

TOOLKIT ON COVID-19 VACCINE: HEALTH INSURANCE ISSUERS AND MEDICARE ADVANTAGE PLANS

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Introduction

The Centers for Medicare & Medicaid Services (CMS) released a set of toolkits for providers, states and issuers to help the health care system prepare to swiftly administer the vaccine once it is available. These resources are designed to increase the number of providers that can administer the vaccine and ensure adequate reimbursement for administering the vaccine in Medicare, while making it clear to private issuers and Medicaid programs their responsibility to cover the vaccine and its administration at no charge to beneficiaries. In addition, CMS is taking action to increase Medicare reimbursement for any new COVID treatments that are approved by the FDA.

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Purpose of Toolkit

CMS is committed to ensuring that the private health insurance industry has the necessary tools to respond to the COVID-19 public health emergency (PHE). In anticipation of safe and effective COVID-19 vaccines becoming available, CMS is issuing this toolkit to help health insurance issuers and Medicare Advantage plans identify the issues that need to be considered and addressed in order to provide coverage and reimbursement for vaccine administration. Because COVID-19 vaccines will be federally purchased, this toolkit primarily focuses on vaccine administration. CMS remains available to provide technical assistance to issuers, Medicare Advantage plans, and other stakeholders. This toolkit:

- Provides a list of operational considerations for issuers and Medicare Advantage plans as they design their approach to promoting COVID-19 vaccinations and information on how issuers and Medicare Advantage plans can communicate with providers and enrollees on vaccinations and coverage.
- Outlines recent legislative and regulatory provisions applicable to issuers that ensure that enrollees can receive a COVID-19 vaccine in a convenient setting, with no out-of-pocket costs.
- Encourages issuers and Medicare Advantage plans to implement streamlined processes to quickly administer COVID-19 vaccine coverage.
- Describes how issuers and Medicare Advantage plans can maximize the number of their enrollees who get vaccinated once a COVID-19 vaccine becomes available.

Audience for this Toolkit

This toolkit is designed for Medicare Advantage health plans and issuers of group or individual health insurance coverage. Separate toolkits are available specifically to address the needs of partners in their interactions with consumers, providers and Medicaid state programs at <https://www.cms.gov/covidvax>.

Operational Considerations for Potential COVID-19 Vaccines

While this toolkit will not describe all facets of clinical and operational considerations for COVID-19 vaccines, it highlights important details related to COVID-19 vaccines and distribution.

1. Dose sequence: Candidate vaccines may be a single-dose vaccination or be part of a two dose series. States and organizations should proactively address planning for and identifying resources to engage patients for both initial vaccination and then completion of the vaccine series in advance of vaccine receipt.

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2. **Priority of overall vaccine distribution:** While CMS expects that there will be a sufficient supply of vaccine to distribute to all beneficiaries, distribution may be done in phases. The Advisory Committee on Immunization Practices (ACIP) and the CDC will be issuing guidance on priority of vaccine distribution. State Medicaid and CHIP agencies should coordinate with their state health departments, as well as a wide range of other public and private sector partners and providers to implement this guidance and to also start thinking now about how to outreach to populations that are traditionally hard to reach.
3. **Pharmacy and Provider agreements:** To receive free supplies of the COVID-19 vaccine(s), pharmacies, retail clinics, providers, and any other site of care receiving and administering COVID-19 vaccines must sign an agreement with the U.S. government. Under the agreement, all providers must vaccinate individuals regardless of whether they have health insurance coverage or what type of coverage they have, and are prohibited from balance billing or otherwise charging vaccine recipients. Following vaccination, vaccine recipients must be provided with emergency use authorization (EUA) Fact Sheets on the vaccine and vaccination cards. They must also administer the vaccine in accordance with CDC and ACIP requirements, and must meet storage and recordkeeping requirements, including recording the administration of the vaccine to patients in their own systems within 24 hours, and reporting to public health data systems as soon as practical, and within 72 hours. For more information on the CDC recordkeeping requirements, see the link located in the Education & Outreach section, item 4, Immunization Reporting, below: https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf. Providers administering the vaccine to people without health insurance or whose insurance does not provide coverage of the vaccine, can request reimbursement for the administration of the COVID-19 vaccine through the Provider Relief Fund, see <https://www.hrsa.gov/CovidUninsuredClaim>.

Steps Issuers Can Take to Ensure Their Providers Are Equipped to Provide COVID-19 Vaccines

Issuers should:

- Ensure that providers in your network know how to become vaccinators for the COVID-19 vaccine.
- Ensure providers are aware of their reporting requirements for the vaccination – providers must record details of the vaccination into their system of record within 24 hours, and into the applicable public health system within 72 hours.¹

¹ https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

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- For vaccines that require multiple doses, encourage providers to communicate to their patients to get both doses of the same vaccine.
- Provide a website with FAQs for providers on COVID-19 vaccine administration and reimbursement, including any specific coding instructions.
- Consider how to engage with non-traditional providers, such as local health departments, mobile clinics and mass vaccination sites, so they are able to bill issuers for vaccine administration.

Coverage and Reimbursement for Administration of the Vaccine by Health Insurance Issuers

The vaccine itself will be paid for through funding authorized by the Coronavirus Aid, Relief, and Economic Security (CARES) Act, but administration of the vaccine by a provider will be paid for by the payer (for example, the private insurance company, Medicare in the case of an Medicare Advantage plan, or the Provider Relief Fund). Consumers enrolled in non-grandfathered group or individual health insurance coverage will be able to receive the vaccine and its administration free of charge from a network provider, and during the COVID-19 PHE, will also be able to receive the vaccine and its administration free of charge from an out-of-network provider. Providers are prohibited by agreement with the U.S. Government from billing patients for the vaccine or its administration, including balance billing.

Medicare Advantage Coverage and Reimbursement

- For Calendar Years (CYs) 2020 and 2021, Medicare payment for the COVID-19 vaccine and its administration for beneficiaries enrolled in Medicare Advantage plans will be made through the original fee-for-service Medicare program.
- Medicare Advantage plans should inform their contracted providers about this coverage policy and direct them to submit claims for administering the COVID-19 vaccine to the CMS Medicare Administrative Contractor (MAC) using product-specific codes for each vaccine approved.

Issuer Vaccine Coverage Provisions

- Section 3203 of the CARES Act generally requires issuers offering non-grandfathered group or individual health insurance coverage to cover any qualifying coronavirus preventive service, including a COVID-19 vaccine, without imposing any cost-sharing requirements, such as a copay, coinsurance, or deductible.
- A qualifying coronavirus preventive service means an item, service, or immunization that is intended to prevent or mitigate COVID-19 and that is, with respect to the individual involved—(1) an evidence-based item or service that has in effect a rating of “A” or “B” in the current recommendations of the United States Preventive Services Task Force

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(USPSTF); or (2) an immunization that has in effect a recommendation from the ACIP (regardless of whether the immunization is recommended for routine use).

- This coverage under section 3203 of the CARES Act must be provided no later than 15 business days after the date that ACIP or the USPSTF makes an applicable recommendation relating to the qualifying coronavirus preventive service. To ensure maximum rapid public take-up of the vaccine, we encourage all issuers to prepare to cover administration of the COVID-19 vaccine immediately upon ACIP's recommendation.
- Coverage does not depend on the type of FDA approval (EUA vs BLA) or authorization.
- These coverage requirements do not apply to a plan or coverage that is not required to provide coverage of preventive services without cost sharing under section 2713 of the Public Health Service Act, such as grandfathered health plans, excepted benefits, or short-term limited duration insurance, though we encourage all such plans to provide this coverage to all enrollees without cost sharing.

Issuer Coverage Out Of Network

- Pursuant to a recently issued Interim Final Rule by CMS and the Departments of Labor and the Treasury, issuers of non-grandfathered group or individual health insurance coverage are required to provide coverage, without cost sharing, for in-network qualifying coronavirus preventive services, including a COVID-19 vaccine and its administration, and during the COVID-19 PHE, from out-of-network providers as well.²
- For network providers, issuers will typically pay negotiated rates. For out-of-network providers, issuers will typically pay up to an allowed amount. During the COVID-19 PHE, the amount an issuer reimburses a provider for administration of a COVID-19 vaccine out of network must be reasonable, as determined in comparison to prevailing market rates for such service; one example of reasonable payment would be the Medicare reimbursement rate.

Balance Billing Provisions

- Providers that receive the COVID-19 vaccine free from the federal government are prohibited from seeking reimbursement from consumers for vaccine administration costs – whether as cost sharing or balance billing. Providers that administer vaccinations to patients without health insurance or whose insurance does not provide coverage of vaccination administration fees, may be able to file a claim with the provider relief fund, but may not charge enrollees directly for any vaccine administration costs.

Vaccine Coding

After the emergency use authorization (EUA) or licensure of each COVID-19 vaccine product by FDA, CMS will identify the specific vaccine code(s), by dose if necessary, and specific

² <https://www.cms.gov/files/document/covid-vax-ifc-4.pdf>

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vaccine administration code(s) for each dose for Medicare payment. CMS and the American Medical Association (AMA) are working collaboratively on finalizing a new approach to report use of COVID-19 vaccines.

In order to account for the additional costs of outreach, patient counseling, and reporting into CDC vaccine tracking systems. Medicare payment rates for COVID-19 vaccine administration will be \$28.39 to administer single-dose vaccines. For a COVID-19 vaccine requiring a series of 2 or more doses, the initial dose(s) administration payment rate will be \$16.94, and \$28.39 for the administration of the final dose in the series. These rates recognize the costs involved in administering the vaccine, including the additional resources involved with required public health reporting, conducting important outreach and patient education, and spending additional time with patients answering any questions they may have about the vaccine. These rates will also be geographically adjusted.

Other Reimbursement Considerations

Can an issuer receive reimbursement from the federal government for outreach to enrollees, such as providing notices, direct mail, or calling enrollees? How will outreach costs be handled under medical loss ratio (MLR) rules?

- The federal government will not provide reimbursement for outreach activities by issuers. For purposes of MLR reporting, some issuers may be able to include vaccination outreach costs as community benefit expenditures (CBE) under 45 CFR 158.162(c). This includes Federal income tax exempt issuers, which can deduct CBE from earned premium in the MLR and rebate calculations in addition to state premium taxes, up to the limits specified in 45 CFR 158.162(b)(1)(vii); as well as issuers that are not exempt from Federal income tax, which can deduct CBE from earned premium in the MLR and rebate calculations in lieu of state premium taxes, up to the limits specified in 45 CFR 158.162(b)(1)(viii). To the extent vaccination outreach is conducted as part of a public health education campaign performed in conjunction with State or local health departments, the costs of such outreach may qualify as a health care quality improvement activity under 45 CFR 158.150(b)(2)(iv)(A)(4).

Will issuers need to reimburse state health departments for administration of the vaccine?

- Under the recently issued Interim Final Rule, while the COVID-19 PHE is ongoing, issuers are required to cover, without cost sharing, the administration of a recommended COVID-19 vaccine by any provider authorized to perform the service, regardless of whether the provider is a participating network provider. Issuers should engage with state departments on their intention to bill and work with state entities on how best to allow them to bill issuers directly if needed.

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What other items and services along with vaccine administration fees must be covered (without cost sharing)?

- The recently issued Interim Final Rule clarifies that issuers must also cover, without cost sharing, items and services that are integral to the furnishing of a recommended preventive service, including a recommended COVID-19 vaccine. Additionally, if a COVID-19 vaccine is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of the COVID-19 vaccine, then the issuer may not impose cost-sharing requirements with respect to the office visit.

How will issuers have access to vaccine administration data for tracking purposes?

- CMS intends to create product-specific vaccine codes for each approved vaccine and issuers should receive claims for vaccine administration of their enrollees. Please review the CDC data tracking guidelines here in the CDC vaccination playbook³

Quality

CMS will also be supporting efforts to encourage COVID-19 vaccination through its quality and value based incentive programs for Exchange and Medicare Advantage plans, and is considering publishing vaccination rates. For example, CMS is soliciting comment on the creation of a quality measure for Part C Star ratings to measure the receipt of the COVID-19 vaccination.

CMS is also partnering with the CDC to develop quality measures to reflect both patient and personnel vaccination measures to be used as appropriate in programs such as those for nursing homes and dialysis facilities. In addition, as a reminder, CMS offers credit in the provider MIPS program for participation in COVID-19 clinical trials and clinical registries, offering points for Improvement Activities.

Enrollee Outreach

Health insurance issuers play an important role in communicating with their enrollees. As stated in the CDC's COVID vaccine playbook, issuers are encouraged to work with states as they convene teams of experts to develop, coordinate, and implement the state vaccine program. In particular, CMS encourages health insurance issuers to help their enrollees, providers, and the larger community understand the importance of vaccination. Health insurance issuers are encouraged to use all available tools to reach out to their enrollees, such as direct-to-consumer channels including emails, phone calls, and mailings. Issuers should make every effort to amplify CDC communications that identify which populations are prioritized for vaccination and how eligible enrollees can access vaccine services.

³ https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf
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The CDC recommends that issuers and plans regularly review resources at
<https://www.cdc.gov/coronavirus/2019-ncov/communication/>

Issuers are encouraged to use the following messaging as a guide in your communications with your enrollees when a COVID-19 vaccine is available

- What enrollees should know: You can get a COVID-19 vaccine at no charge to you.
- What enrollees should do: You can get your COVID vaccine free of charge at a location that is most convenient for you – don’t wait. Use the VaccineFinder app to find a vaccine provider.⁴ More than one COVID-19 vaccine may be available and some vaccines may require a second dose. If an additional dose is required, it’s important you get both doses of the vaccine within the timelines suggested.
- When should enrollees get a vaccine? The CDC has issued guidelines⁵ to help states, localities and territories develop their vaccine programs and establish populations for prioritized vaccination.⁶ You should look to the guidelines issued for your state, locality or territory and see how you fit in.
- What else can enrollees do right now? There have been significant decreases in routine immunizations during the public health emergency. You should get all recommended immunizations and vaccines including your flu vaccine, if you haven’t already. Follow CDC guidelines, including washing your hands often, keeping a social distance, wearing a mask or face covering, , covering your nose and mouth when around others, covering your mouth and nose with a tissue when you cough or sneeze into your elbow if one is not available, cleaning and disinfecting and monitoring your health daily.⁷

Beneficiary Incentives

CMS will be providing more information regarding whether beneficiary incentives will be permitted in connection with COVID-19 vaccination during the public health emergency in the context of Medicaid and Medicare.

⁴ <https://vaccinefinder.org/find-vaccine>

⁵ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html>

⁶ https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

⁷ <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html>

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