

TOOLKIT ON COVID-19 VACCINE: HEALTH INSURANCE ISSUERS AND MEDICARE ADVANTAGE PLANS (Updated January 7, 2021)

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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 and consumers. In addition, CMS is taking action to increase Medicare reimbursement for any new coronavirus disease 2019 (COVID-19) treatments that are authorized or approved by the Food and Drug Administration (FDA).

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). As safe and effective COVID-19 vaccines become available, CMS issued 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 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; and
- 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>.

Updated 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. ***New* Vaccine Emergency Use Authorization:** On December 11, 2020, the FDA issued an Emergency Use Authorization (EUA) for use of the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 for individuals 16 years of age and older, as described in the Scope of Authorization (Section II) of the response letter¹, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act) (21 U.S.C. 360bbb-3). The vaccine contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. It is an investigational vaccine not licensed for any indication. On December 12, 2020, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation² for use of the Pfizer-BioNTech COVID-19 vaccine in persons aged ≥ 16 years for the prevention of COVID-19.³

On December 18, 2020, the FDA issued an EUA for the Moderna COVID-19 Vaccine for use for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. The vaccine contains a nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles.⁴ On December 19, 2020, after a transparent and evidence based review of available data, the ACIP issued an interim recommendation for use of the Moderna COVID-19 vaccine in persons aged ≥ 18 years for the prevention of COVID-19.⁵

2. **Dose sequence:** 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

¹ <https://www.fda.gov/media/144412/download>

² On December 12, 2020, ACIP voted 11–0 (three recusals) in favor of the interim recommendation for use of Pfizer-BioNTech COVID-19 vaccine. Three ACIP members recused themselves because of participation in clinical trials and/or other studies involving companies producing COVID-19 vaccines. The recommendation was adopted by the Director of the CDC on December 13, 2020.

³ <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6950e2-H.pdf>

⁴ <https://www.fda.gov/media/144636/download>

⁵ <https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e1.htm>

resources to engage patients for both initial vaccination and then completion of the vaccine series in advance of vaccine receipt.

3. ***Updated*** Priority of overall vaccine distribution: While vaccine supply is limited, distribution may be done in phases to certain prioritized populations and initially through a limited set of providers and pharmacies. The ACIP and the Centers for Disease Control and Prevention (CDC) have issued recommendations regarding which groups to prioritize for vaccination during the initial phases of vaccine distribution. ACIP recommendations are available at: <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html>. Issuers, 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 these recommendations, and to reach out to enrollees, in particular to populations that are traditionally hard to reach. We encourage issuers to review the CDC Interim playbook for more information on distribution phases, how prioritized populations will be identified, and the types of providers who will be distributing vaccines in each phase (https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf)
4. 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 EUA Fact Sheets on the vaccine and vaccination cards. They must also 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 administration can request reimbursement for the administration of the COVID-19 vaccine through the Provider Relief Fund, see <https://www.hrsa.gov/CovidUninsuredClaim>.

5. ***New*** Cold-chain: While most COVID-19 vaccines are stored in a standard refrigerator or freezer, some COVID-19 vaccines will require ultra-low temperature storage (e.g., -70° Celsius). This may prove challenging for transporting, storing, and handling of the vaccines as temperature fluctuations at any point across the cold chain may influence the efficacy of the vaccine.

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.⁶
- 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.

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

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 (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.

***Updated* Issuer Coverage Out Of Network**

- Pursuant to an Interim Final Rule issued 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.⁷

- 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.
- These out of network provisions will sunset at the end of the PHE.

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 – including through 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.

***New* Out of Network Billing Operations**

CMS has been working to support stakeholders in operationalizing the requirement that private health plans and issuers cover a recommended COVID-19 vaccine and its administration, both in-network and out-of-network, with no cost sharing. Our understanding is that there are a number of pharmacy benefit managers (PBMs) and pharmacy software providers who are making system changes to be able to send reimbursement transactions smoothly. CMS continues to work with stakeholders to ensure that they have the operational systems in place to accept and process out of network claims.

***Updated* Vaccine Coding**

After the 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 vaccine administration code(s) for each dose for Medicare payment. Each vaccine product will have its own codes for the vaccine and administration(s). The [list of codes](#) can be found at the linked page.

⁷ <https://www.cms.gov/files/document/covid-vax-ifc-4.pdf>

Medicare Payment Rates

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. This would mean that there would be two separate administration fees reimbursed to providers administering multi-dose vaccines. 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.

New Therapeutics Coverage

On November 9, 2020, the FDA issued an EUA for the investigational monoclonal antibody therapy, bamlanivimab, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients with positive COVID-19 test results who are at high risk for progressing to severe COVID-19 and/or hospitalization. Bamlanivimab may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary. Review the [Fact Sheet for Health Care Providers EUA of Bamlanivimab regarding the limitations of authorized use](#).

On November 21, 2020, the FDA issued an EUA for the investigational monoclonal antibody therapy, casirivimab and imdevimab, administered together, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients with positive COVID-19 test results who are at high risk for progressing to severe COVID-19 and/or hospitalization. Similar to bamlanivimab, casirivimab and imdevimab may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary. Review the [Fact Sheet for Health Care Providers EUA of Casirivimab and Imdevimab regarding the limitations of authorized use when administered together](#).

During the COVID-19 PHE, Medicare will cover and pay for these infusions (when furnished consistent with their respective EUAs) the same way it covers and pays for COVID-19 vaccines. For more information in how CMS intends to cover and reimburse monoclonal antibody treatment for Medicare beneficiaries please review the program instructions available on our website (<https://www.cms.gov/files/document/covid-medicare-monoclonal-antibody-infusion-program-instruction.pdf>)

New Nursing Home Vaccination Reimbursement

The federal government is contracting with pharmacies to administer vaccines in nursing facilities. Some patients in nursing homes may have commercial insurance, and therefore issuers may receive claims for vaccine administration to these patients. We anticipate that entities administering vaccines to these patients would bill issuers regardless of whether the entity is in the issuers' provider network. Issuers are required, during the PHE, to cover the vaccine administration fee with zero cost sharing both in and out of network. Issuers are not required to add vaccine providers to their networks, but we encourage issuers to take steps to include a wide array of vaccinators in their networks.

New Reimbursement for Vaccination of Health Care Personnel

The federal government has purchased and will be allocating vaccines to providers for essential workers based on state requests for allocation and product availability. The amount allotted will change over time, which may be based on critical populations recommended for vaccination by ACIP (with input from NASEM), COVID-19 vaccine production and availability, and overall population of the jurisdiction.

While some health care facilities may absorb the costs of administration to employees, facilities may also bill issuers for the cost of this vaccine administration to their employees, and issuers should coordinate with facilities on their plans for reimbursement of vaccine administration. Issuers are required, during the PHE, to cover the vaccine administration fee with zero cost sharing both in and out of network.

New Vaccine Tracking

The federal government is using the Tiberius platform, a cutting-edge data platform to collect, correlate and visualize data across the entire operation. It is loaded with data from various sources — U.S. Census, Department of Health and Human Services, State Health Offices and the CDC. Tiberius integrates the data related to manufacturing, clinical trials, supply chain, allocation, state and territory planning, delivery and administration of both vaccine products and kits containing needles, syringes and other supplies needed to administer the vaccine. No personally identifiable or personal health information is contained in the Tiberius system.⁸ Jurisdictions may also have Immunization Information Systems (IISs), also known as "vaccine registries," which are confidential, population-based, computerized databases for recording information on vaccine doses.⁹ Unfortunately, issuers will not have access to the federal and

⁸ <https://www.defense.gov/Explore/News/Article/Article/2410195/technology-expertise-help-determine-vaccine-distribution/>

⁹ https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

state systems for vaccine tracking, similar to the flu vaccination process. However, issuers should receive claims for vaccine administration when it is billed by the provider which may be helpful in identifying enrollee vaccinations.

Updated Other Reimbursement Considerations and Frequently Asked Questions

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). We encourage issuers to work with state and local jurisdictions on their outreach plans.

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

- For the duration of the COVID-19 PHE, 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.

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

- 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 is creating product-specific vaccine codes for each approved vaccine, and issuers will be able to use these codes to track which vaccine enrollees receive, to the extent the issuer is billed for the administration of the vaccine. Please review the CDC data tracking guidelines here in the CDC vaccination playbook¹⁰

***New* Will vaccine be distributed outside of the federal government process and if so, will issuers be expected to reimburse these providers for the cost of the vaccine?**

- At this point, we anticipate that all vaccine in the initial phases will be distributed by the federal government, paid for by the federal government and that providers administering vaccine will be subject to government provider agreements. Issuers will be updated on any changes to the current federal vaccine purchasing system.

***New* What are the expectations for issuers to accept "roster bills" from "non-traditional health care entities" that serve as "mass immunizers"?**

- Issuers are not required to add vaccine providers to their networks, but we encourage issuers to take steps to include a wide array of vaccinators in their networks. There is a list of Medicare providers that are currently enrolled as Mass Immunizers/Centralized flu billers on our website. (<https://data.cms.gov/dataset/Medicare-Enrolled-Mass-Immunizers/6ema-6fpj/>)

***New* Can enrollees file an appeal to their plan for adverse benefit determination if they are denied a COVID-19 vaccine by a provider?**

- No. Section 3203 of the CARES Act generally requires group health plans and health insurance issuers offering group or individual health insurance to cover without cost sharing any qualifying coronavirus preventive service. A decision by a provider, including a provider integrated with a health plan, to delay administration of a vaccination against COVID-19 due to the fact that such vaccination would be inconsistent with CDC priority and or local COVID vaccine distribution guidelines is not an appealable adverse benefit determination made by a health plan or health insurance issuer under Section 2719 of the Public Health Service Act."

¹⁰ https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

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.

Updated 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 to encourage COVID-19 vaccinations. Issuers may also reach out to enrollees to remind them to keep up to date on their routine primary and chronic disease care despite the COVID -19 pandemic. 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.

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.¹¹ More than one COVID-19 vaccine may be available and some vaccines may

¹¹ <https://vaccinefinder.org/find-vaccine>

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 guidelines¹² to help states, localities and territories develop their vaccine programs and establish populations for prioritized vaccination.¹³ 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.¹⁴

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.

¹² <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html>

¹³ https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

¹⁴ <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html>