mNEXSPIKE®
COVID-19 Vaccine, mRNA

Product and Reimbursement Information

mNEXSPIKE (2025–2026 Formula) is available exclusively as a pre-filled syringe[1]

Shipped Frozen	Frozen Storage (Stock)*	Thawing From Frozen	Storage After Thawing†	Preparing for Use
	Store frozen at **-40 °F to 5 °F (-40 °C to -15 °C)**	**Refrigeration Thaw Duration**: 36 °F to 46 °F (2 °C to 8 °C) • **Single syringe (removed from carton):** 1 hour and 40 minutes • **Carton of 10 syringes:** 2 hours and 40 minutes OR **Room Temperature Thaw Duration**: 59 °F to 77 °F (15 °C to 25 °C) • **Single syringe (removed from carton):** 40 minutes • **Carton of 10 syringes:** 1 hour and 20 minutes	**Refrigeration**: 36 °F to 46 °F (2 °C to 8 °C) *Beyond use date: Must not exceed 90 days or up to the carton expiration date, whichever comes first* OR **Room Temperature**: 46 °F to 77 °F (8 °C to 25 °C) *Beyond use date: Must not exceed 24 hours*	• With tip cap upright, remove tip cap by twisting counterclockwise until tip cap releases. Remove tip cap in a slow, steady motion. Avoid pulling tip cap while twisting • Attach the needle by twisting in a clockwise direction until the needle fits securely on the syringe • Immunizer should select a needle of appropriate size and gauge for intramuscular injection • Discard after single use

Transportation of Thawed Syringes at 36 °F to 46 °F (2 °C to 8 °C): Thawed pre-filled syringes can be transported at 36 °F to 46 °F (2 °C to 8 °C) in shipping containers qualified to maintain 36 °F to 46 °F (2 °C to 8 °C). Once thawed and transported at 36 °F to 46 °F (2 °C to 8 °C), pre-filled syringes should not be refrozen and should be stored at 36 °F to 46 °F (2 °C to 8 °C) until use, for up to 90 days or carton expiration date, whichever comes first.[1]

*During storage and after thawing, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.[1]
†After thawing, do not refreeze. Do not shake. Thawed syringes can be handled in room light conditions.[1]

Dosing and administration[1]

For intramuscular injection only.

Indication	Dose and Schedule
Individuals ≥65 years of age	**0.2 mL, single dose** If previously vaccinated, administer ≥3 months after the last dose of COVID-19 vaccine
Individuals 12–64 years of age with ≥1 underlying condition that puts them at high risk for severe outcomes from COVID-19	**0.2 mL, single dose** If previously vaccinated, administer ≥3 months after the last dose of COVID-19 vaccine

Product identification and diagnosis codes

Type	Code		Description
NDC[1]	80777-400-60 (10-digit)	80777-0400-60 (11-digit)	Paperboard tray carton of 10 single-dose pre-filled syringes
	80777-400-17 (10-digit)	80777-0400-17 (11-digit)	Single-dose pre-filled syringe
ICD-10-CM[2]	Z23		Encounter for immunization

COVID-19, coronavirus disease 2019; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; mRNA, messenger RNA; NDC, National Drug Code.

References: 1. mNEXSPIKE Prescribing Information. Moderna; 2025. **2.** ICD10Data.com. 2024 ICD-10-CM diagnosis code Z23. Accessed July 29, 2025. https://www.icd10data.com/ICD10CM/Codes/Z00-Z99/Z20-Z29/Z23-/Z23

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

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

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