

Frequently Asked Questions

Moderna COVID-19 Vaccine EUA Amendments

General

Will there be a new NDC code for the 13-15 dose vial?

Yes, a new NDC code has been provided for the 13-15 dose vial and ancillary kit.

Changes Correlating to Fact Sheet Updates

NDC 80777-273-99 Carton of 10 multiple-dose vials, each vial containing a maximum of 11 doses:
range 10-11 doses (0.5 mL)
(Current NDC with Revised Product Description)

Addition of New Multi-Dose Vial

NDC 80777-273-98 Carton of 10 multiple-dose vials, each vial containing a maximum of 15 doses:
range 13-15 doses (0.5 mL)
(New NDC & New Product Presentation)

NDC 11111-0011-02 Ancillary kit for support of 140-dose order

How will the existing and new Moderna vials be distinguished on the vial label?

Each vial is clearly marked as containing either a maximum of 11 doses or a maximum of 15 doses. The label for the maximum of 15 dose vial also has distinctive blue shading on the bottom half of the label.

How will the 10-11 dose vials phase out over time?

Moderna is planning to transition all manufacturing to the new vial during the month of May. During the month, awardees and partners will receive allocations that include quantities of both Moderna vaccine vials. The proportion of existing Moderna NDC/new Moderna NDC in each awardee's and partner's allocation will evolve over the course of the transition period.

Clinical

Does extraction of 15 doses require the use of low dead-volume syringes?

Moderna worked closely with CDC and United States Pharmacopeia (USP) to test combinations of available needle and syringe supplies to optimize the number of available doses. Results demonstrate that a combination of low dead-volume and non-low dead-volume syringes and needles may be required to consistently extract 11 and 15 doses from both vials addressed in the EUA. **Given the worldwide limited supply of low dead-volume syringes and based on USP's testing and ancillary supply kit quantities, vaccination sites should plan to reliably extract 10 doses from the current vial and 14 doses from the new larger volume vial using the supplies provided.**

What should providers do if they are able to draw 15 doses per vial?

Ancillary kits for the larger-volume Moderna vial contain supplies to support the extraction of 14 doses. A consistent draw of 15 doses per vial may result in insufficient ancillary supplies. If providers are able to consistently extract 15 doses from the vial, they should be prepared to support the additional doses with their available supplies. USG cannot provide supplies to withdraw a 15th dose. If a provider chooses to withdraw a 15th dose from the vial, USG cannot replace the supplies used or provide additional syringes. **Failure to extract a 15th dose does not result in reportable waste.**

Should I consider canceling clinics during this transition?

There should be a seamless transition from the current Moderna vial to the larger volume vial, so no cancellation of clinics should be necessary. You will need to be aware of the quantity of each of the two Moderna vials you have in inventory to schedule administration rates that are consistent with the number of doses on hand.

Are there materials and messages we can share with providers about these changes?

CDC clinical training and other materials are being updated to reflect the new guidance. These materials can be accessed from the Moderna COVID-19 vaccine web page at [Moderna COVID-19 Vaccine Information | CDC](#).

Ancillary Kits

When will providers receive new ancillary kits to support this transition?

The new ancillary kits are currently being produced and will be shipped concurrently when orders of the new NDC begin to ship to administration sites.

What are the contents of the new Moderna ancillary kits?

The items contained in the new Moderna ancillary kit will be sufficient to support delivery of 140 doses plus 5%. Just as it works currently, ancillary kits will be shipped to coincide with the size of the order placed.

Will the kits contain low dead-volume syringes?

The types of items contained in both Moderna ancillary kits remain consistent, but some of the added components will include low dead volume needles and syringes to support the administration of 140 doses. Ancillary kits for the current Moderna vials will not change and do not contain low dead-volume syringes.

Will the larger kits be shipped with the larger volume vials to ensure sufficient supply of syringes?

The NDC ordered during the transition will determine which ancillary kit is included in your vaccine order. McKesson will continue to ship kits consistent with the number of doses in each order.

Wastage

If the 15th dose cannot be extracted, must it be reported as waste?

No. Ancillary kits will be shipped with enough supplies to extract 14 doses per vial. Therefore, consistently extracting the 15th dose is not expected and failure to extract the 15th dose does not result in reportable waste.

Will the increases in reported waste be available to the public?

No. The reporting of waste will remain consistent throughout the transition.

Allocations/Ordering Caps/Inventory

Will this change impact my minimum order size?

The new minimum order for Moderna vaccine with the larger volume vial will be 140 doses.

Will vials already received need to be re-inventoried?

The transition to the larger volume Moderna vial will have no impact on inventory already received.

Will the ordering or distribution systems be disrupted by this process?

There will be no interruptions to CDC IT systems during this transition.

Will the expiration dates for on-hand vaccines and supplies be extended?

Moderna as well as Pfizer and Johnson & Johnson/Janssen vaccines are preservative-free and have a 90- to 120-day expiration date. However, as more stability data become available, the expiration date may be extended. Scan the QR code located on the outer carton or check with the manufacturer before discarding vaccine based on the expiration date.

When ordering second doses for 10-11 dose vials, will the vials be switched to the 13-15 dose vials?

No. Allocations for 10-11 dose vials will be held to fill orders for second doses.

Data Systems

What will be updated in Tiberius/VTrckS/VPOP/VAMS?

- VTrckS
 - New ancillary kit NDC to support administration of 140 doses of vaccine
 - New vaccine NDC with a 140-dose minimum order size and increment
 - NDC crosswalk tables: [IIS](#) | [NDC Crosswalk tables](#) | [Code Sets](#) | [HL7 Data](#) | [Vaccines](#) | [CDC](#)
(During the transition period, awardees and partners will receive allocations of both the current and the new Moderna NDC)
- Tiberius
 - New NDC with an updated dose count/vial
 - New allocations for the new vaccine NDC
- VPOP
 - New dose count/vial
 - Update number of doses per package
- There will be no system changes for
 - VAMS (updated vaccine table will allow users to add new Moderna NDC and log 14 doses per vial for inventory)
 - VaccineFinder (users will be able to log into the portal, add the new Moderna NDC, and report 14 doses per vial for inventory)

How will updates be incorporated in VaccineFinder?

VaccineFinder users will be able to log into the portal, add the new Moderna NDC, and report 14 doses per vial for inventory.

What are recommendations for jurisdictions when updating their immunization information systems (IIS)?

CDC and HHS systems (VTrckS, VPOP, and Tiberius) will be updated to include the new NDC by April 25. During the week of April 25, IISs should activate the new NDC. Allocations will be made in Tiberius on April 27. IISs should see the first order cap in VTrckS on Friday, April 29.

Storage and Handling

Is there any change to the transportation guidance for the new (14-dose) vials?

Transport guidance will remain the same with the new frozen temperature range. CDC clinical training and other materials have been updated to reflect the new storage and handling guidance. These materials can be accessed from the Moderna COVID-19 vaccine web page at [Moderna COVID-19 Vaccine Information | CDC](#).

Is the new vial a larger size than the existing vial?

The 13-15 dose vial will remain the same size as the 10-11 dose vial but will be filled to the higher volume.

Each carton still contains 10 multi-dose vials. The carton size remains the same, but the number of doses per carton is increased because of the increased number of doses per vial. The new carton has a distinctive blue label similar to the vial.

Other

Who should providers contact with logistics questions related to the change?

Questions about vaccine ordering or distribution of the new Moderna vaccine and associated ancillary kit should be directed to CDC or to the state or territorial health department.