

CLINICAL **ADVISORY**

September | 2023

PharMerica

Monovalent mRNA COVID-19 Vaccines Update – September 28, 2023

BACKGROUND

9/11/2023: the [U.S. Food and Drug Administration \(FDA\) granted approvals and emergency use authorizations to updated Moderna and Pfizer COVID-19 vaccines](#). These updated 2023-24 formulations are monovalent (including one viral strain), designed to target the XBB.1.5 Omicron strain and to protect against serious consequences of this and other cross-reactive circulating SARS-CoV-2 variants.

9/12/2023: the [CDC officially adopted recommendations](#), per ACIP vote, in favor (13-1) of providing updated COVID-19 vaccines to all American 6 months and older.

COVID-19 VACCINE INFORMATION

- **Effective immediately, bivalent (two viral strain) Moderna and Pfizer-BioNTech COVID-19 vaccines are **no longer authorized** in the U.S.**
- **Monovalent** COVID-19 vaccines for individuals 12 years of age and older are now **FDA-approved** and marketed as commercial products. Vaccine Information Statements (VIS) are not currently available (check [here](#) for future availability), but the following patient package inserts can be used in the interim:
 - Pfizer-BioNTech - COMIRNATY® - [Patient Package Insert - 12+ - COMIRNATY](#)
 - Moderna - SPIKEVAX® - [Patient Package Insert - 12+ - SPIKEVAX](#)
- Monovalent COVID-19 vaccines for individuals 6 months through 11 years of age are still under **Emergency Use Authorization**:
 - [Pfizer-BioNTech COVID-19 Vaccine \(2023-2024 Formula\) EUA Fact Sheet - 6mo through 11yr](#)
 - [Moderna COVID-19 Vaccine \(2023-2024 Formula\) EUA Fact Sheet - 6mo through 11yr](#)
- **Individuals 5 years of age and older regardless of previous vaccination** are eligible to receive a single dose of an updated mRNA COVID-19 vaccine at least **2 months** since the last dose of any COVID-19 vaccine.
 - Please refer to the **CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States** for additional clinical information and recommendations:
 - <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>
- Per a CDC Health Alert Network memo, providers may simultaneously administer COVID-19, influenza, and respiratory syncytial virus (RSV) vaccines to eligible patients.
 - Different anatomic sites should be used for vaccine administration (e.g., injections in same limb separated by at least 1 inch; high-dose influenza vaccines given in different limb).
 - [CDC Health Alert Network \(HAN\) memo](#)

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ORDERING INFORMATION

- Availability of the monovalent mRNA COVID-19 vaccines is limited as the FDA begins to approve and release more lots from the manufacturers to our wholesaler
 - Availability is expected to improve over the next 7 to 10 days but in the short term expect delays
 - PharMerica pharmacy directors may provide a memo for written documentation of unable-to-fulfill orders during this global period of high demand versus supply
- For **Skilled Nursing Facilities**, please place orders as you would for other Part B vaccines such as influenza and pneumococcal vaccines for residents.
 - Please place orders with your servicing pharmacy so that we can in turn communicate demand to our wholesaler

Skilled Nursing Facility 2023-2024 COVID-19 Vaccine Pricing		
Product	PharMerica Per Dose Cost	CMS National Payment Allowance
MODERNA - SPIKEVAX 2023-24(12Y UP) SYRINGE	\$ 125.00	\$ 145.92
MODERNA - SPIKEVAX 2023-24(12Y UP) VIAL	\$ 125.00	\$ 145.92
PFIZER - COMIRNATY 2023-24(12Y UP) VIAL	\$ 125.00	\$ 131.10

- For Private Pay or Commercial residents, we will bill the resident or payor accordingly
- For staff, we recommend they receive the vaccine from community pharmacies or their healthcare providers

DOCUMENTATION/BILLING INFORMATION

- For adults with Medicare, COVID-19 Vaccines are reimbursed under Medicare Part B, even if in Part A stay
 - See additional resource documents:
 - **Did-You-Know 2023 Medicare Part B Vaccine Billing**
 - **AHCA Medicare Billing Guidance Respiratory Vaccines**

CPT/HCPCS Code	Labeler Name	Vaccine Name	National Payment Allowance	Effective Dates
90480	-	COVID-19 Vaccine Administration	\$40.00	9/11/23 – TBD
91320	Pfizer-BioNTech	COMIRNATY (2023-24 Formula)	\$131.10	9/11/23 – TBD
91322	Moderna	SPIKEVAX (2023-24 Formula)	\$145.92	9/11/23 – TBD

- Pharmacy no longer needs copies of informed consent, vaccine administration records, or waste information
- Facilities should continue to document administration and consent per their policies and procedures, and may be responsible for reporting to state immunization registries, if applicable

ADDITIONAL RESOURCES

[CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States](#)
[FDA Fact Sheets for Health Care Providers and Patients](#)