



Monkeypox Frequently Asked Questions For Pharmacy Partners

Medicare

Is monkeypox vaccine administration covered under Medicare?

Currently, monkeypox vaccine and its administration is only covered under Medicare Part B when provided to an individual who has had direct exposure to the monkeypox virus. This is because Original Medicare only covers items and services when reasonable and necessary for the diagnosis or treatment of an illness or injury. Original Medicare does cover four statutorily specified preventive vaccines and their administration (at section 1861(s)(10) of the Social Security Act): influenza, pneumococcal, hepatitis B (for those at high or intermediate risk of contracting hepatitis B), and COVID-19. Monkeypox vaccine is not included among them.

Medicare Advantage (MA) plans are required to cover the same benefits available under Medicare Part B through their contracted network of providers, with additional out of network coverage required in limited circumstances or offered as part of the plan design. However, MA plans can also offer, as supplemental benefits, coverage for items and services that are not covered under Original Medicare and that are not Part D drugs. MA plans that offer Part D prescription drug coverage could cover a monkeypox vaccine if it meets the statutory definition of a covered Part D drug.

Under Medicare Part D, a monkeypox vaccine could meet the statutory definition of a covered Part D drug if the vaccine is licensed under section 351 of the Public Health Service Act and if payment is not available under Parts A or B for the vaccine as prescribed and dispensed, or administered, with respect to that individual. (If the vaccine is not licensed, it would not meet the definition of a covered Part D drug). As such, if there is a monkeypox vaccine that is licensed under section 351 of the PHSA and that is not covered under Parts A or B, it could be covered, along with its administration, under Part D if it meets all Part D requirements. Payment would be determined by the beneficiary's Part D plan.

Can pharmacists bill Medicare for administering monkeypox vaccine? Under what conditions/limitations?



The Medicare Part B statute does not currently allow for direct payment to pharmacists for services they furnish.

Under Part B, payment can be made for services performed by a pharmacist incident to the services, and under the appropriate level of supervision, of a billing physician or nonphysician practitioner (NPP), if payment for the services is not made under the Medicare Part D benefit. Therefore, Medicare Part B will make payment to a physician or NPP for a pharmacist administering monkeypox vaccine if the vaccine is administered incident to a physicians' or NPP's service, while under the appropriate level of supervision and billed by the physician or NPP.

As previously noted, Medicare Advantage (MA) plans are required to cover the same benefits available under Medicare Part B. An in-network pharmacist can bill an MA plan for administering monkeypox vaccine if the vaccine is administered incident to a physicians' or NPP's service, while under the appropriate level of supervision, or if the vaccine is administered as a supplemental benefit. A pharmacist that is not contracted with the patient's MA plan may check with the MA plan to see if the patient has coverage for out of network benefits.

Under Medicare Part D, as noted above, if there is a monkeypox vaccine that is licensed under section 351 of the PHSA and that is not covered under Parts A or B, it could be covered, along with its administration, under Part D if it meets all Part D requirements. Payment would be determined by the contract between pharmacy and the Part D plan.

Do HHS' recent amendments to the PREP Act declaration for smallpox, monkeypox, and orthopoxvirus medical countermeasures affect Medicare coverage for monkeypox vaccine administered by pharmacists?

No. Recent amendments to the PREP Act declaration have expanded the pool of providers who - with outlined training and supervision--are "covered persons" authorized to administer vaccines and therapeutics against smallpox (variola virus), monkeypox virus, and other orthopoxviruses.

Under the PREP Act, these covered persons—which now include pharmacists, pharmacy technicians and pharmacy interns—are immune from suit and liability under federal and state law with respect to all claims for loss resulting from the administration or use of a covered countermeasure if a declaration under the PREP Act has been issued with respect to such countermeasure.



Medicare coverage and payment requirements are not affected by the declaration.

Which billing codes should be used for submitting claims for monkeypox vaccine administration?

The appropriate CPT billing codes for vaccine administration would be 90460 or 90471 and pays about \$17.

These codes should be used regardless of administration route: there is currently no CPT code that specifically describes the service for intradermal administration that can be used to bill for the administration of the Jynneos vaccine.

Is monkeypox vaccine eligible for roster billing?

No, roster billing is not available for monkeypox vaccine, as it is only available for **preventive** vaccines covered under Part B, which do not require a physician's order and can be administered without physician supervision.

Currently, the Part B preventive vaccine benefit specifies only **four** vaccines in statute (at section 1861(s)(10) of the Social Security Act): influenza, pneumococcal, hepatitis B (only for those at high or intermediate risk of contracting hepatitis B), and COVID-19.

What are the Medicare billing rules for pharmacies that receive vaccine, drugs, or other supplies from the Strategic National Stockpile (SNS) or another governmental entity?

Pharmacies receiving monkeypox vaccine procured or provided by a governmental entity should not seek additional payment for the vaccine or associated supplies (see CMS Internet Only Manual, Pub. 100-04, Chapter 32, Section 67).

In addition, providers and suppliers that submit Medicare cost reports should not reflect the costs of free drugs or supplies on their cost reports.

Rather, providers and suppliers should follow ordinary billing rules for drugs or supplies provided at no cost by governmental entities.



Medicaid

Is monkeypox vaccine administration covered under Medicaid?

Monkeypox vaccine administration is mandatorily covered under Medicaid in certain circumstances; otherwise, coverage is at state option. States must cover, for beneficiaries under age 21 who are eligible for Early and Periodic Screening, Diagnostic, and Treatment (EPSDT), any service that states could cover under section 1905(a) of the Social Security Act, including monkeypox vaccination, if the service is determined to be medically necessary for the beneficiary based on an individualized assessment and state medical necessity criteria. States may look to current ACIP and/or CDC recommendation criteria as the basis for determining medical necessity, at a minimum, and should also consider whether exposure or risk of exposure to the monkeypox virus would make vaccination medically necessary. Additionally, states that have opted to receive an extra percentage point of federal match for covering approved ACIP-recommended vaccinations for adults would be required to cover monkeypox vaccination for those who meet the ACIP recommendation's criteria, without cost sharing.

States have the option to provide monkeypox vaccination coverage for other Medicaid beneficiaries, such as those enrolled in an Alternative Benefit Plan. Monkeypox vaccines and vaccine administration can be covered under the optional preventive services benefit and other benefits such as physicians' services and other licensed practitioner services. Additional information regarding coverage of monkeypox vaccination can be found in the following materials that CMS presented to state Medicaid agencies on September 13, 2022:

<https://www.medicaid.gov/resources-for-states/downloads/covid19allstatecall09132022.pdf>

(see esp. slides 3 through 13)

Can pharmacists bill Medicaid for administering monkeypox vaccine? Under what conditions/limitations?

States are required to identify a pathway to providing payment to pharmacists for administering monkeypox vaccine, if the pharmacist is qualified to administer the vaccine (including if the pharmacist is authorized to administer it under an HHS PREP Act declaration), and if Medicaid coverage of the vaccination is otherwise available. States still must meet all other applicable federal requirements for covering the applicable benefit, such as reimbursing only those providers that are enrolled as Medicaid providers and covering vaccinations only for eligible individuals. See the question below for additional information on the monkeypox-applicable HHS PREP Act declaration and authorizations



States generally have discretion to set Medicaid payment rates, subject to federal requirements. Medicaid coverage and payment changes may require a state plan amendment.

Do HHS’ recent amendments to the PREP Act declaration for smallpox, monkeypox, and orthopoxvirus medical countermeasures affect Medicaid coverage for monkeypox vaccine administered by pharmacists?

As indicated above, Medicaid coverage for monkeypox vaccination is currently mandatory for certain beneficiaries; coverage is at state option for most other Medicaid beneficiaries. The HHS PREP Act declaration does not change Medicaid coverage rules or require states to cover monkeypox vaccine administration for additional Medicaid beneficiaries. The HHS PREP Act declaration does affect what providers are qualified to provide monkeypox vaccine administration, for purposes of the Medicaid free choice of provider requirement. .

Recent amendments to the PREP Act declaration for smallpox, monkeypox, and orthopoxvirus medical countermeasures have expanded the pool of providers who—subject to the conditions outlined in the declaration, including certain training and supervision requirements and the requirement to provide vaccinations according to CDC/ACIP recommendations—are “covered persons” authorized to administer vaccines and therapeutics against smallpox (variola virus), monkeypox virus, and other orthopoxviruses. Under the PREP Act, these covered persons—which now include pharmacists, pharmacy technicians, and pharmacy interns—are immune from suit and liability under federal and state law with respect to all claims for loss resulting from the administration or use of a covered countermeasure if a declaration under the PREP Act has been issued with respect to such countermeasure.

States generally have flexibility to set Medicaid provider qualifications, provided that they do so in a manner consistent with the Medicaid free choice of provider requirement. However, HHS PREP Act authorizations preempt conflicting state laws. Thus, when the state covers monkeypox vaccination for a beneficiary, and a pharmacist is authorized to administer monkeypox vaccine to that beneficiary under an HHS PREP Act declaration, the state would then be required to provide a pathway to reimbursing that pharmacist reimburse pharmacists for monkeypox vaccine administration, when provided in accordance with PREP Act declaration provisions. States still must meet all other applicable federal requirements for covering the applicable benefit, such as reimbursing only those providers that are enrolled as Medicaid providers and covering vaccinations only for eligible individuals.



More context on the Medicaid implications of HHS PREP Act authorizations can be found in the *Coverage and Reimbursement of COVID-19 Vaccines, Vaccine Administration, and Cost Sharing under Medicaid, the Children’s Health Insurance Program, and Basic Health Program* toolkit (see <https://www.medicaid.gov/state-resource-center/downloads/covid-19-vaccine-toolkit.pdf>). CMS is available to provide technical assistance about this topic.

Private Health Insurance

Is monkeypox vaccine administration covered by QHPs or other commercial insurance plans?

Coverage, cost sharing, and the use of utilization management tools for monkeypox vaccination are currently at the discretion of plans and issuers, subject to applicable state law. In some states and under some plans, some or all monkeypox testing and treatment may be covered as an essential health benefit.

CMS encourages issuers to work with their enrollees and providers to ensure adequate access to covered drugs subject to cost-sharing requirements. Enrollees in non-grandfathered individual and small group market health insurance coverage may use the drug exceptions process to request coverage for non-formulary drugs, pursuant to 45 CFR 156.122(c), including on an expedited basis due to exigent circumstances.

Can pharmacists bill commercial plans--like Qualified Health Plans (QHPs) listed on the Marketplace--for administering monkeypox vaccine? Under what conditions/limitations?

Subject to applicable state law, plans have discretion over coverage of vaccine administration by a pharmacist or in a pharmacy.

Do HHS’ recent amendments to the PREP Act declaration for smallpox, monkeypox, and orthopoxvirus medical countermeasures affect commercial/QHP coverage for monkeypox vaccine administered by pharmacists?

No. Recent amendments to the PREP Act declaration have expanded the pool of providers who - with outlined training and supervision--are “covered persons” authorized to administer vaccines and therapeutics against smallpox (variola virus), monkeypox virus, and other orthopoxviruses.



Under the PREP Act, these covered persons—which now include pharmacists, pharmacy technicians and pharmacy interns—are immune from suit and liability under federal and state law with respect to all claims for loss resulting from the administration or use of a covered countermeasure if a declaration under the PREP Act has been issued with respect to such countermeasure.

Subject to applicable state law, plans still have discretion to determine whether, and under what circumstances, they will cover monkeypox vaccine administered within pharmacies/by pharmacists.