Leading the Way in Respiratory Health

Moderna 2025–2026 Respiratory Vaccine Portfolio

mNEXSPIKE®
COVID-19 Vaccine, mRNA

spikevax®
COVID-19 Vaccine, mRNA

mRESVIA®
(Respiratory Syncytial Virus Vaccine)

Available **exclusively** as **ready-to-use pre-filled syringes** for the 2025–2026 season.

Moderna vaccines are ready to use once thawed to room temperature.[1–3]

mNEXSPIKE® INDICATION

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 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.

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.

SPIKEVAX® INDICATION

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.

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.

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.

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.

Please see continued IMPORTANT SAFETY INFORMATION throughout, and scan or click the QR codes on page 3 for mNEXSPIKE Full Prescribing Information, SPIKEVAX Full Prescribing Information, and mRESVIA Full Prescribing Information.

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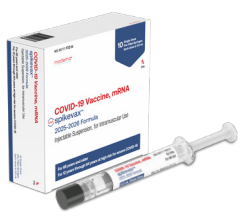
	STORAGE AND HANDLING[1–3]	BILLING CODES[1–3,9–11]
mNEXSPIKE® COVID-19 Vaccine, mRNA **A new and different COVID-19 vaccine[1]** 	**Frozen Storage:** -40 °F to 5 °F (-40 °C to -15 °C) **Thawing From Frozen:** • **Refrigeration:** 36 °F to 46 °F (2 °C to 8 °C) • **Room Temperature:** 59 °F to 77 °F (15 °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:** 334 **MVX:** MOD **CPT®*:** • 91323 • 90480 **ICD-10-CM:** Z23
spikevax® COVID-19 Vaccine, mRNA **First and only FDA-approved COVID-19 vaccine for high-risk individuals as young as 6 months of age[1,2,4–6‡]**  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) **The only ready-to-use RSV vaccine in a pre-filled syringe[3,7,8]** 	**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

*CPT is a registered trademark of the American Medical Association (AMA). †Children and adolescents with ≥1 underlying condition are at high risk for severe COVID-19 outcomes. Select underlying conditions include medical complexity, genetic, neurologic, and metabolic conditions, congenital heart disease, obesity, diabetes, asthma or chronic lung disease, sickle cell disease, and immunocompromised status.[2] Risk for severe COVID-19 outcomes in adults increases with age and presence of ≥1 underlying conditions. Select underlying conditions include cancer, cerebrovascular disease, chronic kidney disease, chronic liver diseases, chronic lung diseases, diabetes type 1 and 2, heart conditions, and overweight or obesity.[2] ‡Moderna COVID-19 Vaccine was previously available for pediatric populations under Emergency Use Authorization (EUA).

mNEXSPIKE IMPORTANT SAFETY INFORMATION (CONT.)

Warnings and Precautions (cont.)

- **Syncope (fainting):** May occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

SPIKEVAX IMPORTANT SAFETY INFORMATION (CONT.)

Warnings and Precautions (cont.)

- **Syncope (fainting):** May occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

mRESVIA IMPORTANT SAFETY INFORMATION (CONT.)

Warnings and Precautions (cont.)

- **Altered Immunocompetence:** Immunocompromised individuals, including those receiving immunosuppressive therapy, may have a diminished immune response to mRESVIA.

Please see continued IMPORTANT SAFETY INFORMATION throughout, and scan or click the QR codes on page 3 for mNEXSPIKE Full Prescribing Information, SPIKEVAX Full Prescribing Information, and mRESVIA Full Prescribing Information.

Explore Available Resources

Scan or click the QR codes for additional product and reimbursement information

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mNEXSPIKE IMPORTANT SAFETY INFORMATION (CONT.)

Warnings and Precautions (cont.)

- **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 (cont.)

- **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.)

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.

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

COVID-19, coronavirus disease 2019; CPT, Current Procedural Terminology; CVX, vaccine administered; FDA, US Food and Drug Administration; ICD-10-CM, International Classification of Disease, Tenth Revision, Clinical Modification; 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 20, 2025. https://www.cdc.gov/covid/risk-factors/index.html **5.** COMIRNATY Prescribing Information. Pfizer Inc; 2025. **6.** NUVAXOVID Prescribing Information. Novavax Inc; 2025. **7.** AREXVY Prescribing Information. GlaxoSmithKline Biologics; 2025. **8.** ABRYSVO Prescribing Information. Pfizer Inc; 2025. **9.** CDC. Accessed August 4, 2025. https://www.cdc.gov/iis/code-sets/fall-season-respiratory-codes.html **10.** CMS. Accessed August 4, 2025. https://www.cms.gov/medicare/payment/covid-19/coding-covid-19-vaccine-shots **11.** 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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