# PUBLICATION

## CMS Issues Guidance for COVID-19 Treatments & Vaccines

**December 2020**

**Over the past weeks, CMS has issued billing and coding guidance for newly authorized COVID-19 vaccines and treatments. This guidance information further implements policy and regulatory revisions made by CMS in the Interim Final Rule published in the Federal Register on November 6, 2020 (IFR), the agency's fourth COVID-19 rulemaking. Since the issuance of the IFR, CMS has provided instructions and toolkits via its website concerning billing for COVID-19 vaccines and monoclonal antibody COVID-19 infusion, and most recently, on December 18, 2020, for the new COVID-19 Treatments Add-On Payment payable to hospitals under the Medicare Inpatient Prospective Payment System (IPPS).**

**COVID-19 Vaccines:** Implementing Sections 3203 and 3713 of the CARES Act and 6008 of the Families First Coronavirus Response Act, CMS, along with the Departments of Labor and Treasury, provided rules for widespread coverage across federal programs and other payers, ensuring the availability of COVID-19 vaccines without cost-sharing obligations for Medicare beneficiaries, Medicaid recipients, and enrollees in nearly all private health plans. For the Medicare program, coverage and reimbursement is available for the vaccine and its administration as a result of amendments made to the Social Security Act § 1861(s)(10) and 42 C.F.R. §§ 410.57, 410.152, 411.15, 414.701, 414.707, 414.900, and 414.904.

These statutory and regulatory amendments together incorporate COVID-19 vaccines as preventative immunizations under the Medicare Part B benefit available to beneficiaries without application of the Part B annual deductible or other co-insurance obligations. Payment under these rules is available generally at 95 percent of the average wholesale price (AWP) of the vaccine. However, when the vaccine is furnished in a hospital outpatient department, rural health clinic, federally qualified health center, skilled nursing facility, or by a home health agency, payment will be based on reasonable cost. While CMS has provided a payment methodology for the vaccine, providers should not bill for the vaccine if they receive it for free. Indeed, CMS anticipates that providers will not initially incur a cost for the vaccine because the federal government, through Operation Warp Speed, has purchased and arranged for the distribution of the vaccine for administration. Thus, for Medicare billing purposes, CMS has instructed, "[w]hen COVID-19 vaccine doses are provided by the government without charge, only bill for the vaccine administration. Don't include the vaccine codes on the claim when the vaccines are free."

CMS has established interim unique codes and payment amounts for each of the two COVID-19 vaccines that have thus far received Emergency Use Authorization (EUA) approval by the FDA. The Pfizer-BioNTech COVID-19 vaccine, which received EUA approval on December 11, 2020, has been assigned Code 91300, with administration codes 0001A and 0002A, and the Moderna COVID-19 vaccine, which received EUA approval on December 18, 2020, has been assigned Code 91301, with administration codes 0011A and 0012A. Both vaccines require two doses and Medicare will reimburse dose 1 at $16.94 and dose 2 at $28.39, subject to geographic adjustments. It is anticipated that adjustments finalizing coding and payment amounts will occur through future notice-and-comment rulemaking.

**COVID-19 Therapeutics:** Through the IFR, CMS also provided an additional payment amount for treatments to hospitals under IPPS and for separate payment under the Hospital Outpatient Prospective Payment System (OPPS) during the remainder of the public health emergency for COVID-19 (PHE).

Implementing Section 3710 of the CARES Act, CMS is providing temporary enhanced IPPS payment for eligible inpatient cases that involve the use of certain new drug or biological products that have received FDA authorization or approval to treat COVID-19. In accordance with the existing rule for add-on payments or new technology set forth at 42 C.F.R. § 412.88(b)(2), this new COVID-19 Treatment Add-On Payment (NCTAP) will be equal to the lesser of (1) 65 percent of the operating outlier threshold for the claim or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment (including a 20 percent adjustment to the relative weighting factor for the DRG). The NCTAP will be available for COVID-19 cases during the PHE that meet the following criteria:

- **The case must involve the use of a drug or biological product authorized or approved by FDA to treat COVID-19.** Currently, FDA has issued EUAs for convalescent plasma, remdesivir (Veklury), and the use of baricitinib (Olumiant) in combination with remdesivir (Veklury).
- **The case must be eligible for the 20 percent increase in the weighting factor for the assigned MS-DRG for an individual diagnosed with COVID-19 discharged during the period of the PHE.** Section 3710 of the CARES Act provided for an increase in the weighting factor for an assigned DRG by 20 percent for an individual diagnosed with COVID-19 discharged during the PHE. Eligibility will be based on the presence of a positive COVID-19 laboratory test in the beneficiary's medical record. CMS stated in the IFR that it may conduct post-payment medical review to confirm the presence of the positive COVID-19 test and would seek to recoup the NCTAP if such documentation is missing.
- **The operating costs of the case must exceed the operating Federal payment under IPPS, including the add-on payment under section 3710 of the CARES Act.** CMS has instructed that the cost of the case is determined by multiplying the covered charges by the operating cost-to-charge ratio. This is the same determination that is made for new technology add-on payments and operating outlier payments.

CMS stated in the IFR that the goal of the NCTAP is to mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments. CMS, however, is not fully offsetting costs that exceed Medicare payment. The NCTAP will only partially offset such costs in order to "preserve some of the incentives inherent under an average based prospective payment system."

On December 18, 2020, CMS updated its website with COVID-19 Treatments Add-On Payment coding guidance, setting forth the specific ICD-10-PCS codes for the use of:

- Remdesivir (Veklury) or COVID-19 convalescent plasma for hospital discharges on or after November 2, 2020;
- Baricitinib (Oluminiant) for hospital discharges on or after November 19, 2020, and on or before December 31, 2020; and
- Baricitinib (Oluminiant) for hospital discharges on or after January 1, 2021, through the duration of the PHE.

CMS has also provided a methodology for hospitals to seek separate OPPS payment for new COVID-19 treatments when such drugs are provided in hospital outpatient settings. CMS acknowledges in the IFR that treatment of COVID-19 is evolving rapidly and, therefore, has created an exception to its OPPS comprehensive ambulatory payment classification (C-APC) policy.

Although CMS anticipates that most drugs or biologicals approved or authorized to treat COVID-19 in the outpatient setting will have separate APC payment status indicators, the agency stated that "these products could be packaged into a C-APC when provided on the same claim as a C-APC service, in which case separate payment would not be made for these products." In other words, when the COVID-19 treatments are adjunctive to a primary C-APC service, payment for the adjunctive service, which can include all drugs,

biologicals and radiopharmaceuticals (except those that qualify for pass-through payment), regardless of cost, are packaged in with payments for the primary service.

CMS does not generally expect COVID-19 treatments to be adjunctive to other primary C-APC services. Specifically, beneficiaries are unlikely to both receive a primary C-APC service (most of which are surgical or intensive procedures) and a COVID-19 therapeutic that would be reported on the same claim. In the event this were to happen, CMS created an exception to the OPPS C-APC policy for COVID-19 treatments that meet the following two criteria:

- **The treatment must involve the use of a drug or biological product authorized or approved by FDA to treat COVID-19.**
- **The FDA approval / authorization must authorize the use of the product in the outpatient setting or otherwise not limit the use to the inpatient setting.** As of the date of the IFR, the FDA has not yet approved or authorized any COVID-19 treatments for use in outpatient settings.

Note, however, as discussed below, that the FDA has issued EUAs for monoclonal antibody infusion therapies, which for coverage and payment purposes are treated as a vaccine, that can be used in hospital outpatient infusion centers, among other settings.

On November 9, 2020 and November 21, 2020, respectively, the FDA issued EUAs for bamlanivimab, and for casirivimab and imdevimab, which are investigational monoclonal antibody infusion therapies. These products are intended for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients with positive COVID-19 test results who are at risk for progressing to severe COVID-19 and/or hospitalization. The EUAs limit administration to settings in which health care providers have immediate access to medications to treat severe infusion reaction (e.g., anaphylaxis) and the ability to activate the emergency medical system. Settings that would be able to satisfy these requirements include hospital-based infusion centers, as well as other settings not subject to OPPS, including freestanding infusion centers, home health agencies, and nursing homes.

CMS issued updated guidance on December 9, 2020, concerning monoclonal antibody COVID-19 infusion, which includes instructions for uses consistent with the EUA, and coding and payment information. Monoclonal antibody COVID-19 infusion products are considered by CMS to be COVID-19 vaccines, and therefore, coverage and reimbursement for the products will be the same as for the COVID-19 vaccines. That is, Medicare will pay for these products furnished in physician office settings at 95 percent of AWP and at reasonable cost when furnished in hospital outpatient settings. Medicare will also reimburse hospital outpatient departments based on a national average payment rate ($310) for infusion administration of monoclonal antibody products, which is for one hour of infusion and post-administration monitoring in a hospital outpatient setting. Hospitals may not seek NCTAP for these products, and no provider may charge cost-sharing amounts to beneficiaries who receive them.

CMS has made clear that hospitals should not seek the NCTAP or additional OPPS payment on claims for any drugs or biologicals, including monoclonal antibody therapy, that the government has procured or provided to the hospital at no cost. This same rule also applies to other types of providers / suppliers who receive products for the treatment of COVID-19 at no cost.

## Take-Aways

The fourth COVID-19 IFR set forth, among other things, the foundation for coverage and reimbursement for COVID-19 vaccines and therapeutics. Given the evolving circumstances and immediate need providers have

for billing and payment guidance, CMS has been issuing instructions via its website in real time with FDA issuances of EUAs for COVID-19 vaccines and treatments. The agency has stated that it will likely revisit its coding and payment policies through formal notice-and-comment rulemaking. In the interim period, however, CMS instructions on these and other issues are accessible and routinely updated here.

For more information, please contact any member of Baker Donelson's reimbursement team.