COVID-19 VACCINE, MRNA (MODERNA) (2025-2026)

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On January 5, 2026, the US Department of Health and Human Services (HHS) announced the approval of a revised US childhood and adolescent immunization schedule ([Web]). Under the revised recommendations, CDC continues to organize the childhood immunization schedule in three distinct categories (Immunizations Recommended for All Children, Immunizations Recommended for Certain High-Risk Groups or Populations, and Immunizations Based on Shared Clinical Decision-Making) but changes individual vaccine placement within those categories. For additional information, see [Web] .

Introduction

COVID-19 vaccine, mRNA (Moderna) is a nucleoside-modified mRNA vaccine used to stimulate active immunity to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).[1,3]

Uses

■ Prevention of Coronavirus Disease 2019 (COVID-19)

COVID-19 vaccine, mRNA (Moderna) is used for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2.[1,3] There are 2 preparations of COVID-19 vaccine, mRNA (Moderna) currently available in the US (Spikevax® and mNexspike®).[1,3] Spikevax® (2025-2026 Formula) is FDA-labeled for use in individuals ≥65 years of age, or in individuals 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, and mNexspike® (2025-2026 Formula) is FDA-labeled for use in individuals ≥65 years of age, or in individuals 12–64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.[1,3,4] Underlying conditions for which there is evidence indicating a higher risk of experiencing severe outcomes of COVID-19 include asthma, cancer, cerebrovascular disease, chronic kidney disease, certain chronic lung diseases, certain chronic liver diseases, cystic fibrosis, diabetes mellitus, disabilities, heart conditions, HIV, certain mental health conditions, certain neurologic conditions, obesity, physical inactivity, pregnancy or recent pregnancy, primary immunodeficiencies, smoking (current or former), solid organ or blood stem cell transplantation, tuberculosis, and use of corticosteroids (or other immunosuppressive medications).[76]

COVID-19 vaccine, mRNA (Moderna) was previously available under an emergency use authorization (EUA).[2,74] The initial EUA was issued on December 18, 2020 during the COVID-19 pandemic and amended several times as the scope of authorization changed, the most recent of which was issued on August 22, 2024 for use in individuals 6 months through 11 years of age.[74,501] However, on August 27, 2025, FDA revoked the EUA for COVID-19 vaccine, mRNA (Moderna).[74]

The current preparations of COVID-19 vaccine, mRNA (Moderna) have been specifically formulated for the 2025-2026 season and contain nucleoside modified mRNA encoding the viral spike glycoprotein of SARS-CoV-2 Omicron variant sublineage LP.8.1 (a variant of the JN.1 family of Omicron subvariants).[1,3,14] The Spikevax® formulation codes for the entire spike protein of SARS-CoV12, whereas the mNexspike® formulation codes only for the N-terminal domain and the receptor-binding domain of the spike protein; the more targeted vaccine formulation allows for the administration of a smaller mRNA dose.[5] Previous vaccine presentations, including the initial monovalent formulation (Original strain) and subsequent monovalent and bivalent formulations are no longer available for use in the US.[2] FDA approval for the current COVID-19 vaccine, mRNA (Moderna)(2025-2026 Formula) is principally based on data from previous vaccine presentations targeting SARS-Cov-2 variant Omicron lineages BA.4/BA.5 and XBB.1.5.[1,3]

The US Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) has issued recommendations and clinical considerations for the use of COVID-19 vaccines, including dosage and administration, specific populations and situations, and cautionary information.[13] CDC currently recommends COVID-19

vaccination based on a shared decision-making process between the healthcare provider and the patient or parent/guardian.[80,81,82,83,84] The decision to administer a COVID-19 vaccine should be individualized with consideration that the risk-benefit of vaccination is most favorable for individuals who are at increased risk for severe COVID-19 disease and lowest for those who are not at increased risk.[81,83] There are 2 types of COVID-19 vaccines available in the US (mRNA vaccines and a protein subunit vaccine).[13] An age-appropriate COVID-19 vaccine product should be administered for each dose.[81,83] ACIP states that there is no preferential recommendation for the use of any one COVID-19 vaccine over another when more than one recommended and age-appropriate vaccine is available.[13] For additional information, consult the ACIP recommendations at [Web]

The American Academy of Pediatrics (AAP) recommends COVID-19 vaccination in all infants and children 6 through 23 months of age; 1 or 2 doses of any age-appropriate COVID-19 vaccine product (the most updated version) should be administered depending on previous vaccination status.[78,79] In older children and adolescents 2-18 years of age, a single dose of COVID-19 vaccine is recommended in risk groups (e.g., persons at high risk of severe COVID-19, residents of long-term care facilities or other congregate settings, persons who have never been vaccinated against COVID-19, persons whose household contacts are at high risk for severe COVID-19).[78,79] Children 6 months through 18 years of age who are moderately or severely immunocompromised require 2 or more doses of age-appropriate COVID-19 vaccine depending on previous vaccination status.[78,79] AAP states that children 2-18 years of age not included in specified risk groups whose parent or guardian desires their protection from COVID-19 should be offered a single dose of an age-appropriate 2025-2026 COVID-19 vaccine.[78,79]

The American College of Obstetricians and Gynecologists (ACOG) provides recommendations for the use of COVID-19 vaccines in individuals who are pregnant (or may become pregnant) or lactating.[16] ACOG currently recommends that all pregnant and lactating individuals receive the seasonally updated COVID-19 vaccine booster at any time during pregnancy; the available data support the benefits of vaccination in reducing pregnancy complications and reducing neonatal morbidity and mortality.[16] Pregnant individuals have historically been at increased risk of severe disease, adverse pregnancy outcomes, and maternal death from COVID-19 infection.[16] Additionally, vaccination during pregnancy provides passive immunity to infants, protecting them from COVID-19 in the first few months of life before they can be vaccinated.[16] ACOG states that any of the currently authorized COVID-19 vaccines can be administered to pregnant, recently pregnant, or lactating patients.[16]

The Center for Infectious Disease Research and Policy (CIDRAP) has established the Vaccine Integrity Project to provide evidence-based guidance on vaccines.[77] The Vaccine Integrity Project is an initiative dedicated to providing trusted, science-based information for informed vaccine choices.[77] A multi-disciplinary group of experts was convened by the Vaccine Integrity Project to independently review the available data on vaccine efficacy, effectiveness, and safety of COVID-19, influenza, and RSV immunizations for the 2025-2026 respiratory virus season.[77] A systematic review of 511 published studies (mostly observational) was conducted.[18] Results of the evidence review found that COVID-19 mRNA vaccination against the XBB.1.5 subvariant, a previously circulating variant, was associated with pooled vaccine effectiveness against hospitalization of 46-50% in all adults and 37% in immunocompromised adults.[18] Effectiveness varied based on time since vaccination, study population, and vaccine formulation.[18] Decreased vaccine effectiveness of XBB.1.5-adapted vaccines was observed during periods when another subvariant (JN.1) was predominant.[18] Studies combining data from both the mRNA and protein-based vaccines generally reported lower vaccine effectiveness than studies evaluating mRNA vaccines alone.[18] The evidence was generally more limited with the protein subunit COVID-19 vaccine.[18] For additional information, see [Web] .

Clinical Experience

Adults (Spikevax®)

Efficacy, safety, and immunogenicity of COVID-19 vaccine, mRNA (Moderna) (Spikevax®) for the prevention of COVID-19 have been evaluated principally in a multicenter, randomized, double-blind, placebo-controlled, phase 3 clinical trial using the original monovalent form of the vaccine (NCT04470427; mRNA-1273-P301; COVE study).[1,2,7,8,19] The following information provides historic data from the phase 3 study evaluating the Moderna COVID-19 monovalent vaccine.[1,2]

The phase 3 COVE trial enrolled adults ≥18 years of age who were randomized 1:1 to receive 2 IM doses given 28 days apart of the Moderna COVID-19 vaccine (100 mcg for each dose) (original strain monovalent formulation) or normal saline placebo; randomization was stratified by age and risk criteria into 3 groups (18 to <65 years of age without comorbidities [not at risk for progression to severe COVID-19], 18 to <65 years of age with comorbidities [at risk for progression to severe COVID-19], ≥65 years of age with or without comorbidities).[1,2,19] The study allowed for inclusion of participants with stable preexisting medical conditions, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 3 months before enrollment, as well as participants with stable human immunodeficiency virus (HIV) infection; immunocompromised individuals and those with a known history of SARS-CoV-2 infection were excluded.[1,2] Efficacy of the vaccine in preventing laboratory-confirmed, symptomatic COVID-19 with onset at least 14 days after the second dose in participants with negative SARS-CoV-2 status at baseline was evaluated as the primary efficacy end point.[8,19] Final analysis of efficacy and safety data from the blinded portion of the COVE trial included 28,451 per-protocol participants who were followed for a median of 212 days.[6] In the final per-protocol analysis, there were 55 cases of symptomatic COVID-19 among vaccine recipients and 744 cases among placebo recipients, corresponding to a vaccine efficacy of 93.2% starting at least 14 days after the second dose of the primary vaccination series.[1,6]

Additional primary efficacy analyses indicated that vaccine efficacy generally was consistent across subgroups defined by age, sex, race, ethnicity, and risk for severe disease.[6,17,19] Analyses by time interval since completion of the primary vaccination series demonstrated that efficacy of vaccine remained >90% through at least 4 months following the second dose of the primary vaccination series.[6]

Secondary efficacy end points include prevention of severe COVID-19, asymptomatic COVID-19, death due to COVID-19, and COVID-19 occurring at least 14 days after the first dose.[6,17] At the time of FDA's efficacy review for the EUA, there were a total of 30 cases of severe COVID-19 (as defined in the protocol) reported at least 14 days after the second dose (9 required hospitalization, 1 fatality) in the per-protocol participants and these severe cases all occurred in the placebo group, suggesting benefit of the vaccine in preventing severe COVID-19.[17]

Final analysis of data reported a vaccine efficacy in preventing severe disease of 98.2% in the per-protocol population (106 severe cases in the placebo group versus 2 in the vaccine group) starting 14 days after the second dose of the primary vaccination series.[6] For prevention of asymptomatic COVID-19 infection, vaccine efficacy was 63% starting 14 days after the second dose of the primary vaccination series.[6] COVID-19-related deaths occurred in 3 individuals in the placebo group and 1 in the COVID-19 vaccine (Moderna) group; however, the participant in the COVID-19 vaccine (Moderna) group had only received 1 dose of the vaccine.[6]

The effectiveness of booster doses of Moderna COVID-19 vaccine (original monovalent and subsequent bivalent formulations) is based principally on immunogenicity assessments of geometric mean antibody titers and seroresponse rates against previous circulating strains of SARS-CoV-2.[3]

Efficacy and safety of an additional dose of the Moderna COVID-19 vaccine (original strain monovalent formulation) in immunocompromised adults were evaluated in a double-blind, randomized, placebo-controlled trial that included 120 solid organ transplant recipients (NCT04885907).[61] Individuals included in the study were adults who had previously received various solid organ transplants (heart, kidney, kidney-pancreas, liver, lung, pancreas), had a functioning graft, had no history of COVID-19, and previously had received a 2-dose vaccination series of the Moderna COVID-19 vaccine administered at the recommended interval; exclusion criteria included treatment with immune globulin IV (IGIV) in the previous 4 weeks, treatment with rituximab in the previous 6 months, and treatment for acute rejection in the previous 30 days.[61] Patients were randomized 1:1 to receive a third dose of the Moderna COVID-19 vaccine or saline placebo approximately 2 months after the second vaccine dose (60 transplant recipients in each group).[61] At baseline (i.e., prior to the third vaccine dose), immunosuppressive therapy, the degree of immunosuppression, existing levels of anti-SARS-CoV-2 antibodies, and other patient characteristics were similar between groups (median age was 66.6 years, median time from transplantation to the third vaccine dose was 3.16 years); immunosuppressive therapy included prednisone (77%), calcineurin inhibitors (98%), mycophenolate (75%), azathioprine (10%), and sirolimus (9%).[61] The primary outcome was the percentage of patients with anti-SARS-CoV-2 antibodies at 4 weeks indicating a significant immune response (defined as titer of antibody against the spike protein receptor-binding domain [RBD] of 100 units/mL or greater).[61] Results indicated that anti-RBD antibody levels at 4 weeks after the third vaccine dose were 100 units/mL or greater in 55% of those who received a third dose of the Moderna COVID-19 vaccine compared with 17.5% of those who received placebo.[2] The trial had short follow-up and lacked sufficient power to detect differences in clinical outcomes following the third vaccine dose in solid organ transplant recipients.[61]

Adults and Adolescents 12 Years of Age and Older (mNexspike®)

Efficacy, safety, and immunogenicity of the mNexspike® preparation of COVID-19 vaccine, mRNA (Moderna) for the prevention of COVID-19 in adults and adolescents 12 years of age or older were evaluated in a randomized, observer-blind, active-controlled, phase 3 trial (NextCOVE; NCT05815498).[3,4,92]

Participants were stratified into 3 age groups (12 through 17 years, 18 through 64 years, and 65 years of age or older) and then randomized 1:1 to receive Moderna COVID-19 vaccine (mNexspike®) or a comparator vaccine (Moderna COVID-19 vaccine, bivalent [Original and Omicron BA.4/BA.5]).[3] The mNexspike® vaccine administered in the study contained mRNA encoding the membrane-bound, linked N-terminal domain (NTD) and receptor-binding domain (RBD) of the S glycoprotein from SARS-CoV-2 Original and Omicron variant lineages BA.4/BA.5; the comparator vaccine was a previously authorized formulation of COVID-19 vaccine, mRNA that is no longer available for use in the US.[3] The study allowed for inclusion of participants with stable preexisting medical conditions, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 2 months before enrollment, as well as participants with stable HIV infection.[3] A total of 11,366 participants were included in the efficacy population for analysis.[3] All participants except for one in the mNexspike® group previously received at least 1 dose of COVID-19 vaccine prior to study entry with a median interval of 9.8 months since the last dose.[3] Approximately 60% of the trial population in this study had at least one high-risk condition for severe COVID-19.[3] Results of the study demonstrated noninferiority of mNexspike® compared with Moderna COVID-19 vaccine, bivalent against COVID-19 with onset 14 days after study vaccination (relative vaccine efficacy of 9.3%).[3] Immunogenicity end points also showed noninferior antibody responses with the mNexspike® vaccine compared with Moderna COVID-19 vaccine, bivalent.[3]

In a separate observer-blind, active-controlled portion of the NextCOVE study, the immunogenicity of the mNexspike® vaccine was evaluated in 1056 participants 12 years of age or older.[3] A total of 400 COVID-19 vaccine-naïve and 656 COVID-19 vaccine-experienced individuals received mNexspike® (monovalent vaccine formulation encoding the NTD and RBD of the S glycoprotein from SARS-CoV-2 variant Omicron lineage XBB.1.5) in this portion of the study.[3] Descriptive analysis of geometric mean concentrations in COVID-19 vaccine-naïve versus vaccine-experienced participants showed a GMC ratio (vaccine-naïve/vaccine-experienced) of 1.1.[3]

In another phase 3, randomized, observer-blinded, active-controlled study that was conducted in Japan, safety and immunogenicity of the mNexspike® vaccine (monovalent vaccine formulation encoding the NTD and RBD of the S glycoprotein from SARS-CoV-2 variant lineage XBB.1.5) were compared with the Spikevax® mRNA (Moderna) formulation.[3] The study allowed for inclusion of participants with stable

pre-existing medical conditions including those with stable HIV Infection.[3] All participants were vaccine-experienced (had received at least one dose of a COVID-19 vaccine prior to study entry).[3] Participants were randomized 1:1 to receive a single dose of mNexspike® or Spikevax® and followed for 12 months after vaccination.[3] The study demonstrated a noninferior antibody response with mNexspike® compared with Spikevax® based on GMC ratio against Omicron XBB.1.5 and seroresponse rates.[3] A higher antibody response was observed in individuals vaccinated with mNexspike® compared with those receiving the comparator vaccine.[3]

Children ≥6 Months of Age (Spikevax®)

Safety and efficacy of the Moderna COVID-19 vaccine (Spikevax®) for prevention of COVID-19 in children 6 months through 17 years of age are based on data from clinical studies using the original monovalent form of the vaccine, subsequent bivalent boosters, and the 2023-2024 Formula; the following information provides historic data used to support the effectiveness of the current 2025-2026 Spikevax® vaccine formula.[1,2]

One of these trials randomized 3,733 participants 12 through 17 years of age to receive 2 doses of the original monovalent formulation of Moderna COVID-19 vaccine (containing 100 mcg mRNA per dose) or saline placebo[1,2]. Participants with a known history of SARS-CoV-2 infection were excluded from the study.[1,2] SARS-CoV-2 50% neutralizing antibody titers and seroresponse rates 28 days after the second dose were compared between a subset of participants 12–17 years of age from this study and a subset of participants 18–25 years of age who received Moderna COVID-19 vaccine (containing 100 mcg mRNA per dose) in another study.[1,2] Noninferior criteria were met for both geometric mean antibody titers and seroresponse rates.[1,2] Analysis of available descriptive efficacy data from 3,186 participants 12–17 years of age who had a negative baseline SARS-CoV-2 status confirmed that the vaccine was 89.9% effective in preventing COVID-19 (defined as at least one symptom of COVID-19 and a positive SARS-CoV-2 test).[1,2] The median length of follow up for efficacy was 112 days after the second dose.

Another phase 2/3 clinical trial (NCT04796896) evaluated the effectiveness of a 2-dose series of the Moderna COVID-19 vaccine (original strain monovalent formulation) (50 mcg mRNA per dose) in individuals 6 through 11 years of age.[1,2] Participants with a known history of SARS-CoV-2 infection within 2 weeks of study vaccination were excluded.[1,2] The effectiveness of the Moderna COVID-19 vaccine in individuals 6 years through 11 years of age was based on comparison of SARS-CoV-2 50% neutralizing antibody titers and seroresponse rates 28 days after the second dose in a subset of participants 6–11 years of age in this study to a subset of individuals 18–25 years of age who received Moderna COVID 19 vaccine (containing 100 mcg mRNA) in another study.[1,2] Noninferiority criteria were met for both geometric mean antibody titers and seroresponse rates.[1,2]

Safety and effectiveness of the Moderna COVID-19 vaccine (original strain monovalent formulation) for individuals 6 months through 5 years of age were also evaluated in a phase 2/3 clinical trial.[1,2] In this study, 6,712 participants 6 months through 5 years of age were randomized 3:1 to receive 2 doses of Moderna COVID-19 vaccine (25 mcg mRNA per dose) or saline placebo 1 month apart.[1,2] Effectiveness in individuals 6 months through 5 years of age was based on a comparison of immune responses in this age group to adults 18–25 years of age in another clinical study (NCT04470427).[1,2] Noninferiority criteria were met for both geometric mean antibody concentrations and seroresponse rates.[1,2] Analysis of efficacy data from 5,693 participants 6 months through 5 years of age who received 2 doses of Moderna COVID-19 vaccine or placebo and had a negative baseline SARS-CoV-2 status indicated that the vaccine was 46.6% effective in preventing COVID-19 (defined as at least one symptom of COVID-19 and a positive SARS-CoV-2 test) in individuals 2–5 years of age and 43.2% effective in individuals 6–23 months of age.[1,2]

The effectiveness of booster doses of Moderna COVID-19 vaccine (original monovalent and subsequent bivalent formulations) was based principally on immunogenicity assessments of geometric mean antibody titers and seroresponse rates against previous circulating strains of SARS-CoV-2.[1]

An additional open-label clinical trial evaluated the immunogenicity of a single dose of Moderna COVID-19 vaccine (Spikevax® 2023-2024 Formula) in vaccine-naïve children 2 through 4 years of age and a 2-dose series in vaccine-naïve infants 6 through 23 months of age.[1] The primary immunogenicity analysis which compared GMC following the single dose to after the 2-dose primary series showed noninferiority against Omicron XBB.1.5.[1] However, the seroresponse rate difference between the 2 age groups did not meet the noninferiority criterion.[1]

Dosage and Administration

■ General

Pretreatment Screening

- Screen all individuals for contraindications and precautions prior to vaccination.

Patient Monitoring

- *Monitor all individuals who receive a COVID-19 vaccine for immediate adverse reactions according to CDC (ACIP) guidelines.*[1] ACIP states that vaccination providers should consider observing the following individuals for 30 minutes after receiving the vaccine: those with a history of a non-severe, immediate (onset less than 4 hours) allergic reaction to a previous dose of COVID-19 vaccine, and those with a history of a diagnosed non-severe allergy to a component of the COVID-19 vaccine.[13] Vaccination providers should consider observing all other individuals for 15 minutes after vaccination.[13]

Premedication and Prophylaxis

- Antipyretics or analgesics (e.g., acetaminophen, nonsteroidal anti-inflammatory agents) may be taken for the treatment of postvaccination local or systemic symptoms, if medically appropriate.[13] However, these medications should not be used prophylactically for the purposes of prevention of post-vaccination symptoms.[13]

Dispensing and Administration Precautions

- Appropriate medications and supplies for managing immediate allergic reactions *must* be immediately available in the event that an acute anaphylactic reaction occurs following administration of COVID-19 vaccines.[1,13]

- Syncope may occur following administration of parenteral vaccines, especially in adolescents.[13,20] Patients should be seated or lying down during vaccination.[13] Vaccination providers should consider observing vaccine recipients (especially adolescents) for 15 minutes after vaccination.[13] If syncope develops, patients should be observed until symptoms resolve.[13]

■ Administration

IM Administration

Administer by IM injection only.[1,3]

There are 2 preparations of the Moderna COVID-19 vaccine 2025-2026 Formula (Spikevax® and mNexspike®), each commercially available as prefilled single-dose syringes.[1,3] The specific dose contained in each prefilled syringe differs between the preparations.[1,3]

COVID-19 vaccine (Moderna) must be shipped, stored, and handled under specific conditions at all times, including maintaining cold chain conditions and chain of custody, according to specifications in the EUA fact sheet for healthcare providers and guidance from the manufacturer and CDC.[1] Improper storage or handling of vaccines may reduce or destroy vaccine potency resulting in inadequate or no immune response in vaccinees.[20] Vaccine that has been mishandled or has not been stored at the recommended temperatures should not be administered. The prescribing information should be consulted for additional information on storage, handling, and stability of the vaccine.[1,3]

> #### Spikevax©
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> *The Spikevax® vaccine (2025-2026 Formula) is supplied in 0.25 mL prefilled syringes for use in individuals 6 months through 11 years of age and in 0.5 mL prefilled syringes for individuals ≥12 years of age.*[1] *The vaccine is supplied as a frozen suspension that must be thawed prior to administration.*[1] *See manufacturer's prescribing information for specific instructions for thawing.*[1]
>
> *The thawed vaccine should appear as a white to off-white suspension and may contain white or translucent product-related particles; the vaccine should not be used if it is discolored or contains other particles.*[1] *Vaccine that has been thawed must not be refrozen.*[1]
>
> *Prior to administration, vaccine providers should verify that the 2025-2026 Formula is being used.*[1]

> #### mNexspike®
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> *The mNexspike® vaccine (2025-2026 Formula) is supplied in 0.2 mL prefilled syringes for use in individuals ≥12 years of age.*[3] *The vaccine is supplied as a frozen suspension that must be thawed prior to administration.*[3] *See manufacturer's prescribing information for specific instructions for thawing.*[3]
>
> *The thawed vaccine should appear as a white to off-white suspension and may contain white or translucent product-related particles; the vaccine should not be used if it is discolored or contains other particles.*[3] *Vaccine that has been thawed must not be refrozen.*[3]
>
> *Prior to administration, vaccine providers should verify that the 2025-2026 Formula is being used.*[3]

■ Dosage

Prevention of COVID-19

> #### Spikevax®

In individuals 6 months through 11 years of age, a single dose of Moderna COVID-19 vaccine, mRNA (Spikevax® 2025-2026 Formula) for active immunization to prevent COVID-19 is 0.25 mL.[1] In individuals 12 years of age or older, a single dose of Moderna COVID-19 vaccine, mRNA (Spikevax® 2025-2026 Formula) for active immunization to prevent COVID-19 is 0.5 mL.[1]

In individuals 6 through 23 months of age, the recommended vaccine schedule is determined by the number of previous doses of Moderna COVID-19 vaccine received.[1] In such individuals who have never received any Moderna COVID-19 vaccine, administer 2 doses (0.25 mL each) of Moderna COVID-19 vaccine, mRNA (Spikevax® 2025-2026 Formula) 1 month apart.[1] Individuals turning from 23 months to 2 years of age during the vaccination series should receive both doses with Spikevax®.[1] In individuals 6 months through 23 months of age who received 1 previous dose of Moderna COVID-19 vaccine, administer a single 0.25 mL dose of Moderna COVID-19 vaccine, mRNA (Spikevax® 2025-2026 Formula) 1 month after receipt of a previous dose of any Moderna COVID-19 vaccine.[1] In individuals 6 months through 23 months of age who received 2 or more previous doses of Moderna COVID-19 vaccine, administer a single 0.25 mL dose of Moderna COVID-19 vaccine, mRNA (Spikevax® 2025-2026 Formula) at least 2 months after receipt of the last previous dose of any Moderna COVID-19 vaccine.[1]

In individuals 2–11 years of age, a single 0.25 mL dose of Moderna COVID-19 vaccine, mRNA (Spikevax® 2025-2026 Formula) is recommended irrespective of COVID-19 vaccination status. If previously vaccinated with any COVID-19 vaccine, administer the dose at least 2 months after the last dose of COVID-19 vaccine.[1]

In individuals 12 years of age or older, a single 0.5 mL dose of Moderna COVID-19 vaccine, mRNA (Spikevax® 2025-2026 Formula) is recommended irrespective of COVID-19 vaccination status.[1] If previously vaccinated with any COVID-19 vaccine, administer the dose at least 2 months after the last dose of COVID-19 vaccine.[1]

mNexspike®

For active immunization to prevent COVID-19 in individuals 12 years of age or older, a single 0.2 mL dose of Moderna COVID-19 vaccine, mRNA (mNexspike® 2025-2026 Formula) should be administered.[3] If previously vaccinated with any COVID-19 vaccine, administer the dose at least 3 months after the last dose of COVID-19 vaccine.[3]

Cautions

Contraindications

- Individuals with known history of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or individuals who had a severe allergic reaction (e.g., anaphylaxis) following a previous dose of a Moderna COVID-19 vaccine.[1,3]

Warnings/Precautions

Hypersensitivity Reactions

At the time that FDA's safety and efficacy analysis of data from the randomized, double-blind, placebo-controlled, phase 3 trial evaluating COVID-19 vaccine (Moderna) was performed for the EUA, hypersensitivity reactions had been reported in 1.5% of vaccine recipients and 1.1% of placebo recipients, but there were no reports of anaphylactic or severe hypersensitivity reactions with close temporal relation to the vaccine.[1,17] Hypersensitivity events reported in the vaccine group that were likely related to vaccination included injection site rash and injection site urticaria.[1,2] The trial excluded participants with known or suspected history of allergic reaction to components of the Moderna COVID-19 vaccine, but did not exclude participants with other allergies.[17]

Although immediate allergic reactions were not reported in the original clinical trials evaluating the Moderna COVID-19 vaccine, severe allergic reactions, including anaphylaxis, have been reported rarely following administration of mRNA COVID-19 vaccines during postmarketing experience.[13,17,23,26,29,37,40]

Following issuance of the original FDA EUA for the Moderna COVID-19 vaccine, safety monitoring data identified 10 cases of anaphylaxis among 4,041,396 individuals in the US who received the first dose of the vaccine (2.5 cases per million vaccine doses administered); this included 9 cases in individuals with a documented history of allergies or allergic reactions to drugs, contrast media, or food (5 with a history of anaphylaxis).[29] The median interval from receipt of the vaccine dose to onset of symptoms was 7.5 minutes (range: 1–45 minutes); 9 of the 10 individuals had onset within 15 minutes and one had onset after 30 minutes.[29] All 10 individuals were treated with epinephrine.[29] No fatalities from anaphylaxis were reported; 4 individuals were treated in an emergency department and the other 6 were hospitalized (including 5 in an intensive care unit).[29]

From December 21, 2020 to January 10, 2021, safety monitoring data for individuals who received the first dose of the Moderna COVID-19 vaccine identified 43 cases of nonanaphylactic allergic reactions; 26 of these cases (60%) were classified as nonserious.[29] Commonly reported symptoms included pruritus, rash, itchy sensations in the mouth and throat, sensations of throat closure, and respiratory symptoms.[29] The median interval from receipt of the vaccine dose to onset of symptoms was 15 minutes (range: <1 minute to 24 hours); in 30 cases (73%), onset of symptoms occurred within 30 minutes.[29]

Delayed-onset local reactions (e.g., erythema, induration, pruritus, tenderness) around the injection site area have been reported in some vaccine recipients, including some clinical trial participants, after the first dose of an mRNA COVID-19 vaccine, including the Moderna COVID-19 vaccine.[1,11,13,19,38] These local reactions may begin from a few days through the second week after the first dose and may be quite large.[13,38] In some reported cases, such delayed-onset local reactions after the first vaccine dose resolved in a

median of 6 days (range: 2–11 days), and some individuals had similar (but less severe) local reactions after the second dose of the vaccine.[38] ACIP states that a delayed-onset local reaction after the first dose of an mRNA COVID-19 vaccine is *not* a contraindication or precaution to administration of a second dose.[13]

ACIP considers a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine a contraindication to vaccination with the mRNA COVID-19 vaccines.[13] Consideration can be given to using an alternative COVID-19 vaccine type in such individuals provided certain measures are taken.[13] Consultation with an allergist-immunologist is encouraged.[13]

ACIP states to consider monitoring the following individuals for 30 minutes after vaccination: those with a history of a non-severe, immediate (onset less than 4 hours) allergic reaction to a previous dose of COVID-19 vaccine, and those with a history of a diagnosed non-severe allergy to a component of the COVID-19 vaccine; in all other individuals, providers should consider observing the vaccine recipient for 15 minutes after vaccination.[13,22] In addition, vaccine recipients should be instructed to seek immediate medical care if they develop signs or symptoms of an allergic reaction after their observation period ends and they have left the vaccination site.[23]

Appropriate medications (including age-appropriate epinephrine) and supplies to assess and manage immediate allergic reactions *must* be immediately available in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 vaccine.[1,22,23]

If a hypersensitivity reaction, including anaphylaxis, occurs following COVID-19 vaccination, the case should be reported to VAERS.[13]

Myocarditis and Pericarditis

Myocarditis and pericarditis have been reported in recipients of mRNA COVID-19 vaccines during post-authorization and post-marketing surveillance; the onset is typically within the first week following vaccination.[1,13,54,55,56,57,58] The observed risk has been highest in males 12 through 24 years of age; however, cases have also been reported in females and after other doses.[13]

Although some individuals were hospitalized for short periods and some required intensive care support, available data suggest that the majority of these individuals responded to conservative treatment with rapid improvement or resolution of symptoms.[1,13,54,55,56,57] Additional data are needed regarding the potential for long-term sequelae.[1]

An analysis of data from commercial health insurance claims with the 2023-2024 Formula of mRNA COVID-19 vaccines found that the estimated unadjusted incidence of myocarditis and/or pericarditis was approximately 27 cases per million doses in males 12 through 24 years of age.[1] Symptoms usually resolved within a few days with conservative management; however, intensive care support was required in some cases.[1] In a longitudinal retrospective observational study, abnormal cardiac magnetic imaging findings were reported 5 months post-vaccination in patients who developed myocarditis after receiving a COVID-19 vaccine.[1] The clinical and prognostic significance of these findings is not known.[1] In a systematic review, myocarditis associated with COVID-19 vaccines occurred at rates of 1.3 to 3.1 per 100,000 doses in adolescents; there was a lower risk with longer dosing intervals.[18]

The possibility of myocarditis and pericarditis should be considered in the differential diagnosis for any individual, particularly in adolescents and young adults, who develop acute chest pain, shortness of breath, or palpitations after receipt of an mRNA COVID-19 vaccine.[13,54,58] During initial evaluation of suspected cases, the vaccine recipient should be queried about prior COVID-19 vaccination and pertinent medical, travel, and social history; in addition, assessment of ECG, troponin levels, and inflammatory markers such as C-reactive protein and erythrocyte sedimentation rate should be considered. Expert consultation should be considered regarding diagnosis, management, and follow-up.

Individuals receiving an mRNA COVID-19 vaccine, especially males 12–39 years of age, should be informed about the possibility of myocarditis or pericarditis after receiving the vaccine and the possibility of myocarditis or pericarditis occurring following SARS-CoV-2 infection and advised to seek medical care if symptoms of myocarditis or pericarditis occur after vaccination.[13] Extending the interval to 8 weeks between the first and second doses of vaccine for some people might reduce the rare risk of vaccine-associated myocarditis and pericarditis.[13]

If myocarditis or pericarditis occurs following receipt of a COVID-19 vaccine, the case should be reported to VAERS.[13] ACIP states that development of myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine is a precaution to a subsequent dose of any COVID-19 vaccine, and subsequent doses should generally be avoided.[13] People who have a history of myocarditis or pericarditis that occurred before COVID-19 vaccination or more than 3 weeks after a COVID-19 vaccine dose may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved.[13]

Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines.[1,501] Procedures should be in place to avoid injury from fainting.[1,501] ACIP states to consider observing individuals receiving the vaccine, especially adolescents, for 15 minutes after vaccination.[13]

Concomitant Illness

A decision to administer or delay vaccination in an individual with a current or recent febrile illness depends on the severity of symptoms and etiology of the illness.[20]

ACIP states that a moderate or severe acute illness is a precaution for administration of vaccines and states that a risk assessment should be performed with potential deferral of vaccination.[13] Deferring vaccination until an individual has recovered avoids superimposing adverse effects of the vaccine on the underlying illness or mistakenly concluding that a manifestation of the underlying illness resulted from vaccination.[20]

Individuals with a History of Multisystem Inflammatory Syndrome

ACIP states that the benefits of COVID-19 vaccination for individuals with a history of multisystem inflammatory syndrome in adults (MIS-A) or in children (MIS-C) outweigh the risks.[13] ACIP has published considerations for initiating COVID-19 vaccination in such individuals.

If MIS-A or MIS-C develops more than 60 days after the most recent COVID-19 vaccine dose, administration may be considered for those who achieve clinical recovery (including return to normal cardiac function).[13]

If the onset of MIS is 60 days or fewer after the most recent COVID-19 dose, the decision whether or not to administer a subsequent COVID-19 vaccine dose(s) should be made on an individual basis by the clinical care team and patient or parent or guardian.[13] *Subsequent doses of COVID-19 should especially be considered if there is strong evidence that MIS was a complication of a recent SARS-CoV-2 infection.*[13]

Individuals with Underlying Medical Conditions

Individuals with altered immunocompetence, including those receiving immunosuppressive therapy, may have diminished immune responses to vaccines, including the Moderna COVID-19 vaccine.[1,20]

Although a causal relationship has not been established, several cases of Bell's palsy have been reported in COVID-19 vaccine trials.[1] If Bell's palsy occurs following COVID-19 vaccination, the case should be reported to VAERS.[13]

Individuals with Increased Bleeding Risk

Individuals who have bleeding disorders or are receiving anticoagulant therapy and/or their caregiver should be advised about the risk of hematoma from IM injections.[20]

ACIP states that IM vaccines may be given to individuals who have bleeding disorders if a clinician familiar with the individual's bleeding risk determines that the preparation can be administered IM with reasonable safety.[20] *In these cases, a fine needle (23 gauge or smaller) should be used to administer the vaccine and firm pressure applied to the injection site (without rubbing) for at least 2 minutes.*[20] *In individuals receiving therapy for hemophilia, IM vaccines can be scheduled for administration shortly after a dose of such therapy.*[20]

Individuals receiving anticoagulation therapy presumably have the same bleeding risk as patients with clotting factor disorders and should follow the same guidelines for IM administration.[20] *If possible, IM vaccines could be scheduled prior to use of an anticoagulant so that the individual's risk of bleeding is not increased by the drug's therapeutic action.*[20]

Limitation of Vaccine Effectiveness

COVID-19 vaccine, mRNA (Moderna) may not protect all vaccine recipients against COVID-19.[1,3]

Specific Populations

Pregnancy

Data are insufficient to date regarding use of COVID-19 vaccine (Moderna) in pregnant women to inform vaccine-associated risks during pregnancy.[1]

In a developmental toxicity study in female rats, there was no evidence of vaccine-related adverse effects on female fertility, fetal development, or postnatal development when a vaccine formulation (same quantity of mRNA and other ingredients as that in a single human dose of the Moderna COVID-19 vaccine) was given IM on days 28 and 14 prior to mating and on gestation days 1 and 13.[1]

Available data suggest that, while the absolute risk is low, pregnant and recently pregnant women with COVID-19 are at increased risk of severe illness, including illness resulting in hospitalization, admission to an intensive care unit, mechanical ventilation, extracorporeal membrane oxygenation (ECMO), or death compared with women who are not pregnant.[13,16,34] *Additionally, pregnant women with COVID-19 are at increased risk of preterm birth and may be at increased risk of adverse pregnancy complications and outcomes, such as preeclampsia, coagulopathy, and stillbirth.*[13,34]

Post-authorization surveillance safety data are accumulating regarding COVID-19 vaccination during pregnancy and clinical trials evaluating the safety and efficacy of COVID-19 vaccines in pregnant women are underway or planned.[13,16,49,50] *Early data from VAERS, v-safe active surveillance, and v-safe pregnancy registry have not identified any safety concerns in pregnant women who were vaccinated late in their pregnancy or in their infants; additional evidence has not found an increased risk for miscarriage following receipt of an mRNA vaccine before 20 weeks gestation.*[13] *There is some evidence that pregnant women who receive an mRNA vaccine (Moderna COVID-19 vaccine or Pfizer-BioNTech COVID-19 vaccine) during pregnancy have immune responses comparable to those observed in individuals who are not pregnant and may develop anti-SARS-CoV-2 antibody titers greater than those observed in women diagnosed with SARS-CoV-2 infection during pregnancy.*[16,50,51]

ACIP states that vaccination against COVID-19 is recommended for pregnant women.[13] *These experts state that evidence regarding the safety and efficacy of COVID-19 vaccines available from both animal and human studies indicates that the benefits of vaccination against*

COVID-19 during pregnancy outweigh any known or potential risks.[13]

The American College of Obstetricians and Gynecologists (ACOG) also recommends that pregnant women be vaccinated against COVID-19.[16] Vaccination may occur in any trimester and as soon as possible to maximize maternal and fetal health.[16]

Lactation

Limited data are available to assess whether COVID-19 vaccines administered to a woman who is breast-feeding has any effects on the breast-fed infant or milk production.[1]

ACIP and ACOG recommend COVID-19 vaccination in people who are breastfeeding.[13,16]

Females and Males of Reproductive Potential

ACIP recommends COVID-19 vaccination in people who are pregnant, trying to get pregnant, or might become pregnant in the future.[13]

Pediatric Use

Moderna COVID-19 vaccine (2025-2026 Spikevax®) is FDA-labeled for use in children 6 months of age or older who have at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.[1]

The mNexspike® COVID-19 vaccine (2025-2026 Formula) is FDA-labeled for use in adolescents ≥12 years of age who have at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.[3]

Geriatric Use

Individuals ≥65 years of age have been included in clinical trials evaluating the original Moderna COVID-19 monovalent and bivalent vaccines (no longer authorized for use in the US), and data from such individuals contribute to the overall assessment of safety and efficacy of the vaccine.[1,2]

Some local and systemic adverse reactions were reported in a lower proportion of participants ≥65 years of age compared to participants 18 through 64 years of age in clinical studies.[1,3]

Common Adverse Effects

The most common adverse effects reported in participants 6 months through 36 months of age receiving Spikevax® included irritability/crying (up to 82.8%), pain at the injection site (up to 77.2%), sleepiness (up to 52.2%), loss of appetite (up to 46.5%), fever (up to 26.8%), erythema (up to 19.2%), swelling at the injection site (up to 19.2%), and axillary (or groin) swelling/tenderness (up to 12.2%).[1]

The most common adverse effects reported in participants 37 months through 11 years of age receiving Spikevax® include pain at the injection site (up to 98.4%), fatigue (up to 73.2%), headache (up to 62.2%), myalgia (up to 35.3%), chills (up to 34.6%), nausea/vomiting (up to 29.3%), axillary (or groin) swelling/tenderness (up to 27.0%), fever (up to 25.8%), erythema (up to 24.1%), swelling at the injection site (up to 22.3%), and arthralgia (up to 21.3%).[1]

The most common adverse effects reported in participants 12 years through 17 years of age receiving Spikevax® included pain at the injection site (up to 90.6%), fatigue (up to 58.1%), headache (up to 56.3%), myalgia (up to 40.1%), chills (up to 30.2%), axillary swelling/tenderness (up to 27.8%), arthralgia (up to 23.9%), nausea/vomiting (up to 17.9%), and swelling at the injection site (up to 13.3%).[1]

The most common adverse effects reported in participants 18 years through 64 years of age receiving Spikevax® included pain at injection site (up to 86.3%), fatigue (up to 62.0%), headache (up to 58.9%), myalgia (up to 49.6%), arthralgia (up to 41.9%), chills (up to 40.3%), axillary swelling/tenderness (up to 24.8%), and nausea/vomiting (up to 16.7%).[1]

The most common adverse effects reported in participants 65 years of age and older receiving Spikevax® included pain at injection site (up to 76.3%), fatigue (up to 58.1%), myalgia (up to 47.4%), headache (up to 42.1%), arthralgia (up to 39.5%), chills (up to 18.4%), and axillary swelling/tenderness (up to 14.3%).[1]

The most common adverse effects reported in participants 12 years through 17 years of age receiving mNexspike® included pain at the injection site (up to 68.8%), headache (up to 54.5%), fatigue (up to 47.3%), myalgia (up to 39.2%), axillary swelling or tenderness (up to 34.6%), chills (up to 31.6%), arthralgia (up to 23.9%), and nausea/vomiting (up to 16.1%).[3]

The most common adverse effects reported in participants 18 years through 64 years of age receiving mNexspike® included pain at the injection site (up to 74.8%), fatigue (up to 54.3%), headache (up to 47.8%), myalgia (up to 41.6%), arthralgia (up to 32.4%), chills (up to 24.3%), axillary swelling or tenderness (up to 21.7%), and nausea/vomiting (up to 13.8%).[3]

The most common adverse effects reported in participants 65 years of age and older receiving mNexspike® included pain at the injection site (up to 54.6%), fatigue (up to 43.0%), headache (up to 33.1%), myalgia (up to 30.5%), arthralgia (up to 25.7%), chills (up to 16.5%), nausea/vomiting (up to 11.4%), and axillary swelling or tenderness (up to 10.7%).[3]

Drug Interactions

Analgesic Agents

ACIP does not recommend taking ibuprofen, aspirin, or acetaminophen prior to COVID-19 vaccination to try and prevent side effects.[13]

Immunosuppressive Agents

ACIP states that administration of COVID-19 vaccines should not be delayed in patients taking immunosuppressive therapies.[13] Whenever possible, COVID-19 vaccines should be administered at least 2 weeks before initiation or resumption of immunosuppressive therapies.[13] For patients who receive B-cell-depleting therapies on a continuing basis, COVID-19 vaccines should be administered approximately 4 weeks before the next scheduled therapy.[13]

Nirsevimab

Simultaneous administration of COVID-19 vaccine and nirsevimab is recommended.[13] See ACIP recommendations for additional information.[13]

Vaccines

ACIP states that routine administration of all age-appropriate doses of vaccines simultaneously is recommended in children, adolescents, and adults if there are no contraindications at the time of the healthcare visit.[13]

An interim analysis of a clinical study of 296 persons ≥65 years of age comparing concomitant administration of a quadrivalent inactivated influenza vaccine (HD-IIV4) and a booster dose of an mRNA COVID-19 vaccine (administered in separate upper arm sites) with administration of either vaccine alone did not identify any safety concerns or any evidence of immune interference on influenza hemagglutination inhibition or SARS-CoV-2 binding antibody responses.[589] Local reactogenicity up to 21 days postvaccination was similar between the coadministration group and the group that received the mRNA COVID-19 vaccine alone.[589] Similar frequency of systemic reactions were reported in the coadministration and mRNA groups, but with lower frequencies observed in participants who received HD-IIV4 alone.[589]

In a multicenter, randomized clinical study, 679 adult participants were recruited to receive concomitant administration of either an age-appropriate influenza vaccine or placebo along with their second dose of a COVID-19 vaccine (either an adenovirus viral vector COVID-19 vaccine or an mRNA COVID-19 vaccine).[590] Injections were administered by IM injection in the upper arm, with one injection on each side for the concomitant administration recipients.[590] Analysis up to 21 days after vaccination, did not identify safety concerns or evidence of immune interference on influenza hemagglutination inhibition or SARS-CoV-2 binding antibody responses.[590] The study found similar rates of local reactogenicity between the coadministration group and single vaccine administration group; however, systemic reactions were reported at similar frequencies in the coadministration and mRNA vaccine groups, with lower frequencies observed in participants who received influenza vaccine alone.[590]

Description

COVID-19 vaccine (Moderna) (2025-2026 Formula) is a nucleoside-modified mRNA vaccine formulated in lipid nanoparticles (LNPs).[1,3,10,11,12,25] The mRNA contained in the Moderna COVID-19 Spikevax® vaccine formulation encodes the pre-fusion stabilized Spike glycoprotein (S) of the SARS-CoV-2 Omicron variant sublineage LP.8.1.[1,10,11,25] The Moderna COVID-19 mNexspike® vaccine formulation contains nucleoside-modified mRNA encoding the N-terminal domain (NTD) and receptor-binding domain (RBD) of the Spike glycoprotein of the SARS-CoV-2 Omicron variant sublineage LP.8.1.[3] Following IM injection, the LNPs in the vaccines enable delivery of the mRNA into host cells where it is released and translated to the encoded S antigen of SARS-CoV-2.[1,11] The S antigen elicits an immune response to provide protection against SARS-CoV-2.[1,11]

Advice to Patients

The following information contains important points for the clinician to discuss with patients during counseling. For more comprehensive monographs suitable for distribution to the patient, please refer to the *AHFS Patient Medication Information* monographs available from MedlinePlus (in English and Spanish; written at a 6th- to 8th-grade reading level).

- Advise the vaccine recipient or caregiver to read the FDA-approved patient labeling.[1,3]
- Inform the vaccine recipient or caregiver of the potential benefits and risks of vaccination.[1,3]
- Instruct the vaccine recipient or caregiver to report any adverse events to their healthcare provider or to the Vaccine Adverse Event Reporting System at 1-800-822-7967 or [Web] .[1,3]
- Advise patients to inform their clinician of existing or contemplated concomitant therapy, including prescription and OTC drugs and dietary or herbal supplements, as well as any concomitant illnesses.[1,3]
- Advise women to inform their clinician if they are or plan to become pregnant or plan to breast-feed.[1,3]
- Inform patients of other important precautionary information.[1,3]

Additional Information

The American Society of Health-System Pharmacists, Inc. represents that the information provided in the accompanying monograph was formulated with a reasonable standard of care, and in conformity with professional standards in the field. Readers are advised that decisions regarding use of drugs are complex medical decisions requiring the independent, informed decision of an appropriate health care professional, and that the information contained in the monograph is provided for informational purposes only. The

manufacturer's labeling should be consulted for more detailed information. The American Society of Health-System Pharmacists, Inc. does not endorse or recommend the use of any drug. The information contained in the monograph is not a substitute for medical care.

Preparations

Excipients in commercially available drug preparations may have clinically important effects in some individuals; consult specific product labeling for details.

COVID-19 Vaccine, mRNA (Moderna)

ROUTES	FORMS	STRENGTHS	BRAND NAMES	MANUFACTURER
Parenteral	*Suspension, for IM use*	*10 mcg (of mRNA) per 0.2-mL dose*	*mNexspike (2025-2026 Formula)® (available in single dose prefilled syringes)*	*ModernaTX*
		25 mcg (of mRNA) per 0.25-mL dose	*Spikevax (2025-2026 Formula)® (available in single dose prefilled syringes)*	*ModernaTX*
		50 mcg (of mRNA) per 0.5-mL dose	*Spikevax (2025-2026 Formula)® (available in single dose prefilled syringes)*	*ModernaTX*

† Use is not currently included in the labeling approved by the US Food and Drug Administration.

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