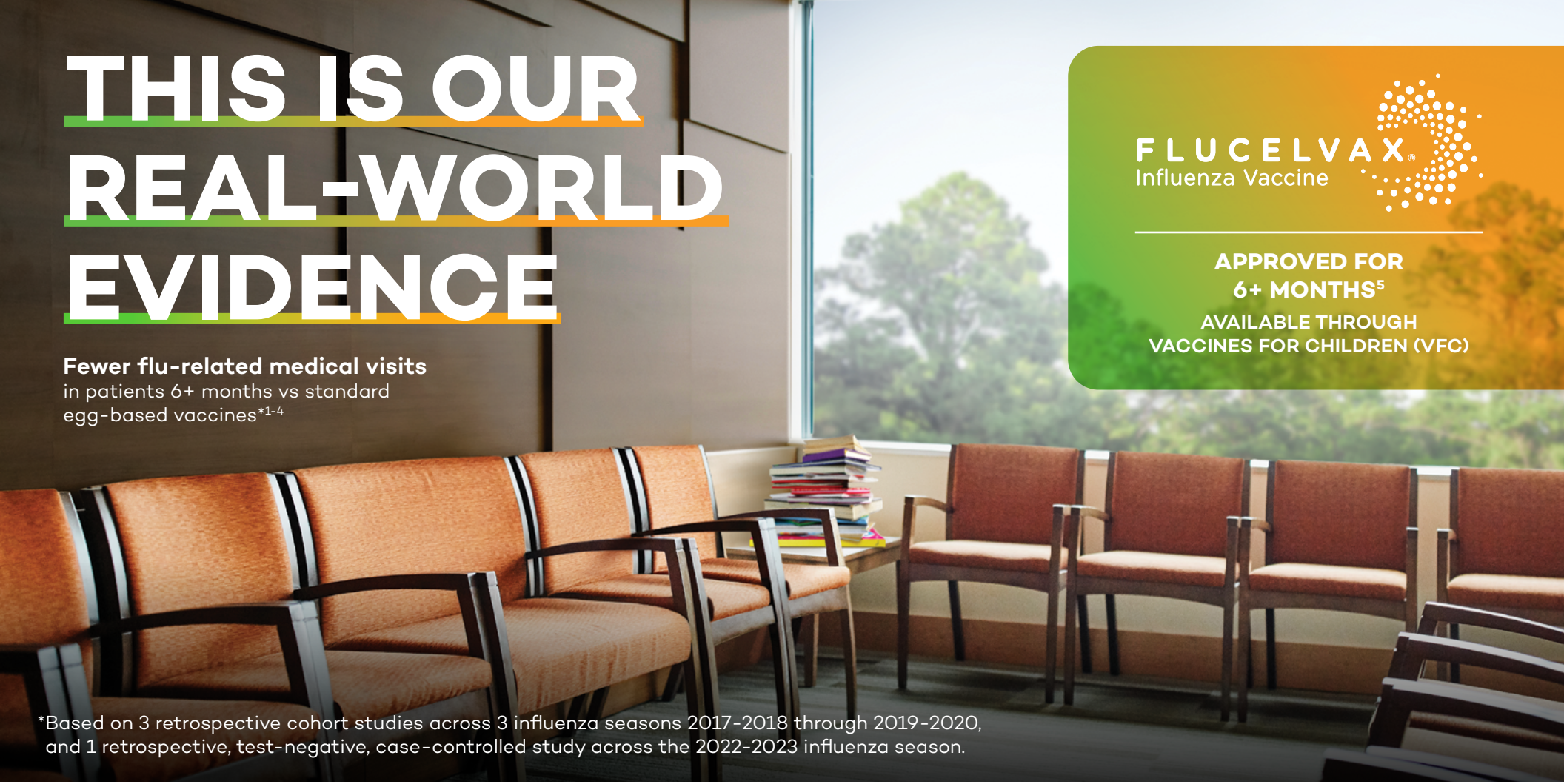
THIS IS OUR REAL-WORLD EVIDENCE

Fewer flu-related medical visits
in patients 6+ months vs standard egg-based vaccines*[1-4]

FLUCELVAX® Influenza Vaccine

APPROVED FOR 6+ MONTHS[5]

AVAILABLE THROUGH VACCINES FOR CHILDREN (VFC)



*Based on 3 retrospective cohort studies across 3 influenza seasons 2017-2018 through 2019-2020, and 1 retrospective, test-negative, case-controlled study across the 2022-2023 influenza season.

FLUCELVAX® (Influenza Vaccine) INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE

FLUCELVAX is an inactivated vaccine indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUCELVAX is approved for use in persons 6 months of age and older.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Do not administer FLUCELVAX to anyone with a history of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.

Please see Important Safety Information throughout and full US Prescribing Information for FLUCELVAX.

For US Healthcare Professional Use Only

CSL Seqirus

FLUCELVAX®
Influenza Vaccine

THE INFLUENZA VACCINE BUILT FOR

REAL-WORLD PROTECTION

RWE offers a complementary approach to clinical trials to assess seasonal influenza vaccine effectiveness

CLINICAL TRIAL DATA

- FLUCELVAX demonstrated efficacy in children 2 through 17 years and adults 18 through 49 years[5]
- FLUCELVAX showed non-inferior immunogenicity and seroconversion vs an egg-based vaccine in children 6 months through 3 years and adults 18 years and older[5]

The data of FLUCELVAX (quadrivalent) are relevant to FLUCELVAX (trivalent) because both vaccines are manufactured using the same process and have overlapping compositions.

FLUCELVAX is the only flu vaccine made with advanced technology to demonstrate a safety profile similar to standard egg-based flu vaccines in both children and adults.[5]

WARNINGS AND PRECAUTIONS

If Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior influenza vaccine, the decision to give FLUCELVAX should be based on careful consideration of the potential benefits and risks.

Please see Important Safety Information throughout and full US Prescribing Information for FLUCELVAX.

ROBUST REAL-WORLD EVIDENCE

FLUCELVAX demonstrated greater reductions in flu and hospitalizations from flu complications vs standard egg-based vaccines in both children and adults*[1-4]

CLOSER MATCH TO CIRCULATING STRAINS

Cell-grown viruses were shown to be consistently more similar to circulating strains than standard egg-grown viruses†[6,7]

THE ONLY CELL-BASED FLU VACCINE

FLUCELVAX is the only flu vaccine approved for patients 6+ months that is made with advanced technology to avoid mutations during production that can reduce vaccine effectiveness[5,7-9]

*Based on 3 retrospective cohort studies across 3 influenza seasons 2017-2018 through 2019-2020, and 1 retrospective, test-negative, case-controlled study across the 2022-2023 influenza season.

†Based on CDC antigenic characterization of the percentage of circulating A/H3N2 flu viruses that were similar to egg- or cell-grown reference viruses across the 2012-2013 through 2019-2020 US influenza seasons.

See the full body of real-world evidence at FLUCELVAX.com

FLUCELVAX® (Influenza Vaccine)
INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE

FLUCELVAX is an inactivated vaccine indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUCELVAX is approved for use in persons 6 months of age and older.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Do not administer FLUCELVAX to anyone with a history of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.

WARNINGS AND PRECAUTIONS

If Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior influenza vaccine, the decision to give FLUCELVAX should be based on careful consideration of the potential benefits and risks.

Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of FLUCELVAX.

Syncope (fainting) has been reported following vaccination with FLUCELVAX. Procedures should be in place to avoid injury from fainting.

After vaccination with FLUCELVAX, immunocompromised individuals, including those receiving immunosuppressive therapy, may have a reduced immune response.

Vaccination with FLUCELVAX may not protect all vaccine recipients against influenza disease.

ADVERSE REACTIONS

Data for FLUCELVAX QUADRIVALENT are relevant to FLUCELVAX because both vaccines are manufactured using the same process and have overlapping compositions.

In children 6 months through 3 years of age who received FLUCELVAX QUADRIVALENT, the most commonly reported injection-site adverse reactions were tenderness (28%), erythema (26%), induration (17%) and ecchymosis (11%). The most common systemic adverse reactions were irritability (28%), sleepiness (27%), diarrhea (18%) and change of eating habits (17%).

In children 4 through 8 years of age who received FLUCELVAX, the most commonly reported local injection-site adverse reactions were pain (29%) and erythema (11%). The most common systemic adverse reaction was fatigue (10%).

In children and adolescents 9 through 17 years of age who received FLUCELVAX, the most commonly reported injection-site adverse reactions were pain (34%) and erythema (14%). The most common systemic adverse reactions were myalgia (15%) and headache (14%).

In adults 18 through 64 years of age who received FLUCELVAX, the most commonly reported injection-site adverse reactions were pain (28%) and erythema (13%). The most common systemic adverse reactions were headache (16%), fatigue (12%), myalgia (11%) and malaise (10%).

In adults ≥65 years who received FLUCELVAX the most commonly reported injection-site reaction was erythema (10%). The most common systemic adverse reactions were fatigue (11%), headache (10%) and malaise (10%).

Other adverse events may occur.

To report SUSPECTED ADVERSE REACTIONS, contact CSL Seqirus at 1-855-358-8966 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

Before administration, please see the full US Prescribing Information for FLUCELVAX.

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FLUCELVAX®
Influenza Vaccine

APPROVED FOR 6+ MONTHS[5]

RECOMMENDED BY ACIP AND AAP[10,11]

Backed by the most real-world evidence (RWE) in both children and adults showing a clinical benefit over standard egg-based influenza vaccines*[12]

*Based on a PubMed search conducted 3/17/25 for published English-language RWE studies that included relative vaccine effectiveness vs a standard flu vaccine comparator.

FLUCELVAX.COM

Contact your CSL Seqirus representative to learn more about the influenza vaccine built for the real world.

DIFFERENT VACCINE. DIFFERENT CPT CODE. DIFFERENT REIMBURSEMENT.[13]

CPT CODE
90661 - SINGLE-DOSE SYRINGE

Order FLUCELVAX through CSL Seqirus or your preferred distributor.

Available through Vaccines for Children (VFC).

CONTRAINDICATIONS

Do not administer FLUCELVAX to anyone with a history of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.

Please see Important Safety Information throughout and full US Prescribing Information for FLUCELVAX.

For US Healthcare Professional Use Only

Seqirus USA Inc., 25 Deforest Avenue, Summit, NJ 07901, USA

GIVE ADULTS 65 YEARS AND OLDER

INDICATION AND USAGE

FLUAD is a vaccine indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUAD is approved for use in adults 65 years of age and older.

This indication is approved under accelerated approval based on the immune response elicited by FLUAD. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

CSL Seqirus

FLUAD®
influenza vaccine, adjuvanted

THE ADJUVANT ADVANTAGE*[1]

*Preferentially recommended by ACIP for adults 65+ over non-adjuvanted, standard-dose influenza vaccines.

ACIP=Advisory Committee on Immunization Practices

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Do not administer FLUAD to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, including egg protein, or to a previous influenza vaccine.

Please see Important Safety Information throughout and accompanying full US Prescribing Information for FLUAD.

PREFERENTIALLY RECOMMENDED BY ACIP FOR ADULTS 65+[1]

GIVE ADULTS 65 YEARS AND OLDER

INDICATION AND USAGE

FLUAD is a vaccine indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUAD is approved for use in adults 65 years of age and older.

This indication is approved under accelerated approval based on the immune response elicited by FLUAD. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

FLUAD®

(Influenza Vaccine, Adjuvanted)

DESIGNED TO ADDRESS 2 KEY CHALLENGES

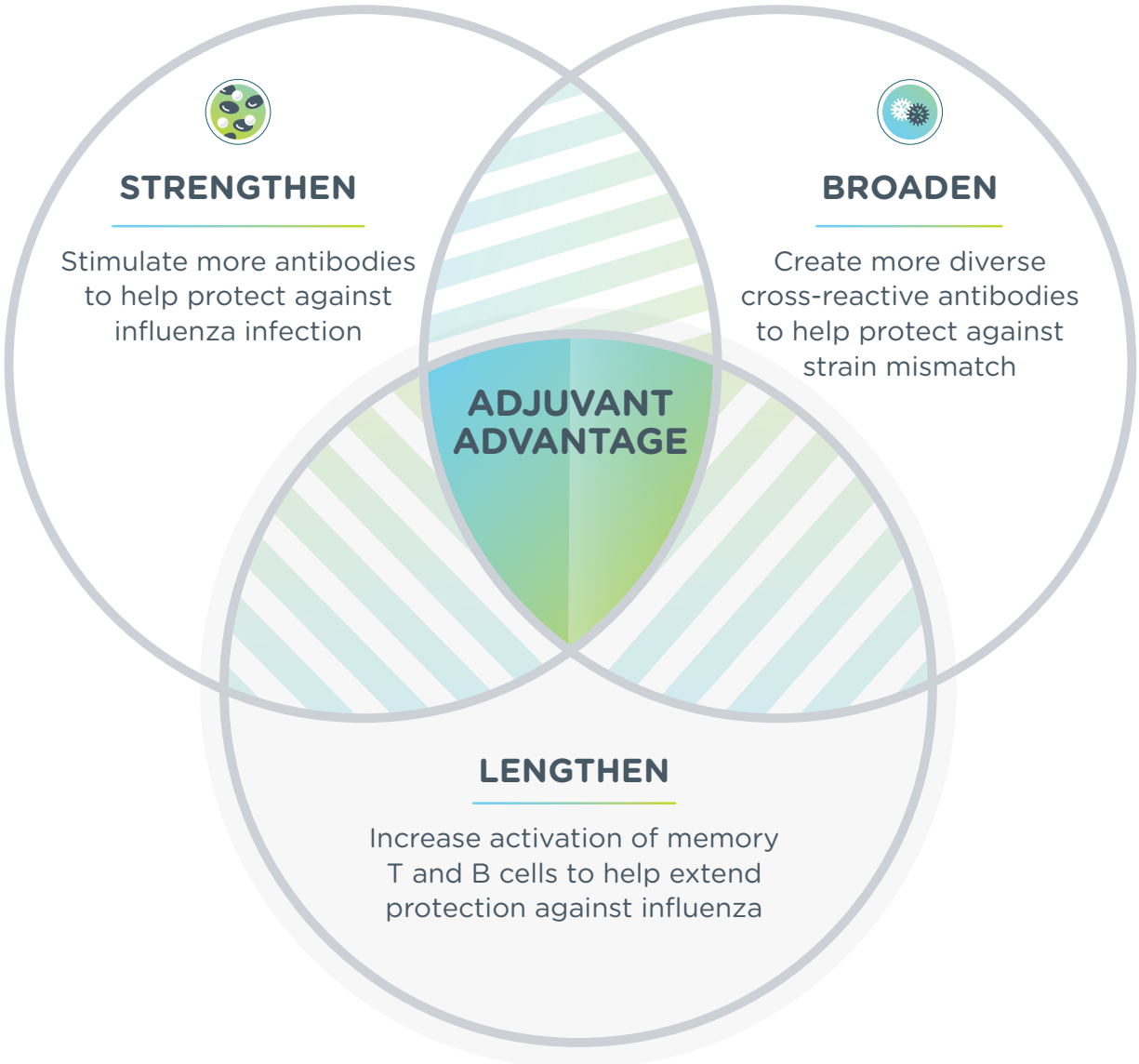
WEAKENED IMMUNE SYSTEM

Vaccine effectiveness may be reduced in adults 65+ as a result of **a weakened immune response** to vaccines[2,3]

STRAIN MISMATCH

Strain mismatch, which occurred in 7 out of 10 flu seasons from 2010-2011 through 2019-2020, **may further reduce vaccine effectiveness**[4-14]

ADJUVANTED TO BOOST THE IMMUNE RESPONSE BEYOND STANDARD-DOSE FLU VACCINES[15-18]



WARNINGS AND PRECAUTIONS

If Guillain-Barré Syndrome (GBS) has occurred within six weeks of previous influenza vaccination, the decision to give FLUAD should be based on careful consideration of the potential benefits and risks.

See how adding MF59® Adjuvant does more than antigen alone.[15-18]

KEEP IN MIND

ACIP Recommended

ACIP preferentially recommended over standard-dose influenza vaccines for adults 65+.[1]

Adjuvant Technology

Adding an adjuvant strengthens, broadens, and lengthens the immune response more than antigen alone.[16-18]

Robust Response

FLUAD produced a robust immune response against all vaccine strains in clinical trials and has a demonstrated safety profile.[14,16-19]

Clinically Effective

20+ years of real-world evidence (RWE) in over 59 million patients supports the clinical effectiveness of the only adjuvanted flu vaccine for adults 65+.[15,20-32]

FLUAD®
influenza vaccine, adjuvanted

THE ADJUVANT ADVANTAGE*[1]

*Preferentially recommended by ACIP for adults 65+ over non-adjuvanted, standard-dose influenza vaccines.

ACIP=Advisory Committee on Immunization Practices

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Do not administer FLUAD to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, including egg protein, or to a previous influenza vaccine.

Please see Important Safety Information throughout and accompanying full US Prescribing Information for FLUAD.

FLUAD® (Influenza Vaccine, Adjuvanted)

INDICATION AND IMPORTANT SAFETY INFORMATION

FLUAD influenza vaccine, adjuvanted

INDICATION AND USAGE

FLUAD is a vaccine indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUAD is approved for use in adults 65 years of age and older.

This indication is approved under accelerated approval based on the immune response elicited by FLUAD. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Do not administer FLUAD to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, including egg protein, or to a previous influenza vaccine.

WARNINGS AND PRECAUTIONS

If Guillain-Barré Syndrome (GBS) has occurred within six weeks of previous influenza vaccination, the decision to give FLUAD should be based on careful consideration of the potential benefits and risks.

Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of FLUAD.

Syncope (fainting) may occur in association with administration of injectable vaccines including FLUAD. Procedures should be in place to avoid injury from fainting.

The immune response to FLUAD in immunocompromised persons, including individuals receiving immunosuppressive therapy, may be lower than in immunocompetent individuals.

Vaccination with FLUAD may not protect all vaccine recipients against influenza disease.

ADVERSE REACTIONS

The most common (≥10%) local and systemic adverse reactions in adults 65 years of age and older who received FLUAD were injection site pain (25%), injection site tenderness (21%), myalgia (15%), fatigue (13%) and headache (13%).

Other adverse events may occur.

To report SUSPECTED ADVERSE REACTIONS, contact CSL Seqirus at 1-855-358-8966 or VAERS at 1-800-822-7967 and www.vaers.hhs.gov.

Before administration, please see the full US Prescribing Information for FLUAD.

References: 1. Grohskopf LA, et al. *MMWR Recomm Rep*. 2023;72(2):1-25. **2.** CDC. Flu & people 65 years and older. Accessed March 5, 2024. https://www.cdc.gov/flu/highrisk/65over.htm **3.** Monto AS, et al. *Vaccine*. 2009;27(37):5043-5053. **4.** Skowronski DM, et al. *PLoS One*. 2014;9(3):e92153. **5.** CDC. *MMWR Morb Mortal Wkly Rep*. 2011;60(21):705-712. **6.** Ohmit SE, et al. *Clin Infect Dis*. 2014;58(3):319-327. **7.** McLean HQ, et al. *J Infect Dis*. 2015;211(10):1529-1540. **8.** Gaglani M, et al. *J Infect Dis*. 2016;213(10):1546-1556. **9.** Zimmerman RK, et al. *Clin Infect Dis*. 2016;63(12):1564-1573. **10.** Jackson ML, et al. *N Engl J Med*. 2017;377(6):534-543. **11.** Rolfes MA, et al. *Clin Infect Dis*. 2019;69(11):1845-1853. **12.** Flannery B, et al. *J Infect Dis*. 2020;221(1):8-15. **13.** Tenforde MW, et al. *Clin Infect Dis*. 2021;73(11):e4244-e4250. **14.** Zost SJ, et al. *Proc Natl Acad Sci USA*. 2017;114(47):12578-12583. **15.** FLUAD. Package insert. Seqirus Inc. **16.** O'Hagan DT, et al. *Vaccine*. 2012;30(29):4341-4348. **17.** O'Hagan DT, et al. *Expert Rev Vaccines*. 2013;12(1):13-30. **18.** Banzhoff A, et al. *Influenza Other Respir Viruses*. 2008;2(6):243-249. **19.** Paules CI, et al. *N Engl J Med*. 2018;378(1):7-9. **20.** Izurieta HS, et al. *Clin Infect Dis*. 2021;73(11):e4251-e4259. **21.** Izurieta HS, et al. *J Infect Dis*. 2020;222:278-287. **22.** Boikos C, et al. *Clin Infect Dis*. 2021;73(5):816-823. **23.** Izurieta HS, et al. *J Infect Dis*. 2019;220:1255-1264. **24.** Pelton SI, et al. *Vaccines (Basel)*. 2020;8(3):E446. **25.** McConeghy KW, et al. *Clin Infect Dis*. 2021;73(11):e4237-e4243. **26.** Cocchio S, et al. *Vaccines*. 2020;8(3):344. **27.** Van Buynder PG, et al. *Vaccine*. 2013;31(51):6122-6128. **28.** Mannino S, et al. *Am J Epidemiol*. 2012;176(6):527-533. **29.** Lapi F, et al. *Expert Rev Vaccines*. 2019;18(6):663-670. **30.** Pelton SI, et al. *Vaccine*. 2021;39(17):2396-2407. **31.** van Aalst R, et al. *Vaccine*. 2020;38(2):372-379. **32.** Data on file. Seqirus Inc; 2023.

CPT CODE 90653:
0.5-mL pre-filled syringe
10 syringes per carton

Skyler Beasley
Vaccine Sales Specialist
CSL Seqirus

Contact your CSL Seqirus representative for more details or order FLUAD on flu360.com.

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