

TOOLKIT ON COVID-19 VACCINE: HEALTH INSURANCE ISSUERS AND MEDICARE ADVANTAGE PLANS (updated as of April 6, 2022)

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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 coronavirus disease 2019 (COVID-19) 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-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 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 to them.

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

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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. Vaccine Emergency Use Authorization and Biologics License Application:

On December 12, 2020, the Advisory Committee on Immunization Practices (ACIP) recommended “For purposes of ACIP’s role under the Affordable Care Act, ACIP recommends use of COVID-19 vaccines within the scope of the Emergency Use Authorization [EUA] or Biologics License Application [BLA] for the particular vaccine.”¹ The Director of the Centers for Disease Control and Prevention (CDC) adopted this recommendation on December 12, 2020. On October 4, 2021, the Departments of Health and Human Services, Labor and the Treasury clarified that non-grandfathered group health plans and non-grandfathered group and individual health insurance coverage must cover COVID-19 vaccines and their administration without cost sharing immediately upon the vaccine becoming authorized under an EUA or approved under a BLA, and consistent with the scope of the EUA or BLA.² This coverage requirement became effective 15 business days after the December 12, 2020 adoption by the CDC. Because plans and issuers may reasonably not have understood when coverage without cost sharing was required to begin under section 3203 of the CARES Act for COVID-19 vaccines authorized or approved (or for which the EUA or BLA was amended) since the December 12, 2020 recommendation was adopted, the Departments will only enforce the timing requirement to cover, without cost sharing, any COVID-19 vaccine authorized under an EUA or approved under a BLA by the FDA immediately upon the vaccine becoming authorized or approved (or the EUA or BLA being amended) prospectively, consistent with the scope of the particular EUA or BLA, to the extent additional coverage beyond what was articulated in previous guidance is required.

¹ See <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-12/COVID-04-VOTE508.pdf>. See also CDC Adult and Child and Adolescent Immunization Schedules, incorporating the December 12, 2020 ACIP recommendation, respectively at <https://www.cdc.gov/vaccines/schedules/downloads/adult/adultcombined-schedule.pdf> and <https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combinedschedule.pdf>.

² FAQs About Affordable Care Act Implementation Part 50, Health Insurance Portability and Accountability Act and Coronavirus Aid, Relief, and Economic Security Act Implementation. October 4, 2021.

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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 letter³, 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.

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 February 27, 2021, the FDA issued an EUA for the Janssen COVID-19 Vaccine for use for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older. The vaccine contains a recombinant, replication-incompetent human adenovirus serotype 26 (Ad26) vector, encoding the SARS-CoV-2 viral spike (S) glycoprotein, stabilized in its pre-fusion form.⁵

On May 10, 2021, the FDA expanded the EUA for the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 caused by SARS-CoV-2 to include adolescents 12 through 15 years of age. The FDA amended the EUA originally issued on December 11, 2020, for administration in individuals 16 years of age and older.

On August 12, 2021, the FDA amended the EUAs for both the Pfizer-BioNTech COVID-19 Vaccine and the Moderna COVID-19 Vaccine to allow for the use of an additional dose in certain immunocompromised individuals, specifically, solid organ transplant recipients or those who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.⁶

On August 23, 2021, the FDA approved the Pfizer-BioNTech COVID-19 vaccine, which is now being marketed as Comirnaty, for the prevention of COVID-19 in individuals ages 16

³ <https://www.fda.gov/media/144412/download>

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

⁵ [Janssen COVID-19 Vaccine EUA Letter of Authorization \(fda.gov\)](https://www.fda.gov/oc/2021/02/janssen-covid-19-vaccine-eua-letter-of-authorization)

⁶ <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised>.

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and older.⁷ The Pfizer-BioNTech COVID-19 vaccine continues to be available under the previous EUA for individuals ages 12 to 15, as well as for certain immunocompromised individuals who are eligible to receive a third dose.

On September 22, 2021, the FDA amended the EUA for the Pfizer-BioNTech COVID-19 vaccine to allow for use of a single booster dose administered at least six months following the completion of the primary series for the following populations: 1) individuals 65 years and older; 2) individuals 18-64 at high risk of severe COVID-19; and 3) individuals 18-64 whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.⁸

On October 20, 2021, the FDA amended the EUAs for currently available COVID-19 vaccines to expand the use of a booster dose in eligible populations.⁹ Specifically, the FDA authorized the use of a single booster dose of the Moderna COVID-19 vaccine that may be administered at least six months after the completion of the two-dose primary series to individuals: 1) 65 years of age and older, 2) ages 18-64 at high risk of severe COVID-19, and 3) ages 18-64 with frequent institutional or occupational exposure to SARS-CoV-2. Additionally, the FDA authorized the use of a single booster dose of the Janssen COVID-19 vaccine that may be administered at least two months after completion of the single-dose primary regimen to individuals 18 and older. The FDA also authorized the use of a heterologous booster dose for each FDA-authorized or approved COVID-19 vaccine to eligible individuals following completion of the primary vaccination with a different available COVID-19 vaccine. The FDA also clarified that a single booster dose for the Pfizer-BioNTech COVID-19 vaccine may be administered at least six months after the completion of the primary series to individuals 18-64 with frequent institutional or occupational exposure to SARS-CoV-2.

On October 29, 2021, the FDA amended the EUA for the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 to include children ages 5 through 11.¹⁰

⁷ <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine>

⁸ <https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations>

⁹ <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines>

¹⁰ <https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age>

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On November 19, 2021, the FDA amended the EUAs for both the Moderna and Pfizer-BioNTech COVID-19 vaccines to authorize use of a single booster dose for all individuals 18 and older.¹¹ Additionally, individuals must have completed the primary vaccination series for the Moderna or Pfizer-BioNTech COVID-19 vaccine at least six months prior to receiving their booster dose, and at least two months after completion of the primary vaccination with the Janssen COVID-19 vaccine.

On December 9, 2021, the FDA amended the EUA for the Pfizer-BioNTech COVID-19 vaccine to authorize the use of a single booster dose to individuals ages 16 and 17 at least six months after completing the primary vaccination series with the Pfizer-BioNTech COVID-19 vaccine.¹²

On January 3, 2022, the FDA amended the EUA for the Pfizer-BioNTech COVID-19 vaccine to: 1) expand the use of a single booster dose to include use in individuals ages 12-15 years, 2) shorten the time between completion of the primary vaccination series for the Pfizer-BioNTech COVID-19 vaccine and a booster dose to at least five months, and 3) allow for a third primary series dose for certain immunocompromised children ages 5-11.¹³

On January 7, 2022, the FDA amended the EUA for the Moderna COVID-19 vaccine to shorten the time between completion of the primary vaccine series and the booster dose to at least five months for individuals 18 and older.¹⁴

On January 31, 2022, the FDA approved the Moderna COVID-19 vaccine, which is now being marketed as Spikevax, for the prevention of COVID-19 in individuals ages 18 and older.¹⁵

On March 29, 2022, the FDA amended the EUAs for the Pfizer-BioNTech and Moderna COVID-19 vaccines to authorize a second booster dose for older individuals and certain

¹¹ <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-covid-19-vaccine-boosters>

¹² <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-pfizer-biontech-covid-19-booster-dose-16-and-17>

¹³ <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-multiple-actions-expand-use-pfizer-biontech-covid-19-vaccine>

¹⁴ <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-shortens-interval-booster-dose-moderna-covid-19-vaccine-five-months>

¹⁵ <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine>

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immunocompromised individuals.¹⁶ This second booster dose of either the Pfizer-BioNTech COVID-19 vaccine or the Moderna COVID-19 vaccine may be administered to individuals ages 50 and older at least four months after the first booster dose of any authorized or approved COVID-19 vaccine. A second booster dose of the Pfizer-BioNTech COVID-19 vaccine may be administered to individuals ages 12 and older with certain kinds of immunocompromise¹⁷ at least four months after receiving the first booster dose of any authorized or approved COVID-19 vaccine. A second booster dose of the Moderna COVID-19 vaccine may be administered to individuals ages 18 and older with the same aforementioned kinds of immunocompromise at least four months after receiving the first booster dose of any authorized or approved COVID-19 vaccine.

2. Dose sequence: Vaccine dose sequence varies depending on the vaccine administered.¹⁸ The Pfizer-BioNTech and Moderna COVID-19 vaccines are part of a two-dose primary series, while the Janssen COVID-19 vaccine is a one-dose primary series.¹⁹ Two booster doses are available for the following vaccines: 1) the Pfizer-BioNTech COVID-19 booster doses are authorized for individuals age 12 and older, 2) the Moderna COVID-19 booster doses are authorized for individuals age 18 and older. A single booster dose of the Janssen COVID-19 booster dose is authorized for individuals age 18 and older.²⁰ 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.
3. Priority of overall vaccine distribution: Distribution may be done in phases to certain prioritized populations and initially through a limited set of providers and pharmacies. The ACIP and the CDC issued recommendations regarding which groups to prioritize for vaccination. ACIP recommendations are available at: <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html>. 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

¹⁶ <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-second-booster-dose-two-covid-19-vaccines-older-and>

¹⁷ These are people who have undergone solid organ transplantation, or who are living with conditions that are considered to have an equivalent level of immunocompromise.

¹⁸ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html>

¹⁹ Moderately or severely immunocompromised individuals are also eligible for an additional primary series dose to improve their response to their initial vaccine series. More information can be found at <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html>

²⁰ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html>

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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.
5. Provider Reimbursement for the Uninsured: Providers administering the vaccine to people without health insurance can request reimbursement for the administration of the COVID-19 vaccine through the Provider Relief Fund, specifically the Health Resources and Services Administration (HRSA) COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment, and Vaccine Administration for the Uninsured program (HRSA COVID-19 Uninsured Program). Providers can familiarize themselves with this process at <https://www.hrsa.gov/CovidUninsuredClaim>, and learn more and file claims at <https://coviduninsuredclaim.linkhealth.com/>.
6. Provider Reimbursement for the Underinsured: In addition, providers administering the vaccine to underinsured individuals, that is, individuals with health insurance that either does not include the COVID-19 vaccine administration fees as a covered benefit or covers the COVID-19 vaccination administration but with cost sharing can request reimbursement for the costs incurred for administration of the COVID-19 vaccine through the HRSA COVID-19 Coverage Assistance Fund (CAF). Providers can familiarize themselves with this process at <https://www.hrsa.gov/covid19-coverage-assistance>, and learn more and file claims at <https://covid19coverageassistance.ssigroup.com/>

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7. 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.²¹
- For vaccines that require multiple doses, encourage providers to communicate to their patients to get both doses of the same primary vaccine series, as well as booster doses for individuals 12 and older within the recommended timeline.
- 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.
- Ensure providers are prepared to provide information regarding the effectiveness and safety of the COVID-19 vaccine to children ages 5 to 11 who are receiving the vaccine.

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 Advantage plan as of January 1, 2022, or the Provider Relief Fund). Issuers of non-grandfathered group or individual health insurance coverage are required to cover without cost sharing the vaccine and its administration when provided by a network provider, and during the COVID-19 PHE, are also required to cover without cost sharing the vaccine and its administration when provided by an

²¹ https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

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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 Payment

- For Calendar Years (CYs) 2020 and 2021, Medicare payment for the COVID-19 vaccine (if providers do not receive it for free) and its administration for beneficiaries enrolled in Medicare Advantage plans will be made through the Original Medicare program.
- For CY 2022, Medicare payment for the COVID-19 vaccine (if providers do not receive it for free) and its administration for beneficiaries enrolled in a Medicare Advantage plan will be made by the beneficiary's Medicare Advantage plan. Original Medicare won't pay COVID-19 vaccine administration claims for Medicare Advantage beneficiaries vaccinated on or after January 1, 2022.
- Medicare Advantage plans should update their contracted providers about this coverage policy change in advance of CY 2022 and direct them to submit claims for administering the COVID-19 vaccine to the Medicare Advantage plan.

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—(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 with respect to the individual involved (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. ACIP recommends use of COVID-19 vaccines within the scope of the EUA or BLA for the particular vaccine.²² Thus, issuers must cover administration of a COVID-19 vaccine immediately upon authorization or approval, including an amendment to the applicable EUA or BLA.

²² See <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-12/COVID-04-VOTE508.pdf>. See also CDC Adult and Child and Adolescent Immunization Schedules, incorporating the December 12, 2020 ACIP recommendation, respectively at <https://www.cdc.gov/vaccines/schedules/downloads/adult/adultcombined-schedule.pdf> and <https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combinedschedule.pdf>.

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- The U.S. Department of Health & Human Services (HHS) acknowledges that it would not be possible for issuers to comply with any applicable advance notice of modification requirements regarding qualifying coronavirus preventive services, as such services must be covered on the expedited timeframe specified by statute. Accordingly, HHS will not take enforcement action against any issuer that does not provide at least 60 days' advance notice of a material modification regarding the addition of coverage for qualifying coronavirus preventive services. However, issuers must provide any required notice of changes as soon as reasonably practicable.
- 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 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 qualifying coronavirus preventive services, including a COVID-19 vaccine and its administration, provided by in-network providers and during the COVID-19 PHE, when provided by out-of-network providers as well.²³
- For in-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

²³ <https://www.cms.gov/files/document/covid-vax-ifc-4.pdf>

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provider relief fund, but may not charge enrollees directly for any vaccine administration costs.

Out of Network Billing Operations

CMS has been working to support stakeholders in operationalizing the requirement that issuers of non-grandfathered health insurance coverage 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.

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. Additionally, on October 6, 2021, the American Medical Association issued Current Procedural Terminology codes for the pediatric (ages 5-11) vaccine and administration. This will allow issuers and plans to update their systems to allow proper coding for the administration of the COVID-19 vaccines for pediatric populations.²⁴

Medicare Payment Rates

On March 15, 2021, CMS updated the Medicare payment rates for administering COVID-19 vaccines. On August 12, 2021, the FDA updated the emergency use authorizations (EUAs) for the Pfizer-BioNTech and Moderna COVID-19 vaccines to authorize the use of additional doses of the vaccine for immunocompromised individuals. The FDA updated EUAs to authorize booster doses for certain populations:

- September 22, 2021: Pfizer-BioNTech vaccine
- October 20, 2021: Moderna and Janssen vaccines
- March 29, 2022: Pfizer-BioNTech and Moderna vaccines

For COVID-19 vaccines administered on or after March 15, 2021; additional doses of the COVID-19 vaccine administered to immunocompromised individuals on or after August 12, 2021; and booster doses administered to certain populations on or after September 22, 2021, for the

²⁴ <https://www.ama-assn.org/press-center/press-releases/ama-announces-cpt-update-pediatric-covid-19-vaccine-candidate>

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Pfizer-BioNTech vaccine and October 20, 2021, for the Moderna and Janssen vaccines, the Medicare payment rates for administering the vaccines are:

- Approximately \$40 for single-dose vaccines
- For vaccines requiring multiple doses, approximately \$40 for each dose in the series, including any additional doses and booster doses

These rates reflect updated information about the costs involved in administering the COVID-19 vaccine for different types of providers and suppliers and the additional resources you need to safely and appropriately administer the vaccine.

We generally implement changes to Medicare payment rates for specific services through notice and comment rulemaking. In this case, however, we implemented the payment rate changes for these specific services to respond quickly to new information during the COVID-19 public health emergency (PHE).

For COVID-19 vaccines administered before March 15, 2021, the Medicare payment rates are:

- \$28.39 for single-dose vaccines
- For vaccines requiring a series of 2 or more doses:
 - \$16.94 for the initial dose(s) in the series
 - \$28.39 for the final dose in the series

For all COVID-19 vaccine payment rates listed above, we also geographically adjust the rates based on where you administer the vaccine.

Note:

These rates don't apply if Medicare pays you for preventive vaccines and their administration at reasonable cost (for example, federally qualified health centers, rural health clinics, and hospital-based renal dialysis facilities). Also, as indicated in the [2021 Medicare Physician Fee Schedule Final Rule](#), we continue to seek additional information from the public for further consideration as we review and establish payment rates for vaccine administration services during the PHE and on a longer term basis.

[Get the most current list of billing codes, payment allowances and effective dates.](#)

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Additional Payment for Administering the Vaccine in the Patient's Home

View the infographic ([English \(PDF\)](#)) ([Spanish \(PDF\)](#)) for COVID-19 vaccine administration in the home.

Effective June 8, 2021, Medicare's additional payment amount for administering the COVID-19 vaccine in the home for certain Medicare patients is approximately \$35 per dose. This payment also applies when:

- Additional doses of the COVID-19 vaccine are administered in the home to certain Medicare patients on or after August 12, 2021
- Booster doses are administered in the home to certain Medicare patients on or after September 22, 2021, for the Pfizer-BioNTech vaccine and October 20, 2021, for the Moderna and Janssen vaccines.

Medicare will pay approximately the \$35 amount in addition to the standard administration amount (approximately \$40 per COVID-19 vaccine dose), for a total payment of approximately \$75 for a vaccine dose administered in a patient's home. We also geographically adjust the additional amount and administration rate based on where you administer the vaccine.

We established this payment amount of approximately \$35 on a preliminary basis to ensure access to COVID-19 vaccines during the PHE. We continue to evaluate the needs of Medicare patients and these policies, and we'll address them in the future, as needed.

When Can I Get the Additional In-Home Payment for Administering the COVID-19 Vaccine?

You can get the additional payment for administering the COVID-19 vaccine in Medicare patients' homes when either of these situations applies:

- The patient has difficulty leaving the home to get the vaccine, which could mean any of these:
 - They have a condition, due to an illness or injury, that restricts their ability to leave home without a supportive device or help from a paid or unpaid caregiver
 - They have a condition that makes them more susceptible to contracting a pandemic disease like COVID-19

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- They are generally unable to leave the home, and if they do leave home it requires a considerable and taxing effort
- The patient is hard-to-reach because they have a disability or face clinical, socioeconomic, or geographical barriers to getting a COVID-19 vaccine in settings other than their home. These patients face challenges that significantly reduce their ability to get vaccinated outside the home, such as challenges with transportation, communication, or caregiving.

Unlike the requirements under the Medicare home health benefit, you or another allowed practitioner don't need to certify that the Medicare patient is homebound, but you must document in the patient's medical record their clinical status or the barriers they face to getting the vaccine outside the home.

What Locations Qualify for the Additional In-Home Payment?

Many types of locations can qualify as a Medicare patient's home for the additional in-home payment amount, such as:

- A private residence
- Temporary lodging (for example, a hotel or motel, campground, hostel, or homeless shelter)
- An apartment in an apartment complex or a unit in an assisted living facility, group home or non-Medicaid nursing facility
- A Medicare patient's home that's made provider-based to a hospital during the COVID-19 PHE
- Effective August 24, 2021, communal spaces of a multi-unit or communal living arrangement
- Effective August 24, 2021, assisted living facilities participating in the CDC's Pharmacy Partnership for Long-Term Care Program when their residents are vaccinated through this program

Note:

In response to the COVID-19 PHE, [CMS issued several 1135 waivers \(PDF\)](#) to let hospitals provide services, including administering vaccines, in temporary expansion sites. CMS doesn't pay for preventive vaccine administration under the Outpatient Prospective Payment System (OPPS) or the Physician Fee Schedule (PFS). So, we pay hospitals to administer COVID-19 vaccines at the same rate even in a non-accepted off-campus

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provider-based department (PBD), including a patient's home that is made provider-based to a hospital during the COVID-19 PHE.

These locations don't qualify as a home for the additional payment amount:

- Prior to August 24, 2021, communal spaces of a multi-unit living or communal arrangement
- Hospitals (except when the Medicare patient's home has been made provider-based to a hospital during the COVID-19 PHE)
- Medicare skilled nursing facilities (SNFs) and Medicaid nursing facilities, regardless of whether they're the patient's permanent residence

What Other Restrictions Apply?

Medicare only pays the additional amount for administering the COVID-19 vaccine in the home if the sole purpose of the visit is to administer a COVID-19 vaccine. Medicare doesn't pay the additional amount if you provide another Medicare service in the same home on the same date. In those situations, Medicare pays for administering the COVID-19 vaccine at the standard amount (approximately \$40 per dose).

If you administer the COVID-19 vaccine to more than 1 Medicare patient in a single home in the same multi-unit or communal living arrangement on the same day, Medicare pays:

- Approximately \$40 to administer each dose of the COVID-19 vaccine, including additional doses and booster doses
- For dates of service between June 8, 2021 and August 24, 2021, Medicare pays the additional payment amount of approximately \$35 only once per date of service in that home regardless of how many Medicare patients receive the vaccine
- Effective on August 24, 2021, Medicare pays the additional payment amount (approximately \$35 per dose administered), for up to a maximum of 5 vaccine administration services per home unit or communal space within a single group living location; but only when fewer than 10 Medicare patients receive a COVID-19 vaccine dose on the same day at the same group living location. When 10 or more Medicare patients receive a COVID-19 vaccine dose at a group living location on the same day, the

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additional payment can only be billed once per home (whether the home is an individual living unit or a communal space).

For example, if you administer a COVID-19 vaccine on the same date between June 8, 2021 and August 24, 2021 to 2 Medicare patients in the same home, Medicare pays approximately \$115 (\$35 for the in-home vaccine administration, plus 2 x \$40 for each dose of the COVID-19 vaccine).

Effective August 24, 2021, if you administer a dose of the COVID-19 vaccine on the same date to 2 Medicare patients in the same home, Medicare pays approximately \$150 (2 x \$35 for the in-home vaccine administration, plus 2 x \$40 for each dose of the COVID-19 vaccine). Similarly, effective August 24, 2021, if you administer a dose of the COVID-19 vaccine on the same date to 9 Medicare patients in the same home (including a communal space in a group living setting), Medicare pays approximately \$535 (5 x \$35 for the in-home vaccine administration, plus 9 x \$40 for each dose of the COVID-19 vaccine). Similarly, effective August 24, 2021, if you administer a dose of the COVID-19 vaccine on the same date to 12 Medicare patients in the same home (which could be an individual living unit or a communal space in a group living location), Medicare would pay approximately \$515 (12 x \$40 for each dose of COVID-19 vaccine, and 1 x \$35 for one in-home vaccine administration – only one home add-on payment is billable in this circumstance because 10 or more Medicare patients were vaccinated at the same group living location on the same date). If you instead administer a dose of the COVID-19 vaccine on the same date to 12 Medicare patients in 12 different homes (i.e. each one administered in a distinct individual living unit or communal space of a group living location), Medicare would pay approximately \$900 (12 x \$40 for each dose administered, and 12 x \$35 for each in-home vaccine administration). Similarly, effective August 24, 2021, if you administer a dose of the COVID-19 vaccine on the same date to 5 Medicare patients in a communal space in a group living setting and to 3 additional Medicare patients in their individual rooms, Medicare would pay approximately \$600 (5 x \$35 for the in-home vaccine administration services in the single communal space, plus 3 x \$35 for each of the in-home vaccine administration services in individual homes, plus 8 x \$40 for each dose of the COVID-19 vaccine).

Therapeutics Coverage

Monoclonal Antibody Products to Treat COVID-19

[Review the infographic \(PDF\) on coverage of monoclonal antibody products to treat COVID-19.](#)

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[Review the most current and up to date information on Medicare payment for monoclonal antibody products to treat COVID-19](#)

The following the investigational monoclonal antibody therapies are available under FDA emergency use authorization (EUA):

- Casirivimab and imdevimab, administered together (EUA issued November 21, 2020, latest update July 30, 2021)
- Bamlanivimab and etesevimab, administered together (EUA issued February 9, 2021)
- Sotrovimab (EUA issued May 26, 2021)
- Tocilizumab (EUA issued June, 24 2021)

The FDA authorized the use of these monoclonal antibody therapies to treat mild-to-moderate COVID-19 in adults and pediatric patients when both of these apply:

- The patient has a positive COVID-19 test result
- The patient is at high risk for progressing to severe COVID-19, hospitalization, or both.

Note:

- Under the terms of the EUA, health care providers may only administer tocilizumab to hospitalized patients with severe COVID-19 illness. [See the FDA EUA for more information.](#)
- Under the terms of the EUA, casirivimab and imdevimab, administered together, are authorized in adult and pediatric individuals for treatment of COVID-19 and post-exposure prophylaxis for certain individuals who have been exposed to COVID-19 positive persons. [See the FDA EUA for more information and further limitations.](#)
- The FDA provided updates on the effectiveness of bamlanivimab and etesevimab, administered together, against different variants of COVID-19. [Get information on whether these are authorized in your area.](#)

[Learn more about treatment guidelines and recommendations for using monoclonal antibody therapies.](#)

For more information about the limits of authorized use for these monoclonal antibody therapies, including information about viral variants and antiviral resistance, review the following:

- [Fact Sheet for Health Care Providers EUA of Casirivimab and Imdevimab \(PDF\)](#)
- [Fact Sheet for Health Care Providers EUA of Bamlanivimab and Etesevimab](#)

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- [Fact Sheet for Health Care Providers EUA of Sotrovimab](#)
- [Fact Sheet for Health Care Providers EUA of Tocilizumab \(ZIP\)](#)

Important Update about Viral Variants

On April 16, 2021, [the FDA revoked the EUA for bamlanivimab, when administered alone](#), due to a sustained increase in COVID-19 viral variants in the U.S. that are resistant to the solo product.

Importantly, although the FDA revoked the EUA for bamlanivimab, when administered alone, alternative monoclonal antibody therapies remain available under EUA, including REGEN-COV (casirivimab and imdevimab, administered together), and bamlanivimab and etesevimab, administered together, for the same uses as previously authorized for bamlanivimab alone. The FDA indicates that alternative monoclonal antibody therapies remain appropriate to treat COVID-19 patients, and health care providers may continue using these authorized therapies:

- Casirivimab and imdevimab, administered together
- Bamlanivimab and etesevimab, administered together ([Get information on whether these are authorized in your area](#))
- Sotrovimab
- Tocilizumab

The FDA indicates using these other therapies may reduce the risk of treatment failure for patients infected with a COVID-19 viral variant that's resistant to bamlanivimab when administered alone. For details about specific variants and resistance, review the Antiviral Resistance information in Section 15 of each of the Fact Sheets listed above.

[Following your existing ordering and reporting procedures](#), you can still order the following from the authorized distributor:

- Casirivimab and imdevimab, to be administered together
- Bamlanivimab and etesevimab, to be administered together ([Get information on whether these are authorized in your area](#))

For more information about viral variants in your area to help you make treatment decisions:

- [Visit the CDC's website on Variant Proportions in the U.S.](#)
- Refer to information from your state and local health authorities

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Medicare Coverage for Monoclonal Antibody Products to Treat COVID-19

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.

Note: Medicare will only cover and pay for bamlanivimab (administered alone) if it was furnished, consistent with the terms of the EUA, between November 10, 2020 - April 16, 2021.

Our approach to paying for these products as COVID-19 vaccines during the PHE allows a broad range of providers and suppliers to administer these treatments, including but not limited to:

- Freestanding and hospital-based infusion centers
- Home health agencies
- Nursing homes
- Entities with whom nursing homes contract to administer treatment

To help skilled nursing facilities (SNFs) efficiently administer COVID-19 vaccines (including monoclonal antibody products to treat COVID-19) to residents, CMS has exercised enforcement discretion for certain statutory provisions and any associated statutory references and implementing regulations, including as interpreted in pertinent guidance (collectively, “SNF Consolidated Billing Provisions”). We allow Medicare-enrolled immunizers including, but not limited to, pharmacies working with the U.S., infusion centers, and home health agencies to bill directly and get direct payment from the Medicare Program for vaccinating Medicare SNF residents.

Health care providers administering the infusions of monoclonal antibody products to treat COVID-19 will follow the same enrollment process as those administering the COVID-19 vaccines. [Get provider enrollment information.](#)

Medicare Payment for Administering Monoclonal Antibody Products to Treat COVID-19

To ensure immediate access during the COVID-19 PHE, Medicare covers and pays for these infusions in accordance with [Section 3713 of the Coronavirus Aid, Relief, and Economic Security Act \(CARES Act\)](#). CMS will address potential refinements to payment for administering monoclonal antibody products to treat COVID-19 through future notice-and-comment rulemaking.

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Payment for Infusion

On May 6, 2021, CMS updated the Medicare payment rates for the administration of COVID-19 monoclonal antibody products. Effective for services furnished on or after May 6, 2021, the new Medicare payment rate for administering COVID-19 monoclonal antibody products, authorized or approved by the FDA, is approximately \$450. This rate applies to all providers and suppliers not paid reasonable cost for furnishing these products. The new rate reflects updated information about the costs involved in administering monoclonal antibody products for different types of providers and suppliers, and the additional resources necessary to ensure the products are administered safely and appropriately to COVID-19 positive patients. The rate is geographically adjusted based on where the service is furnished.

Note:

- Under the terms of the EUA, health care providers can only administer tocilizumab to hospitalized patients in limited clinical situations. The Medicare payment rate of approximately \$450 for the administration of COVID-19 monoclonal antibody products will apply for the administration of tocilizumab when you furnish it in accordance with the EUA.
- The EUA for tocilizumab also allows for 2 infusions for the same patient in limited situations. Medicare will pay approximately \$450 per infusion when 2 infusions are clinically necessary. As with payments for administering other COVID-19 monoclonal antibodies, the separate Medicare payment amount of \$450 per infusion of tocilizumab applies to all hospitals not paid reasonable cost for furnishing these products consistent with the EUA. CMS geographically adjusts the rate based on where you furnish the service. [Get the most current geographically adjusted rates.](#)

Note:

- The July 30, 2021 revised EUA for casirivimab and imdevimab allows for its use for post-exposure prophylaxis for certain patients who have been exposed to (or are at high risk of exposure to) a person with COVID-19. In these situations, use the following HCPCS codes to bill for casirivimab and imdevimab:
 - M0243 or M0244 when billing for the administration of the initial dose in a health care setting or the home
 - M0240 or M0241 when billing for the administration of any subsequent repeat doses in a health care setting or the home

Medicare also pays for treatment to address major complications:

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- As needed and appropriate
- Consistent with existing payment methodologies for the care setting where you provide the treatment

For COVID-19 monoclonal antibody products administered before May 6, 2021, the Medicare payment rate is approximately \$310.

Medicare will establish codes and rates for administering new products as the FDA approves or authorizes each product.

[Get the most current list of billing codes, payment allowances, and effective dates for currently authorized monoclonal antibody products.](#)

Payment for Infusion at Home

Beginning on May 6, 2021, Medicare established separate coding and payment for administering COVID-19 monoclonal antibody products in a patient's home or residence. Effective for services furnished on or after May 6, 2021, the Medicare payment rate for administering monoclonal antibody products in a patient's home or residence is approximately \$750. This rate reflects updated information about the costs involved in furnishing these complex products in a patient's home. For many providers and suppliers, CMS also geographically adjusts this rate based on where you furnish the service.

Note:

These rates don't apply if Medicare pays you for preventive vaccines and their administration at reasonable cost (for example, federally qualified health centers, rural health clinics, and hospital-based renal dialysis facilities). Also, as indicated in the [2021 Medicare Physician Fee Schedule Final Rule](#), we continue to seek additional information from the public for further consideration as we review and establish payment rates for vaccine administration services during the PHE and on a longer term basis.

Providers and suppliers may bill for the higher home payment rate when they furnish a COVID-19 monoclonal antibody product in a "home or residence." This includes circumstances such as a Medicare patient's permanent residence, temporary lodging (for example, hotel or motel, hostel, or homeless shelter), and homes or residences that have been made provider-based to the hospital during the COVID-19 PHE.

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If your Medicare patient's permanent residence is a setting that provides health care services, such as an intermediate care facility, nursing facility, or skilled nursing facility, that setting would also qualify as a "home or residence" for purposes of billing codes M0241, M0244, M0246, or M0248. However, if the patient is only in that location temporarily (such as if your patient has a permanent home but is in a post-acute stay in a skilled nursing facility), the setting isn't considered a patient's "home or residence" for this purpose, and you shouldn't bill for the higher "at home" HCPCS codes M0241, M0244, M0246, or M0248.

If you administer COVID-19 monoclonal antibodies to Medicare patients in traditional health care locations (for example, a hospital outpatient infusion clinic or freestanding infusion clinic), continue to bill HCPCS codes M0240, M0243, M0245, or M0247, as applicable. Inpatient locations, such as inpatient hospitals, inpatient psychiatric hospitals, long-term care hospitals, and inpatient rehabilitation hospitals, would never qualify as the "home or residence" for purposes of HCPCS codes M0241, M0244, M0246, or M0248.

Note:

Under the terms of the EUA, tocilizumab may only be infused in the hospital setting, in limited clinical situations. Providers may not furnish tocilizumab in the "home or residence," including homes or residences that have been made provider-based to the hospital during the COVID-19 PHE. As a result, Medicare hasn't created a separate HCPCS code for billing for the higher Medicare payment amount for administering tocilizumab in the home.

[Get the most current list of billing codes, payment allowances, and effective dates for currently authorized monoclonal antibody products.](#)

Payment for Product

In response to the COVID-19 PHE, the government initially purchased the monoclonal antibody products to treat COVID-19 and made them available for free. Medicare doesn't pay for the monoclonal antibody products to treat COVID-19 that providers get for free, including:

- Casirivimab and imdevimab, to be administered together
- Bamlanivimab and etesevimab, to be administered together

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The government won't purchase sotrovimab or tocilizumab and make them available for free. [Get the most current payment allowances and effective dates for the product.](#)

Note:

CMS pays for tocilizumab based on the number of units administered, so you should include the total number of units administered on the claim per day. For example, if you administer 200mg of tocilizumab in 1 infusion, you should add 200 as the number of units on the claim. If you give 2 infusions in the same day, you should include the total units for both infusions with the product code Q0249 on 1 line (per day).

CMS set the payment rate for COVID-19 monoclonal antibody products the same way we set the payment rate for COVID-19 vaccines. For example, Medicare will pay 95% of AWP for COVID-19 vaccines provided in the physician office setting, and pay hospital outpatient departments at reasonable cost for COVID-19 vaccines. Because CMS considers monoclonal antibody products to treat COVID-19 to be COVID-19 vaccines, they aren't eligible for the [New COVID-19 Treatments Add-on Payment \(NCTAP\)](#) under the Inpatient Prospective Payment System (IPPS).

federal federally-purchased

There's No Cost for Medicare Patients

There's no cost sharing for people with Medicare for these monoclonal antibody products to treat COVID-19:

- No copayment/coinsurance
- No deductible

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 subject to the requirement to cover certain preventive services without cost sharing 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.

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Additionally, the Social Security Act requires SNFs to bill for certain services, including vaccine administration, even when SNFs rely on an outside vendor to perform the service. See Social Security Act §§ 1862(a)(18), 1842(b)(6)(E). However, in order to facilitate the efficient administration of COVID-19 vaccines to SNF residents, CMS is exercising enforcement discretion with respect to these statutory provisions as well as any associated statutory references and implementing regulations, including as interpreted in pertinent guidance (collectively, “SNF Consolidated Billing Provisions”). Through the exercise of this discretion, CMS is allowing Medicare-enrolled immunizers, including but not limited to pharmacies working with the United States, to bill directly and receive direct reimbursement from the Medicare program for vaccinating Medicare SNF residents.

CMS is exercising this discretion (1) during the emergency period defined in paragraph (1)(B) of section 1135(g) of the Social Security Act (42 U.S.C. § 1320b-5(g)) and ending on the last day of the calendar quarter in which the last day of such emergency period occurs; or (2) so long as CMS determines that there is a public health need for mass COVID-19 vaccinations in congregate care settings—whichever is later. While CMS exercises this enforcement discretion, compliance with SNF Consolidated Billing Provisions is not material to CMS’ decision to reimburse for COVID-19 vaccine administration. If CMS decides in the future to cease exercising this enforcement discretion, CMS will provide public notice in advance and allow at least 60 days for affected outside immunizers to modify their business practices.

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 subject to the requirement to cover certain preventive services without cost sharing are required, during the PHE, to cover the vaccine administration fee with zero cost sharing both in and out of network.

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, HHS, State Health Offices and the CDC. Tiberius integrates the data

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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.²⁵ 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.²⁶ Unfortunately, issuers will not have access to the federal and 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.

Other Reimbursement Considerations and Frequently Asked Questions

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

- Although the federal government does not provide reimbursement for outreach activities by issuers, we strongly encourage issuers to help ensure that their eligible enrollees who have not yet gotten a vaccine or a booster shot, get one as soon as possible. Vaccines are the most powerful tools we have to protect people from serious illness and death, and boosters significantly strengthen protection against variants. 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, who 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 who are not exempt from Federal income tax, that 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 expense under 45 CFR 158.150(b)(2)(iv)(A)(4). We encourage issuers to work with state and local jurisdictions on their vaccination outreach plans. The costs of vaccination outreach may also qualify for MLR reporting and rebate calculation purposes as a health care quality improvement activity expense under 45

²⁵ <https://www.defense.gov/Explore/News/Article/Article/2410195/technology-expertise-help-determine-vaccine-distribution/>

²⁶ https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf
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CFR 158.150(b)(2)(iii), which provides for reporting of activities primarily designed to lower infection and mortality rates as quality improvement activity expenses.

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

- For the duration of the COVID-19 PHE, issuers subject to the requirement to cover certain preventive services without cost sharing are required to cover, without cost sharing, the administration of a recommended COVID-19 vaccine, regardless of whether the provider is a participating network provider. Issuers should engage with state departments on their intention to bill issuers, 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 must cover the office visit and 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 in the CDC vaccination playbook.²⁷

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

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

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

²⁷ https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

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- 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/search?keywords=Medicare%20Enrolled%20Mass%20Immunizers>)

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

- No. A decision by a provider, including a provider integrated with a health plan, to decline to administer a COVID-19 vaccine because an individual is not within a category prioritized for vaccination is not an adverse benefit determination made by a health plan or health insurance issuer, and therefore, the provider's decision is not appealable under section 2719 of the Public Health Service Act.²⁸

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 has solicited comment in the CY 2022 Advance Notice, issued on October 30, 2020, on the creation of a quality measure for Part C Star ratings to measure the receipt of the COVID-19 vaccination; a summary of those comments appeared in the CY 2022 Rate Announcement issued on January 15, 2021.²⁹

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 Skilled Nursing Facilities and ESRD facilities. In addition, as a reminder, under the MIPS program, CMS adopted the COVID-19 Clinical Data Reporting with or without Clinical Trial improvement activity for which eligible clinicians may receive credit for through the CY 2021 performance period.

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 and booster shots. Health insurance issuers are encouraged to use all available tools to reach out to their enrollees, such

²⁸ <https://www.cms.gov/files/document/faqs-part-44.pdf>

²⁹ The CY 2022 Advance Notice and CY 2022 Rate Announcement are available online at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents>.

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as direct-to-consumer channels including emails, phone calls, and mailings to encourage COVID-19 vaccinations and boosters. 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 or booster at no charge to you.
- What enrollees should do: You can get your COVID vaccine or booster free of charge at a location that is most convenient for you – don't wait. Use the VaccineFinder app to find a vaccine provider.³⁰ More than one COVID-19 vaccine may be available and some vaccines may require a second dose, or a booster. If an additional dose is required, it's important you get additional doses of the vaccine within the timelines suggested. Everyone age 16+ should get a booster shot as soon as you're eligible.
- When should enrollees get a vaccine? The CDC has issued guidelines³¹ to help states, localities and territories develop their vaccine programs and establish populations for prioritized vaccination.³² 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.³³

Incentives for COVID-19 Vaccine Shots

The Office of the Inspector General (OIG) released [FAQs](#) about applying its administrative enforcement authorities to situations related to the COVID-19 public health emergency,

³⁰ <https://vaccinefinder.org/find-vaccine>

³¹ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html>

³² https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

³³ <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html>

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including incentives for people who get the COVID-19 vaccine. [Read the OIG's response to: **Would the offer or provision of cash, cash-equivalent, or in-kind incentives or rewards to Federal health care program beneficiaries who receive COVID-19 vaccinations during the public health emergency violate OIG's administrative enforcement authorities?**](#)

The Departments of HHS, Labor, and the Treasury released FAQs to address whether group health plans and health insurance issuers offering group health insurance coverage may provide incentives, such as a premium discount, under the Patient Protection and Affordable Care Act and Health Insurance Portability and Accountability Act wellness program rules to encourage individuals to receive COVID-19 vaccines and how those incentives are treated for purposes of assessing affordability of coverage under the Patient Protection and Affordable Care Act. For more information, see <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-50.pdf>.

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