

Access to Vaccine and Therapeutics Update

Background



On October 28, 2020 CMS announced an Interim Final Rule with Comment Period (IFC) addressing coverage of Covid-19 Coronavirus vaccines and other therapeutics.¹

To ensure broad access to a vaccine for America's seniors, the IFC "establishes that any vaccine that receives Food and Drug Administration (FDA) authorization, either through an Emergency Use Authorization (EUA) or licensed under a Biologics License Application (BLA), will be covered under Medicare as a preventive vaccine at no cost to beneficiaries. The IFC also implements provisions of the CARES Act that ensure swift coverage of a COVID-19 vaccine by most private health insurance plans without cost sharing from both in and out-of-network providers during the course of the public health emergency (PHE)."

To ensure broad and consistent coverage across programs and payers, CMS created toolkits that have specific information for several programs, including:

Medicare: Beneficiaries with Medicare pay nothing for COVID-19 vaccines and their copayment/coinsurance and deductible are waived.

Medicare Advantage (MA): For calendar years 2020 and 2021, Medicare will pay directly for the COVID-19 vaccine and its administration for beneficiaries enrolled in MA plans. MA plans would not be responsible for reimbursing providers to administer the vaccine during this time. Medicare Advantage beneficiaries also pay nothing for COVID-19 vaccines and their copayment/coinsurance and deductible are waived.

Medicaid: State Medicaid and CHIP agencies must provide vaccine administration with no cost sharing for most beneficiaries during the public health emergency. Following the public health emergency, depending on the population, states may have to evaluate cost sharing policies and may have to submit state plan amendments if updates are needed.

Private Plans: CMS, along with the Departments of Labor and the Treasury, is requiring that most 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. The rule also provides that out-of-network rates cannot be unreasonably low, and references CMS's reimbursement rates as a potential guideline for insurance companies.

Uninsured: For individuals who are uninsured, providers will be able to be reimbursed for administering the COVID-19 vaccine to individuals without insurance through the Provider Relief Fund, administered by the Health Resources and Services Administration (HRSA).

Information on these toolkits and other topics including becoming a mass immunizer, may be found at <https://www.cms.gov/covidvax> and <https://www.cms.gov/covidvax-provider>.

The IFC news release also indicates that after the FDA either approves or authorizes a vaccine for COVID-19, CMS will identify the specific vaccine codes, by dose if necessary, and specific vaccine administration codes for each dose for Medicare payment. CMS and the American Medical Association (AMA) are working collaboratively on finalizing a new approach to report use of COVID-19 vaccines, which include separate vaccine-specific codes. Providers and insurance companies will be able to use these to bill for and track vaccinations for the different vaccines that are provided to their enrollees.

On November 10, 2020 the AMA subsequently published the vaccine codes and administration codes that will be available for use and effective upon each new coronavirus vaccine receiving Emergency Use Authorization (EUA) or approval from the Food and Drug Administration (FDA).²

- ✓ **91300** – *Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted, for intramuscular use*
- ✓ **91301** – *Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage, for intramuscular use*

The AMA indicated the CPT Editorial Panel worked with CMS to create new vaccine administration codes that are both distinct to each coronavirus vaccine and the specific dose in the required schedule. This level of specificity is a first for vaccine CPT codes, but offers the ability to track each vaccine dose, even when the vaccine product is

not reported (e.g. when the vaccine may be given to the patient for free). These CPT codes report the actual work of administering the vaccine, in addition to all necessary counseling provided to patients or caregivers and updating the electronic record.

- ✓ **0001A** – *Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted; first dose*
- ✓ **0002A** – *Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted; second dose*
- ✓ **0011A** – *Immunization administration by intramuscular injection of Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage; first dose*
- ✓ **0012A** – *Immunization administration by intramuscular injection of Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage; second dose*

The IFC included payment rates for administration services:

“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 two or more doses, the initial dose(s) administration payment rate will be \$16.94, and \$28.39 for the administration of the final dose in the series. These rates will be geographically adjusted and 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.”

CMS has created a link to a page that displays the vaccine codes and reimbursement amounts that will be updated as these become available. Providers may find this page at: <https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies>

CMS also released an MLN special edition article on October 28, 2020. This article discusses coverage of potential vaccines as well as coverage of other therapeutics used in the treatment of COVID-19:

“In anticipation of the availability of new COVID-19 treatments, the IFC also establishes additional Medicare hospital payment to support Medicare patients’ access to these potentially life-saving COVID-19 therapies. In Medicare, hospitals are generally reimbursed a fixed payment amount for the services they provide during an inpatient stay, even if their costs exceed that amount. Under current rules, hospitals may qualify for additional “outlier payments,” but only when their costs for a particular patient exceed a certain threshold.

Under this IFC, hospitals would qualify for additional payments when they treat patients with innovative new products approved or authorized to treat COVID-19 to mitigate any losses they may experience from making these therapies available, even if they do not reach the current outlier threshold.

The IFC also makes changes to reimbursement for outpatient hospital services to ensure payment for certain innovative treatments for COVID-19 that occur outside of bundled arrangements and are paid separately. In addition, CMS released information to prepare hospitals to bill for the outpatient administration of a monoclonal antibody product in the event one is approved under an emergency use authorization (EUA).³

On November 9, 2020, the U.S. 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.⁴

On November 10, 2020 following the FDA approval on November 9th CMS released a special news bulletin indicating “Medicare beneficiaries can receive coverage of monoclonal antibodies to treat coronavirus disease 2019 (COVID-19) with no cost-sharing during the public health emergency (PHE).”⁵

In addition, the November 11th CMS Special Edition article specifies that “Medicare will not pay for the monoclonal antibody products that providers receive free, but today’s action provides for reimbursement for the infusion of the product. When health care providers begin to purchase monoclonal antibody products, Medicare anticipates

setting the payment rate in the same way it set the payment rates for COVID-19 vaccines, such as based on 95% of the average wholesale price for COVID-19 vaccines in many provider settings.”

State and territorial Medicaid programs “may receive a temporary 6.2 percentage point increase in the Federal Medical Assistance Percentage (FMAP), through the end of the quarter in which the COVID-19 PHE ends. A condition for receipt of this enhanced federal match is that a state or territory must cover COVID-19 testing services and treatments, including vaccines and their administration, specialized equipment, and therapies for Medicaid enrollees without cost sharing. This means that this monoclonal antibody infusion is expected to be covered when furnished to Medicaid beneficiaries, in accordance with the EUA, during this period, with limited exceptions.”

The Monoclonal Antibody COVID-19 Infusion Program Instruction may be found at:

<https://www.cms.gov/files/document/covid-medicare-mono-clonal-antibody-infusion-program-instruction.pdf>

For those qualified to administer and bill for bamlanivimab (Eli Lilly and Company's Antibody Bamlanivimab (LY-CoV555) EUA effective November 9, 2020) CMS identified specific code(s) for the monoclonal antibody product and specific administration code(s) for Medicare payment.⁶

- ✓ **Q0239** – *Injection, bamlanivimab-xxxx, 700 mg*
- ✓ **M0239** – *Intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring*

When COVID-19 monoclonal antibody doses are provided by the government without charge, providers should only bill for the administration. Health care providers should not include the monoclonal antibody codes on the claim when the product is provided for free.

The CMS monoclonal-antibody page indicates that initially, for the infusion of the bamlanivimab product, the Medicare payment rate for the administration of bamlanivimab will be \$309.60. This payment rate is based on one hour of infusion and post-administration monitoring in the hospital outpatient setting. This rate will also be geographically adjusted.⁷

As well as requirements for providers to enroll to provide this therapy several additional links can be found on this page (<https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion>) to help providers prepare.

Guidance

- ✓ Determine if vaccines or other therapeutics will be administered at your location.
- ✓ Review guidelines and validate each locations eligibility to render these services.
- ✓ Follow registration guidelines as needed.
- ✓ Add new charges for vaccines, therapeutics, and administration as appropriate.
- ✓ Create a charge capture mechanism to ensure all services are captured and reported appropriately.



Sources

1. <https://www.cms.gov/files/document/covid-vax-ifc-4.pdf>
2. <https://www.ama-assn.org/press-center/press-releases/ama-announces-vaccine-specific-cpt-codes-coronavirus-immunizations>
3. CMS MLN Special Edition, October 28, 2020.
4. <https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion>
5. CMS.gov Newsroom, Special Release, CMS Takes Steps to Ensure Medicare Beneficiaries Have Wide Access to COVID-19 Antibody Treatment, November 11, 2020.
6. <https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion>
7. <https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-mono-clonal-antibodies> ■