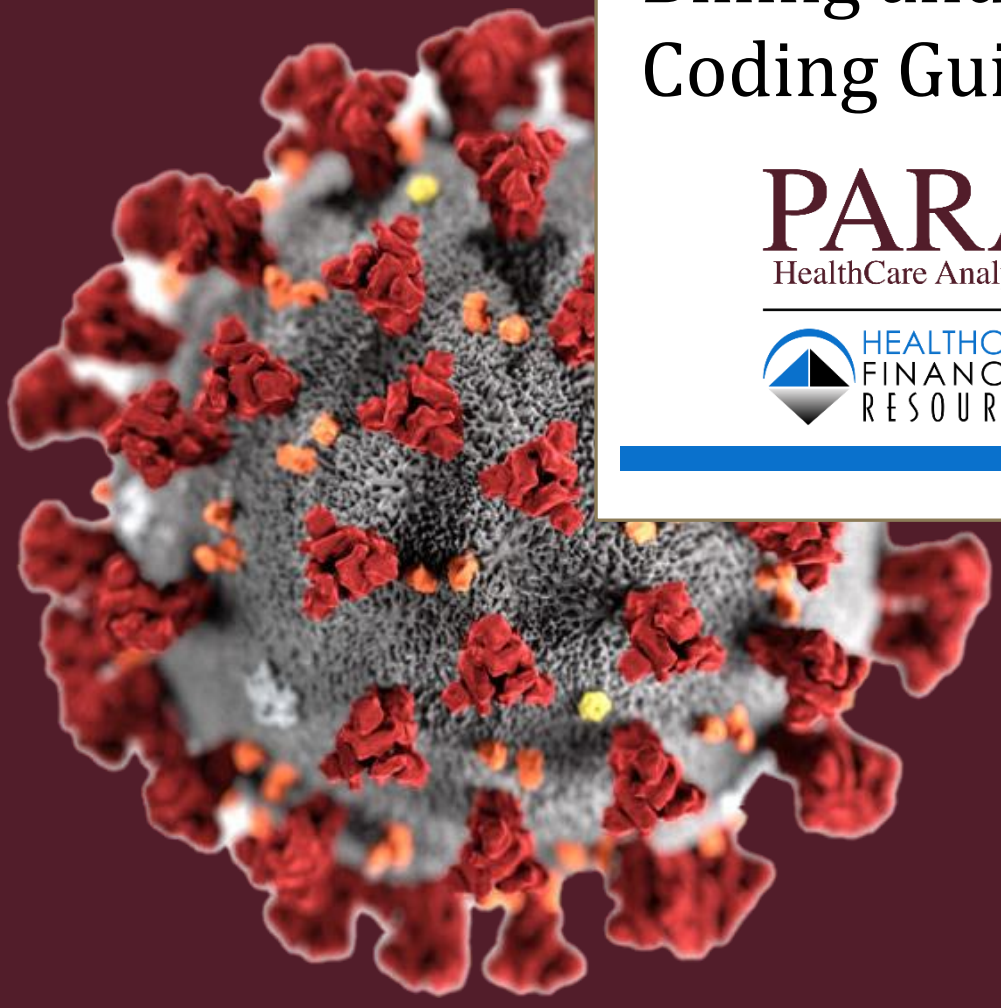
Updated April 27, 2021

Comprehensive COVID-19 Billing and Coding Guide

PARA
HealthCare Analytics

HEALTHCARE FINANCIAL RESOURCES



COVID-19 (Updated 04/27/2021)

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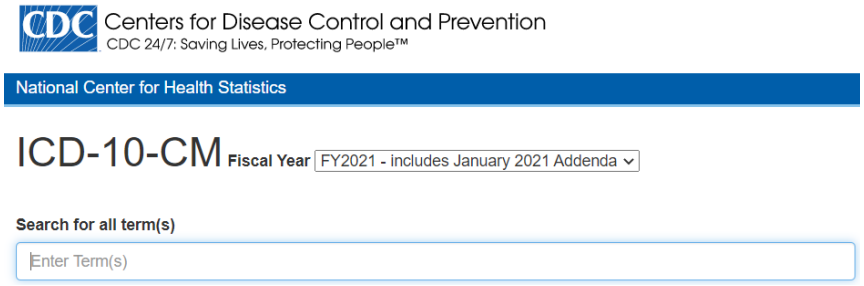
Coding for COVID-19

PARA updates COVID-19 coding and billing information based on CMS and payors' frequently changing guidelines regulations. Medical record documentation should support medical necessity and coding.

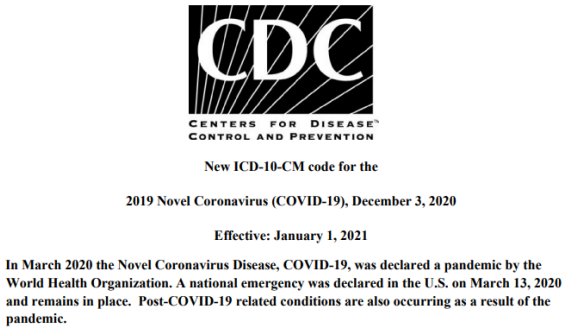
The CDC offers a ICD-10 tool to assist in COVID-19 coding:

https://icd10cmtool.cdc.gov/?fy=FY2021



Under the CDCs and Prevention's National Center for Health Statistics (CDC/NCDHS), new ICD-10 codes are effective January 1, 2021:

https://www.cdc.gov/nchs/data/icd/Announcement-New-ICD-code-for-coronavirus-19-508.pdf



CENTERS FOR DISEASE CONTROL AND PREVENTION

New ICD-10-CM code for the

2019 Novel Coronavirus (COVID-19), December 3, 2020

Effective: January 1, 2021

In March 2020 the Novel Coronavirus Disease, COVID-19, was declared a pandemic by the World Health Organization. A national emergency was declared in the U.S. on March 13, 2020 and remains in place. Post-COVID-19 related conditions are also occurring as a result of the pandemic.

ICD-10 Code	ICD-10 Description
J12.82	Pneumonia due to coronavirus disease
M35.81	Multisystem inflammatory syndrome (MIS)
M35.89	Other specified systemic involvement of connective tissue
Z11.52	Encounter for screening for COVID-19
Z20.822	Contact with and (suspected) exposure to COVID-19
Z86.16	Personal history of COVID-19

ICD-10-CM Official Coding and Reporting Guidelines for Coronavirus, effective October 1, 2020 – September 30, 2021, may be downloaded from the link below:

https://www.cdc.gov/nchs/data/icd/10cmguidelines-FY2021.pdf

ICD-10-CM Official Guidelines for Coding and Reporting
FY 2021
(October 1, 2020 - September 30, 2021)

Narrative changes appear in bold text
Items underlined have been moved within the guidelines since the FY 2020 version
***Italics* are used to indicate revisions to heading changes**

ICD-10-CM Official Coding and Reporting Guidelines for Coronavirus, effective April 1, 2020, through September 30, 2020, may be downloaded from the link below:

https://www.cms.gov/files/document/se20015.pdf

ICD-10-CM Official Coding and Reporting Guidelines
April 1, 2020 through September 30, 2020

1. Chapter 1: Certain Infectious and Parasitic Diseases (A00-B99)

g. Coronavirus Infections

1) COVID-19 Infections (Infections due to SARS-CoV-2)

Coding for Confirmed COVID-19

Effective April 1, 2020, report ICD-10 CM code **U07.1 (COVID-19)** for confirmed cases of COVID-19**.** An exception to hospital inpatient guideline Section II, H, allows a physician's documentation of a COVID-19 positive patient sufficient to code U07.1. A positive test result is not needed as confirmation of COVID-19 for an inpatient.

Except in obstetric patients, sequence U07.1 first, followed by appropriate codes for associated manifestation(s). Patients admitted or present for a healthcare encounter because of confirmed COVID-19 during pregnancy, childbirth, or post-partum should be reported with a principal diagnosis of **O98.5 (Other viral diseases complicating pregnancy, childbirth and the puerperium.)** U07.1 should follow O98.5 then any appropriate codes for associated manifestation(s).

Condition	Primary code	Secondary Code
Acute bronchitis confirmed as due to COVID-19	U07.1 (COVID-19)	J20.8 (acute bronchitis due to other specified organisms)
Pneumonia confirmed as due to COVID-19	U07.1 (COVID-19)	J12.89 (other viral pneumonia)

(continued)

Coding for Confirmed COVID -- continued

Condition	Primary code	Secondary Code
Acute bronchitis confirmed as due to COVID-19	U07.1 (COVID-19)	J20.8 (acute bronchitis due to other specified organisms)
Bronchitis not otherwise specified (NOS) due to COVID-19	U07.1 (COVID-19)	J40 (bronchitis, not specified as acute or chronic)
Lower respiratory infection NOS confirmed as due to COVID-19	U07.1 (COVID-19)	J22 (unspecified acute lower respiratory infection)
Respiratory infection NOS confirmed as due to COVID-19	U07.1 (COVID-19)	J98.8 (other specified respiratory disorders
Acute respiratory distress syndrome (ARDS) due to COVID-19	U07.1 (COVID-19)	J80 (acute respiratory distress syndrome)
Acute respiratory failure due to COVID-19	U07.1 (COVID-19)	J96.0 (acute respiratory failure)

Coding for Exposure to COVID-19

Report **Z20.828 (contact with and (suspected/possible) exposure to other viral communicable diseases)** for asymptomatic patients with actual exposure to someone who is confirmed or suspected (not ruled out) to have COVID-19. Report Z20.828 for patients with symptoms who have been exposed to someone either with COVID-19 or suspected exposure Report any signs or symptoms associated with COVID-19 if present.

Report **Z03.818 (encounter for observation for suspected exposure to other biological agents ruled out)** when there is a concern of possible exposure to COVID-19, but after evaluation of the patient was ruled out.

Report **P00.2** (Newborn affected by maternal infectious and parasitic diseases) when a newborn is born to a COVID-positive mother and the baby's COVID-19 status is unknown.

Coding for Screening of COVID-19

Per the ICD-10-CM Official Guidelines for Coding and Reporting that became effective on October 1, 2020*, during the Public Health Emergency (PHE), a screening code to test for COVID-19 is not appropriate. Asymptomatic patients should be coded with **Z20.828** (**Contact with and (suspected) exposure to other viral communicable diseases**).

Source: https://journal.ahima.org/ahima-and-aha-faq-on-icd-10-cm-coding-for-covid-19/

For services provided prior to October 1, 2020, report **Z11.59 (encounter for screening for other viral diseases)** for COVID-19 screening of asymptomatic patients who have had no known virus exposure and the test results are either unknown or negative.

Coding for Preprocedural or Admission Protocol COVID-19

Effective 1/1/2021, report ICD-10 diagnosis code, **Z20.822** - Contact with and suspected exposure to COVID-19 for asymptomatic patients receiving COVID-19 pre-op testing.

CMS provides official guidance on reporting this new code:

https://www.cms.gov/files/document/2021-coding-guidelines-updated-12162020.pdf

ICD-10-CM Official Guidelines for Coding and Reporting
FY 2021 – UPDATED January 1, 2021
(October 1, 2020 - September 30, 2021)

On page 31, the ICD-10-CM Official Guidelines provide coding and reporting assistance:

"During the COVID-19 pandemic, a screening code is generally not appropriate. Do not assign code Z11.52, Encounter for screening for COVID-19. For encounters for COVID-19 testing, including preoperative testing, code as exposure to COVID-19 (guideline I.C.1.g.1.e)."

e) Exposure to COVID-19

For asymptomatic individuals with actual or suspected exposure to COVID-19, assign code Z20.822, Contact with and (suspected) exposure to COVID-19.

For symptomatic individuals with actual or suspected exposure to COVID-19 and the infection has been ruled out, or test results are inconclusive or unknown, assign code Z20.822, Contact with and (suspected) exposure to COVID-19. See guideline I.C.21.c.1, Contact/Exposure, for additional guidance regarding the use of category Z20 codes.

CMS addresses pre-surgery COVID-19 testing in its Frequently Asked Questions on Medicare FFS Billing. If the services are part of the global surgical period, the COVID-19 test should be packaged with the surgery.

https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf

15. Question: Can physicians/NPPs apply the Cost Sharing (CS) modifier to claims for pre-surgery examination services that include COVID-19 testing?
Answer: The CS modifier should not be used when pre-surgery examination services are not paid separately, for example if particular services are considered to be part of services with a global surgical period, End Stage Renal Disease (ESRD) services with a monthly capitation payment or maternity package services.

During the COVID-19 PHE, the modifier can be reported with separately reported visit codes that result in an order for or administration of a COVID-19 test, when they are related to furnishing or administering such a test or are for the evaluation of an individual for purposes of determining the need for such a test.
New: 7/28/20

Hospitals paid under Inpatient Prospective Payment System (IPPS) must bill COVID-19 testing services performed before admission based on the 72-hour rule. When the test is performed three or fewer days prior to admission, the charge for a COVID-19 test must be included on the inpatient claim. Critical Access Hospitals are not subject to this policy and will receive separate payment for COVID-19 testing performed in the outpatient department prior to the patient admission.

Prior to January 1, 2021 encounters related to COVID-19 testing done as protocol for a procedure or admission – asymptomatic patients report **Z01.812** (Encounter for preprocedural laboratory examination) followed by **Z20.828**.

Source: https://journal.ahima.org/ahima-and-aha-faq-on-icd-10-cm-coding-for-covid-19/

Coding for Signs and Symptoms without a Definitive Diagnosis of COVID-19

For patients presenting with signs or symptoms of COVID-19 but do not have a definitive diagnosis of COVID-19, report the appropriate code(s) for any associated manifestations.

ICD10 Code	Description
R05	Cough
R0602	Shortness of breath
R509	Fever, unspecified
J1289	Other viral pneumonia
J208	Acute bronchitis due to other specified organisms
J22	Unspecified acute lower respiratory infection
J40	Bronchitis, not specified as acute or chronic
J80	Acute respiratory distress syndrome
J9601	Acute respiratory failure with hypoxia
J988	Other specified respiratory disorders

COVID-19 Specimen Collection

Hospital Outpatients -- Effective March 1, 2020, HCPCS **C9803** (hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), any specimen source)) may be reported by outpatient hospitals for collecting COVID-19 test swabs when no other evaluation and management code are reported. Append modifier CS to C9803 to ensure that patient liability is waived for medically necessary COVID-19 services**.**

Modifier Lookup

Codes and/or Descriptions: **cs**
Total Possible Matches: 1
Results Returned (below): 0

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Modifier	Description
CS	Cost-sharing waived for specified covid-19 testing-related services that result in and order for or administration of a covid-19 test and/or used for cost-sharing waived preventive services furnished via telehealth in rural health clinics and federally qualified health centers during the covid-19 public health emergency

Free-standing physician practices may report evaluation and management code CPT® **99211** for COVID-19 swab collection for both new and established patients when no other E/M service is rendered. CMS states in its FAQ, that the physician/non-physician practitioner does not need to be present to report 99211 for the COVID-19 swab collection.

Independent labs may report **G2023** (specimen collection for severe acute respiratory syndrome coronavirus 2(SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source) and **G2024** (specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), from an individual in a SNF or by a laboratory on behalf of a HHA, any specimen source).

Inpatient Treatment for COVID-19

On August 17, 2020, CMS revised its payment policy on inpatient admissions DRG payments. Beginning with admissions on or after September 1, 2020, only when a patient has been tested and found to be COVID-19 positive will the hospital receive the 20 percent increase in MS-DRG reimbursement. CMS states that tests performed within 14 days of admission **may be manually documented** in the patient's record and that hospitals should code diagnoses in accordance with ICD-10-CM coding guidelines. CMS states they may conduct post-payment record reviews to verify documentation of the positive COVID-19 test. When not documented appropriately, the payment is subject to recoupment.

https://www.cms.gov/files/document/se20015.pdf

New COVID-19 Policies for Inpatient Prospective Payment System (IPPS) Hospitals, Long-Term Care Hospitals (LTCHs), and Inpatient Rehabilitation Facilities (IRFs) due to Provisions of the CARES Act

MLN Matters Number: SE20015 Revised
Article Release Date: August 17, 2020
Related CR Transmittal Number: N/A
Related Change Request (CR) Number: N/A
Effective Date: N/A
Implementation Date: N/A

Remdesivir (Veklury)

On October 22, 2020, the FDA approved Veklury (Remdesivir) for the treatment of COVID-19 for adults and pediatrics age 12 and older with a weight of at least 40kg (approximately 88 pounds) when they require hospitalization.

https://www.fda.gov/drugs/drug-safety-and-availability/fdas-approval-veklury-remdesivir-treatment-covid-19-science-safety-and-effectiveness

FDA's approval of Veklury (remdesivir) for the treatment of COVID-19—The Science of Safety and Effectiveness

The EUA, that went into effect for Remdesivir in May 2020, remains in effect. It authorizes administration of the drug to hospitalized COVID-19 pediatric patients weighin less than 40kg or are less than 12 years of age.

https://www.fda.gov/media/137566/download

FACT SHEET FOR HEALTHCARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF VEKLURY® (remdesivir) FOR HOSPITALIZED PEDIATRIC PATIENTS WEIGHING 3.5 KG TO LESS THAN 40 KG *OR* HOSPITALIZED PEDIATRIC PATIENTS LESS THAN 12 YEARS OF AGE WEIGHING AT LEAST 3.5 KG

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of VEKLURY for treatment of suspected or laboratory confirmed coronavirus disease 2019 (COVID-19) in hospitalized pediatric patients weighing 3.5 kg to less than 40 kg *or* hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg.

Convalescent Plasma

On August 23, 2020, the FDA issued an EUA for patients hospitalized with COVID-19 to receive convalescent plasma. Convalescent plasma is collected from a eligible donor patient whose plasma contains COVID-19 antibodies. The FDA provided additional recommendations and guidance on November 16, 2020. It is available through the following link:

https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma

Recommendations for Investigational COVID-19 Convalescent Plasma

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November 16, 2020

FDA issued an EUA for convalescent plasma on August 23, 2020.

New COVID-19 Treatment Add-on Payment (NCTAP)

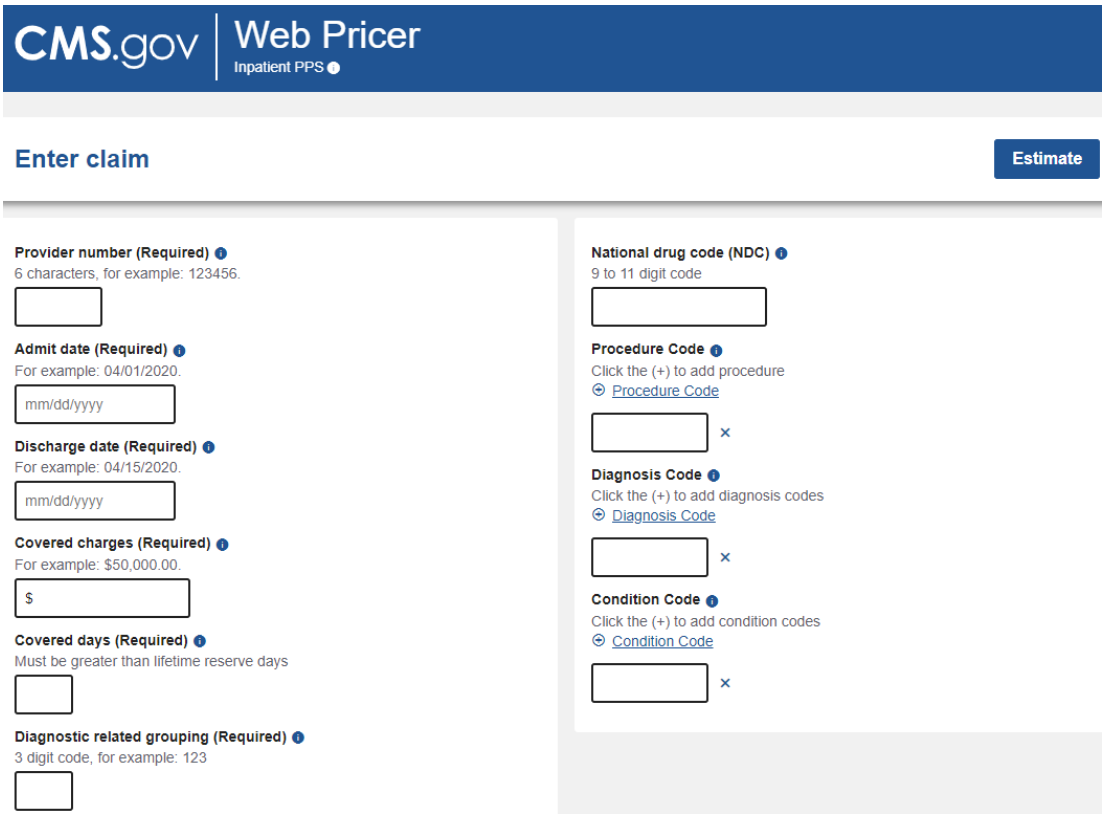
Medicare recently announced a New COVID-19 Treatment Add-On Payment (NCTAP) program for hospitals paid under its Inpatient Prospective Payment System effective November 2, 2020 through the end of the of the Public Health Emergency (PHE). The NCTAP offers enhanced "add-on" payments for inpatient care reimbursed under Medicare's Inpatient Prospective Payment System (IPPS) when certain new products with FDA Administrative approval or emergency use authorization for COVID-19 are provided during an inpatient stay. The new program is not available to Critical Access Hospitals, which are paid on a cost-reimbursement basis for inpatient care. Add-on payments are triggered only if the cost of the case (as measured by the hospital's established Medicare cost to charge ratios) exceeds the amount of the DRG payment under IPPS.

CMS provides a webpage for NCTAP information at the following link:

https://www.cms.gov/medicare/covid-19/covid-19-treatments-add-payment-nctap

The Medicare IPPS Web Pricer includes specific payment information, including NCTAP add-ons, through the following link:

https://webpricer.cms.gov/#/pricer/ipps



Instructions on how to use the web-based program are located at the link below:

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PCPricer/inpatient

The NCTAP add-on payment will be equal to the lesser of:

- 65% of the operating outlier claim threshold OR
- 65% of the costs that exceed the standard DRG payment (including those cases adjusted to the relative weight under section 3710 of the CARES Act.)

For high-cost cases, the NCTAP payments could increase IPPS reimbursement in addition to the 20% bump in the operating portion of IPPS DRG payments for COVID patients previously made available under the CARES Act, announced on September 11, 2020 in MLN Matters SE20015:

https://www.cms.gov/files/document/se20015.pdf

New Waivers for Inpatient Prospective Payment System (IPPS) Hospitals, Long-Term Care Hospitals (LTCHs), and Inpatient Rehabilitation Facilities (IRFs) due to Provisions of the CARES Act

CMS determines NCTAP eligibility based on claims eligible for the 20% add-on payment under section 3710 of the CARES Act based on the presence of specific ICD-10 codes:

- ICD-10-CM Diagnosis Code of U07.1 -COVID-19 **AND**
- An ICD-10-PCS code for Remdesivir (Veklury), COVID-19 convalescent plasma, or Remdesivir administered with Baricitinib (Olumiant)

ICD-10-PCS Code	Description	Treatment	Effective Dates
XW033E5	Introduction of remdesivir anti-infective into peripheral vein, percutaneous approach, new technology group 5	Remdesivir (Veklury)	On or after Nov. 2, 2020
XW043E5	Introduction of remdesivir anti-infective into central vein, percutaneous approach, new technology group 5	Remdesivir (Veklury)	On or after Nov. 2, 2020
XW13325	Transfusion of convalescent plasma (nonautologous) into peripheral vein, percutaneous approach, new technology group 5	Convalescent Plasma	On or after Nov. 2, 2020
XW14325	Transfusion of convalescent plasma (nonautologous) into central vein, percutaneous approach, new technology group 5	Convalescent Plasma	On or after November 2, 2020
XW0DXF5	Introduction of other new technology therapeutic substance into mouth and pharynx, external approach, new technology group 5	Baricitinib (with Remdesivir) *	Nov. 19, 2020 thru Dec. 31, 2020

(Continued)

ICD10 List - Continued

ICD-10-PCS Code	Description	Treatment	Effective Dates
3E0G7GC	Introduction of other therapeutic substance into upper G.I. via natural or artificial opening	Baricitinib (with Remdesivir) *	Nov. 19, 2020 thru Dec. 31, 2020
3E0H7GC	Introduction of other therapeutic substance into lower G.I. via natural or artificial opening	Baricitinib (with Remdesivir) *	Nov. 19, 2020 thru Dec. 31, 2020
XW0DXM6	Introduction of baricitinib into mouth and pharynx, external approach, new technology group 6	Baricitinib (with Remdesivir) *	January 1, 2021 thru end of COVID-19 PHE
XW0G7M6	Introduction of baricitinib into upper GI, via natural or artificial opening, new technology group 6	Baricitinib (with Remdesivir) *	January 1, 2021 thru end of COVID-19 PHE
XW0H7M6	Introduction of baricitinib into lower GI, via natural or artificial opening, new technology group 6	Baricitinib (with Remdesivir) *	January 1, 2021 thru end of COVID-19 PHE

***** The Emergency Use Authorization (EUA) requires the administration of Baricitinib with Remdesivir - ICD-10-PCS code(s) **XW033E5** Introduction of Remdesivir Anti-infective into Peripheral Vein, Percutaneous Approach, New Technology Group 5 or **XW043E5** Introduction of Remdesivir Anti-infective into Central Vein, Percutaneous Approach, New Technology Group 5.

While CMS reminds us that, per Chapter 32 of the Claims Processing Manual – Billing Requirements for Special Services a hospital should not seek additional payment for drugs or biologicals that a governmental entity provided at no cost to to diagnose or treat patients with known or suspected COVID-19, a hospital should report all ICD-10-PCS code(s) associated with the product(s).
Additional billing and reporting information may be obtained from CMS through the following link:

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c32.pdf#

67.2 – Institutional Billing for No Cost Items
(Rev. 4013, Issued: 03-30-18, Effective: 01-01-09, Implementation: 06-29-18)

Because Medicare is currently providing monoclonal antibody therapy products at no cost to providers, those products are not included in the NCTAP. Medicare does, however, cover the administration/infusion of the monoclonal products.

The "COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-For-Service (FFS) Billing" document includes questions on NCTAPs beginning with question number 13 of F. Hospital Inpatient Prospective Payment Systems (IPPS) Payments:

https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf

COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing

Professional Fee for COVID-19 Isolation Counseling

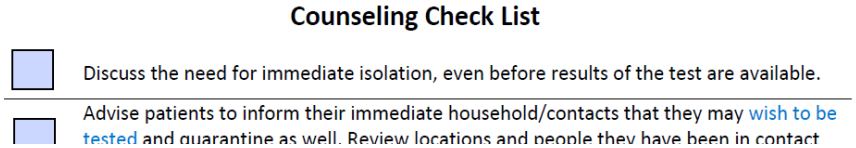
In a press release dated July 30, 2020, CMS announced that professionals may report an E/M code for the service of counseling patients who undergo COVID-19 testing to self-isolate after testing, even before results are available.

https://www.cms.gov/newsroom/press-releases/cms-and-cdc-announce-provider-reimbursement-available-counseling-patients-self-isolate-time-covid-19

According to the press release, "Provider counseling to patients, at the time of their COVID-19 testing, will include the discussion of immediate need for isolation, even before results are available, the importance to inform their immediate household that they too should be tested for COVID-19, and the review of signs and symptoms and services available to them to aid in isolating at home. In addition, they will be counseled that if they test positive, to wear a mask at all times and they will be contacted by public health authorities and asked to provide information for contact tracing and to tell their immediate household and recent contacts in case it is appropriate for these individuals to be tested for the virus and to self-isolate as well."

Providers may claim reimbursement by reporting existing evaluation and management (E/M) codes. Enrolled providers may claim reimbursement for counseling to self-isolate no matter where a test is administered, including doctor's offices, urgent care clinics, hospitals and community drive-thru or pharmacy testing sites. A counseling checklist, which could be helpful in guiding provider documentation of the counseling service, is provided:

https://www.cms.gov/files/document/counseling-checklist.pdf



Counseling Check List

- ☐ Discuss the need for immediate isolation, even before results of the test are available.
- ☐ Advise patients to inform their immediate household/contacts that they may wish to be tested and quarantine as well. Review locations and people they have been in contact

CMS offers an FAQ document for providers at the following link:

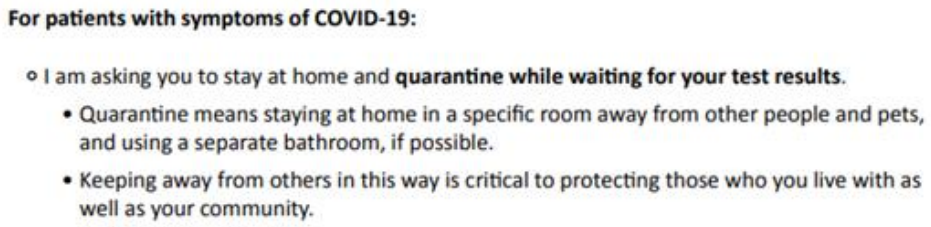
https://www.cms.gov/files/document/covid-provider-counseling-qa.pdf

Provider Q&A

Why is payment being made available for health care providers to counsel patients to isolate/ quarantine at the time of COVID-19 testing?
Models show that when those tested for COVID-19 are placed in isolation immediately, while waiting for test result or onset of symptoms, additional disease transmission in the community may be reduced. By having patients isolated 1-2 days earlier, spread of COVID-19 can be reduced significantly. Modeling shows early isolation can reduce transmission by up to 86 percent.

CMS also provides a Talking Points document to guide providers in having the conversation with patients about self-isolating. A link and an excerpt are provided:

https://www.cms.gov/files/document/covid-provider-patient-counseling-talking-points.pdf



For patients with symptoms of COVID-19:

- I am asking you to stay at home and **quarantine while waiting for your test results**.
  - Quarantine means staying at home in a specific room away from other people and pets, and using a separate bathroom, if possible.
  - Keeping away from others in this way is critical to protecting those who you live with as well as your community.

Professional Special Services, Procedures and Reports

CMS will accept new CPT® 99072 on professional fee claims with dates of service on or after September 8, 2020, although this code will not generate additional reimbursement. This code is not appropriate for facility fee billing. The MPFS Status indicator assigned to 99072 is B, "Bundled code. Payment for covered services are always bundled into payment for other services not specified."

99072 - Additional supplies, materials, and clinical staff time over and above those usually included in an office visit or other non-facility service(s), when performed during a Public Health Emergency as defined by law, due to respiratory-transmitted infectious disease

Documentation requirements and reimbursement of 99072 may vary among payor plans. Many payors are following Medicare's lead by bundling reimbursement for this supply code into the office visit. United Healthcare Medicare Advantage has posted the following announcement:

https://www.uhcprovider.com/content/dam/provider/docs/public/policies/medadv-reimbursement/MEDADV-Supply-Policy.pdf

UnitedHealthcare® Medicare Advantage
Reimbursement Policy
CMS 1500
Policy Number 2020R9037A

Supply Policy, Professional

…

"For reimbursement of covered medical and surgical supplies, an appropriate Level II HCPCS code must be submitted. The non-specific CPT codes 99070 (supplies and materials, except spectacles, provided by the physician or other health care professional over and above those usually included with the office visit or other services rendered [list drugs, trays, supplies, or materials provided]) and 99072 are not separately reimbursable in any setting."

COVID-19 Lab Tests

Code selection depends on the payer and the test performed. Contact your local third-party payer directly to determine their specific reporting guidelines.

For Medicare, report the code that matches the test source (CDC or non-CDC) or the technique. CMS offers guidance at the link below:

https://www.cms.gov/files/document/03052020-medicare-covid-19-fact-sheet.pdf

"There are two new HCPCS codes for healthcare providers who need to test patients for Coronavirus. Healthcare providers using the Centers for Disease Control and Prevention (CDC) 2019 Novel Coronavirus Real Time RT-PCR Diagnostic Test Panel may bill for that test using the newly created HCPCS code (U0001). A second new HCPCS code (U0002) 2019-nCoV Coronavirus, SARS- CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non- CDC can also be used by laboratories and healthcare facilities. Both codes can be used to bill Medicare as well as by other health insurers that choose to utilize and accept the code.

"Additionally, on March 13, 2020, the American Medical Association (AMA) Current Procedural Terminology (CPT) Editorial Panel has created CPT code 87635 (Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique). For more information on how to use the CPT code, please visit https://www.ama-assn.org/press-center/press-releases/newcpt- code-announced-report-novel-coronavirus-test. Laboratories can also use this CPT code to bill Medicare if your laboratory uses the method specified by CPT 87635."

HCPCS	Description	Effective Date
U0001	CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel	02-04-2020
U0002	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC	02-04-2020
0202U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected *(PARA note: Proprietary lab analysis test – PLA – BioFire® Respiratory Panel 2.1 (RP2.1), BioFire®Diagnostics, LLC)*	05-20-2020
0223U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected *(PARA note: Proprietary lab analysis test – PLA – QIAstat-Dx Respiratory SARS-CoV-2 Panel, QIAGEN Sciences, QIAGEN, GMbH)*	06-25-2020
0240U	Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 3 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B), upper respiratory specimen, each pathogen reported as detected or not detected	10/06/2020*
0241U	Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 4 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B, respiratory syncytial virus [RSV]), upper respiratory specimen, each pathogen	10/06/2020*
0225U	Infectious disease (bacterial or viral respiratory tract infection) pathogen-specific DNA and RNA, 21 targets, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected *(PARA note: Proprietary lab analysis test – PLA – Eplex respiratory pathogen panel 2, Genmark Dx, Genmark diagnostics, Inc.)*	10/06/2020*
0226U	Surrogate viral neutralization test (SVNT), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), elisa, plasma, serum *(PARA note: Proprietary lab analysis test – PLA –Ethos Laboratories, Genscript USA Inc.)*	10/06/2020*

(continued)

HCPCS	Description	Effective Date
0241U	**Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 4 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B, respiratory syncytial virus [RSV]), upper respiratory specimen, each pathogen reported as detected or not detected** ***(PARA note: Proprietary lab analysis test – PLA –Xpert® Xpress SARS-CoV-2/Flu/RSV (all targets), Cepheid)***	10/06/2020*
87426	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19]) *(PARA note: 87426 is a child code under parent code 87301)*	06/25/2020
87635	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique	03/13/2020
87636	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) and influenza virus types A and B, multiplex amplified probe technique	10/06/2020*
87637	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), influenza virus types A and B, and respiratory syncytial virus, multiplex amplified probe technique	10/06/2020*
87811	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	10/06/2020*

*Medicare has not published national rates for these codes, but they may be priced by the local MAC.

Rapid card testing - is read visually with lines to indicate positive or negative results like a pregnancy test. Based on the October 30, 2020 CPT® Assistant Guide, 87811 severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (Coronavirus disease [COVID-19]) would be reported for antigen detection of COVID-19 by direct optical observation.

https://www.ama-assn.org/system/files/2020-10/cpt-assistant-guide-coronavirus-october-2020.pdf

Abbott's BinaxNow COVID-19 Ag Card is one of the more common rapid tests approved by the FDA for emergency use during the PHE. The FDA offers additional information on this rapid nasal swab:

https://www.fda.gov/media/141570/download

BinaxNOW™ COVID-19 Ag CARD

For Use Under an Emergency Use Authorization (EUA) Only
For use with nasal swab specimens
For ***in vitro*** Use Only
Rx Only

87811 and 87428 are CLIA-waived tests and may be reported with the QW modifier when performed by a facility with a current CLIA certificate of waiver.

https://www.cms.gov/files/document/mm12093.pdf

Addition of the QW Modifier to Healthcare Common Procedure Coding System (HCPCS) Codes 87811 and 87428

High throughput COVID-19 testing - A high-throughput machine requires specialized technical training. It can process more than 200 specimens a day.

HCPCS	Description	Effective Date
U0003	Infectious agent detection by nucleic acid (DNA or RNA) severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique), making use of high throughput technologies as described by CMS-2020-01-R	04/14/2020
U0004	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R	04/14/2020

Report **U0003** in place of tests that were reported as **87635** *(infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique)* when using high-throughput technology.

Report HCPCS **U0004** in place of **U0002** *(2019-ncov Coronavirus, sars-cov-2/2019-ncov (covid-19), any technique, multiple types or subtypes (includes all targets), non-CDC.)* when using high-throughput technology.

Until January 1, 2021, Medicare will pay $100 under the Clinical Lab Fee Schedule for high-throughput testing. The U0003 and U0004 codes should not be used when testing for COVID-19 antibodies. CMS provides a partial list of accepted technology high-throughput machines In Ruling **2020-1-R** dated April 14, 2020:

https://www.cms.gov/files/document/cms-2020-01-r.pdf

Medicare re-evaluated testing resources in Ruling 2020-1-R2 dated January 1, 2021:

https://www.cms.gov/files/document/cms-ruling-2020-1-r2.pdf

Beginning January 1, 2021, and throughout the Public Health Emergency, Medicare FFS will pay $75 for COVID-19 tests performed using high throughput technology U0003 and U0004. However, Medicare will pay an additional $25 for new add-on HCPCS code **U0005** when the COVID-19 lab test is completed within 2 calendar days of the specimen collection AND the laboratory completed 51% of high throughput testing for all patients (not only Medicare beneficiaries) in the previous month within two calendar days.

HCPCS	Description	Effective Date
U0005	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, CDC or non-CDC, making use of high throughput technologies, completed within two calendar days from date and time of specimen collection. (List separately in addition to either HCPCS code U0003 or U0004)	01/01-2021

The laboratory must maintain records of its monthly assessments of timely results reporting. CMS instructs MACs to conduct claim reviews and audits to ensure providers are compliant with the Ruling.

The U0005 add-on payment is for only Medicare FFS claims. It does not apply to Medicare Advantage plans.

Medicare provides additional information on this requirement in several questions of the Frequently Asked Questions on Medicare FFS Billing on their website. A link and an excerpt are provided on the following page.

https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf

D. High Throughput COVID-19 Testing

1. **Question**: Why did CMS create HCPCS codes U0003, U0004 and U0005?
   Answer: CMS created two new HCPCS codes, effective for dates of service on or after April 14, 2020, specifically for Clinical Diagnostic Laboratory Tests (CDLTs) making use of high throughput technologies, that is, technologies that use a platform that employs automated processing of more than 200 specimens a day, as described in CMS Ruling No. CMS-2020-1-R, available at https://www.cms.gov/files/document/cms-2020-01-r.pdf.

COVID-19 Antibody Testing

Medicare instructs that 86328 is the most appropriate code to report for COVID-19 antibody testing performed in a single step (often a strip) with all critical components for the assay. COVID-19 antibody testing reported as 86769 may involve multi-steps where a diluted sample is incubated.

HCPCS	Description	Effective Date
86408	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-COV-2) (coronavirus disease [COVID-19]); screen	08/10/2020
86049	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-COV-2) (coronavirus disease [COVID-19]); titer	08/10/2020
86413	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) antibody, quantitative	9/8/2020
86328	Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method (eg, reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-COV-2) (coronavirus disease [COVID-19])	04-10-2020
86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]}	04-10-2020
0224U	Antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), includes titer(s), when performed *(PARA note: Do not report 86769 in conjunction with 0224U. proprietary lab analysis test – PLA – COVID-19 Antibody Test, Mt Sinai, Mount Sinai Laboratory)*	06-25-2020

Local Medicare Administrative Contractor (MAC) COVID-19 Payments

Until Medicare establishes national payment rates for COVID-19 tests, they are set by the local MACs. These are available from the following pricing table published on January 25, 2021:

https://www.cms.gov/files/document/mac-covid-19-test-pricing.pdf

MAC COVID-19 Test Pricing

CPT Code	Short Descriptor	JE	JF	JJ	JM	JH	JL	JN	J15	J6	JK	J5	J8
U0001	2019-Ncov Diagnostic P	$35.91	$35.91	$35.91	$35.91	$35.92	$35.92	$35.92	$35.92	$35.91	$35.91	$35.92	$35.92
U0002	Covid-19 Lab Test Non-CDC	$51.31	$51.31	$51.31	$51.31	$51.31	$51.31	$51.31	$51.31	$51.31	$51.31	$51.31	$51.31
87635	SarsCov2 Covid19 Amp Prb	$51.31	$51.31	$51.31	$51.31	$51.31	$51.31	$51.31	$51.31	$51.31	$51.31	$51.31	$51.31
87636	SarsCov2 & Inf A&B Amp Prb	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63
87637	SarsCov2 & Inf A&B&RSV Amp Prb	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63
0240U	Nfct DS Vir Resp RNA 3 Trgt	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63
0241U	Nfct DS Vir Resp RNA 4 Trgt	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63	$142.63
87426	SarsCov Coronavirus AG IA	$35.33	$35.33	$35.33	$35.33	$45.23	$45.23	$45.23	$35.33	$35.33	$35.33	$35.33	$35.33
87428	SarsCov & Inf Vir A&B AG IA	$63.59	$63.59	$63.59	$63.59	$73.49	$73.49	$73.49	$63.59	$63.59	$63.59	$63.59	$63.59
87811	SarsCov2 Covid19 W/Optic	$41.38	$41.38	$41.38	$41.38	$41.38	$41.38	$41.38	$41.38	$41.38	$41.38	$41.38	$41.38
86328	Ia Nfct A&B SarsCov2 Covid19	$45.23	$45.23	$45.23	$45.23	$45.23	$45.23	$45.23	$45.23	$45.23	$45.23	$45.23	$45.23
86408	Neutrlzg Antb SarsCov2 Scr	$42.13	$42.13	$42.13	$42.13	$42.13	$42.13	$42.13	$42.13	$42.13	$42.13	$42.13	$42.13
86409	Neutrlzg Antb SarsCov2 Titer	$79.61	$79.61	$79.61	$79.61	$105.33	$105.33	$105.33	$79.61	$105.33	$105.33	$79.61	$79.61
86413	SarsCov2 Antb Quantative	$51.43	$51.43	$51.43	$51.43	$42.13	$42.13	$42.13	$51.43	$51.43	$51.43	$51.43	$51.43
86769	SarsCov2 Covid19 Antibody	$42.13	$42.13	$42.13	$42.13	$42.13	$42.13	$42.13	$42.13	$42.13	$42.13	$42.13	$42.13
0224U	Antibody SarsCov2 Titer(s)	$42.13	$42.13	$42.13	$42.13	$42.13	$42.13	$42.13	$42.13	$42.13	$42.13	$42.13	$42.13
0226U	Svnt SarsCov2 Elisa Plsm Srm	$42.28	$42.28	$42.28	$42.28	$42.28	$42.28	$42.28	$42.48	$42.28	$42.28	$42.28	$42.28

Monoclonal Antibody COVID-19 Infusion Program

The FDA issued Emergency Use Authorization (EUA) for Monoclonal Antibody treatment of Bamlanivimab on November 9, 2020 and Regeneron drug combination of Casirivimab and Imdevimab on November 21, 2020. On February 9, 2021, the FDA issued an EUA for drug combination of bamlanivimab and etesevimab. The infusion treatment is for high risk COVID-19 positive **outpatients** exhibiting mild to moderate symptoms. The EUAs state the therapy is not authorized for hospitalized patient or patients who require oxygen therapy due to COVID-19. In accordance with the CARES Act, Medicare will cover the infusions in healthcare settings, such as infusion centers and home health agencies, where providers are equipped and capable to treat a severe reaction (such as anaphylaxis) and can activate an EMS if warranted.

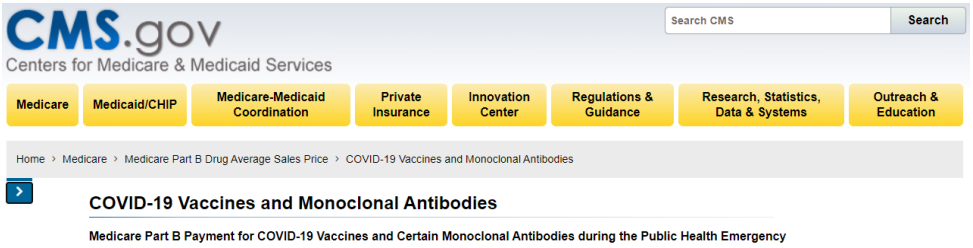
If the patient has a Medicare Advantage plan, report the services to traditional Medicare with the appropriate condition code.

https://www.cms.gov/files/document/COVID-19-toolkit-issuers-MA-plans.pdf

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

Medicare Part B Payment for COVID-19 Vaccines may be found at the following website:

https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies



HCPCS	Description	Labeler	Payment Allowance	Effective Date
Q0239	Injection, bamlanivimab-xxxx, 700 mg	Eli Lily	$ 0.01	11/10/2020
M0239	Intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring **(see FDA Revokes EUA section)**	Eli Lily	$ 309.60*	11/10/2020
Q0243	Injection, casirivimab and imdevimab, 2400 mg	Regeneron	$ 0.01	11/21/2020
M0243	intravenous infusion, casirivimab and imdevimab includes infusion and post administration monitoring	Regeneron	$ 309.60*	11/21/2020
Q0245	Injection, bamlanivimab and etesevimab, 2100 mg	Eli Lily	$ 0.01	02/09/2021
M0245	Bamlan and etesev infusion	Eli Lily	$ 309.60	02/09/2021

Final payment rates for the infusion and monoclonal product have not been established and are not active in Medicare's payment systems. However, CMS states that Medicare will begin paying $309.60, which will be geographically adjusted for the administration of the drug. The payment includes one hour of infusion followed by post-administration monitoring in an outpatient hospital setting.

Medicare is expected to cover Bamlanivimab, Etesevimab and the Regeneron drug combo, when not provided free of cost, at reasonable costs in an outpatient hospital and may base physician office payments based on average wholesale price. Additional payment information will be published in a future CMS transmittal.

Monoclonal AB Infusions				
Service	**Description**	**Rev Code**	**Condition Code(s)**	**Dx Notes**
Bamlanivimab			**A6** - 100% Medicare Payment For patients who have Medicare Advantage Plans, bill services to traditional Medicare and report **Condition Code 78** - New coverage not implemented by Medicare Advantage	**Z23** - Encounter for immunization **U071** - COVID-19
Q0239	Injection, bamlanivimab-xxxx, 700 mg **(DO NOT REPORT IF PROVIDED FREE OF COST) - (see FDA Revokes EUA section)**	0636		
M0239	Intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring **(see FDA Revokes EUA section)**	0771		
Q0245	Injection, bamlanivimab and etesevimab, 2100 mg **(DO NOT REPORT IF PROVIDED FREE OF COST)**	0636		
M0245	Bamlan and etesev infusion	0771		
Regeneron Cocktail				
Q0243	Injection, casirivimab and imdevimab, 2400 mg **(DO NOT REPORT IF PROVIDED FREE OF COST)**	0636		
M0243	Intravenous infusion, casirivimab and imdevimab includes infusion and post administration monitoring	0771		

See Section on Modifiers and Condition Codes for additional information.
Medicare will pay monoclonal antibody products (when not provided free of cost) and their infusions, when administered in accordance with the EUA or approval in the same way it pays for other COVID-19 vaccines.

RHCs and FQHCs cannot bill COVID-19 for monoclonal administration on a claim form. If the patient is there for another reason, the RHC or FQHC should exclude the cost of the monoclonal antibodies. It will be settled on a cost report.

A listing of payment rates by each type of Medicare provider can be found in the Medicare FAQ link.

Medicare Provider	Vaccine Payment	Vaccine Administration Payment
Hospitals – Outpatient Departments	Reasonable Costs*	Separately payable based on established rate for code. Not subject to OPPS.
Hospitals – Inpatients	Reasonable Costs*	Separately payable based on established rate for code.
Critical Access Hospitals (CAHs)	101% of Reasonable Costs	101% of Reasonable Costs
Rural Health Centers (RHCs)	Paid through the cost report	Paid through the cost report

https://medicare.fcso.com/Billing_news/0479121.asp

COVID-19 vaccine and monoclonal antibody billing for Part A providers

This article will assist Medicare Part A providers with proper billing relating to COVID-19 vaccine and monoclonal antibody infusion. Beneficiary coinsurance and deductible are waived.

How to bill for COVID-19 vaccines and monoclonal antibodies

- For billing single claims for COVID-19 vaccines and monoclonal antibodies, follow the instructions in the article below.
- For roster billing and centralized billing reference the Medicare billing for COVID-19 vaccine shot administration page.
- When COVID-19 vaccine and monoclonal antibody 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.
- If the patient is enrolled in a Medicare Advantage (MA) plan, submit your COVID-19 vaccine and monoclonal antibody infusion claims to Original Medicare in 2020 and 2021.

FDA Revokes EUA for "Solo" Bamlanimvimab

On April 16, 2021, the FDA announced that it has revokes the Emergency Use Authorization (EUA) for "solo" Bamlanivimab, the first EUA issued for monoclonal antibody treatment of a COVID-19 positive patient on an outpatient infusion basis. Consequently, Bamlanivimab may no longer be administered *alone*, although a new EUA permits its use only when used in combination with etesivimab.

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-monoclonal-antibody-bamlanivimab

FDA U.S. FOOD & DRUG ADMINISTRATION

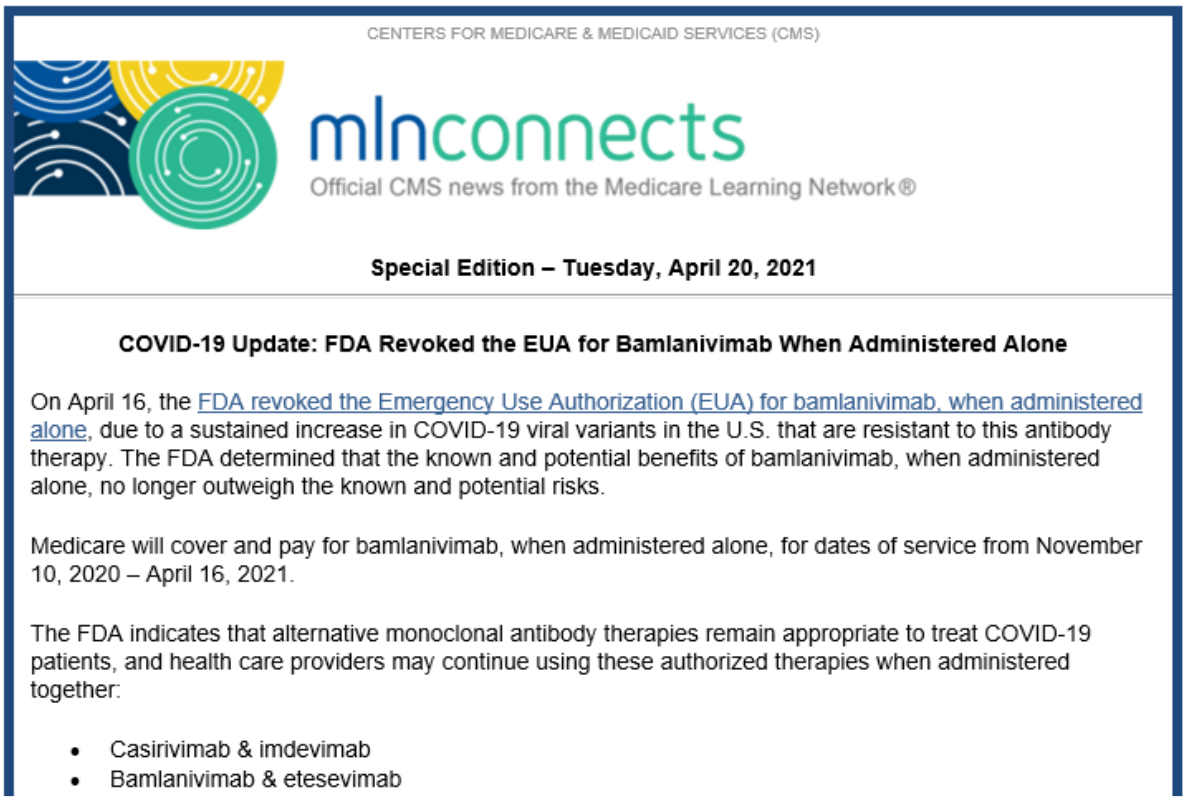
Home / News & Events / FDA Newsroom / Press Announcements / Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Monoclonal Antibody Bamlanivimab

FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Monoclonal Antibody Bamlanivimab

Alternative monoclonal antibody therapies authorized to treat patients with COVID-19 remain available

CMS issued the following MLN announcement via email to its subscribers on **April 20, 2021**:



CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

mlnconnects

Official CMS news from the Medicare Learning Network®

Special Edition – Tuesday, April 20, 2021

COVID-19 Update: FDA Revoked the EUA for Bamlanivimab When Administered Alone

On April 16, the FDA revoked the Emergency Use Authorization (EUA) for bamlanivimab, when administered alone, due to a sustained increase in COVID-19 viral variants in the U.S. that are resistant to this antibody therapy. The FDA determined that the known and potential benefits of bamlanivimab, when administered alone, no longer outweigh the known and potential risks.

Medicare will cover and pay for bamlanivimab, when administered alone, for dates of service from November 10, 2020 – April 16, 2021.

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 when administered together:

- Casirivimab & imdevimab
- Bamlanivimab & etesevimab

Medicare MAC First Coast Service Options has a webpage devoted to billing for COVID-19 vaccines and monoclonal antibodies (next page):

Bamlanivimab was first approved under an Emergency Use Authorization on November 9, 2020. Although the FDA revoked the EUA for solo bamlanivimab, the FDA issued an additional EUA for bamlanivimab in conjuction with etesivimab:

> https://www.fda.gov/media/145801/download
>
> "On February 9, 2021, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of bamlanivimab and etesevimab administered together for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization. …"

The FDA explained the revocation of "solo" Bamlanivimab as due in part to the new resistant variants of the COVID-19 virus:

"While the risk-benefit assessment for using bamlanivimab alone is no longer favorable due to the increased frequency of resistant variants, other monoclonal antibody therapies authorized for emergency use remain appropriate treatment choices when used in accordance with the authorized

labeling and can help keep high risk patients with COVID-19 out of the hospital," said Patrizia Cavazzoni, M.D., director of the FDA's Center for Drug Evaluation and Research.

The FDA has posted a Frequently Asked Questions document; a link and excerpts from the FAQ are provided on the following page.

https://www.fda.gov/media/147639/download

Frequently Asked Questions on the Revocation of the Emergency Use Authorization for Bamlanivimab Administered Alone (EUA 90)

Q. Can health care facilities use their current supplies of bamlanivimab?
A. With the revocation of EUA 90, healthcare facilities and providers may *only* administer bamlanivimab together with etesevimab consistent with the terms and conditions of the EUA for bamlanivimab and etesevimab administered together (EUA 94). With the revocation of EUA 90, bamlanivimab administered alone is no longer authorized for emergency use. Sites intending to use an existing supply of bamlanivimab must order a sufficient supply of etesevimab to pair with the supply of bamlanivimab on hand.

Q. If a health care facility has excess supply of bamlanivimab alone, what should the facility do with the excess supply?
A. Health care facilities with excess supply of bamlanivimab that cannot be paired with etesevimab are asked to continue to store this supply pending further recommendations from the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response (ASPR).

Q. Why was the Emergency Use Authorization (EUA) for bamlanivimab administered alone (EUA 90) revoked?
A. FDA is required to regularly review the circumstances and appropriateness of an Emergency Use Authorization (EUA), including review of emerging scientific data associated with the emergency use of an authorized product. Since the initial authorization of bamlanivimab administered alone for emergency use on November 9, 2020, there has been a sustained increase in SARS-CoV-2 viral variants across the U.S. that are resistant to bamlanivimab alone. Given the frequency of these particular viral variants, and since current testing technologies are not available to ascertain whether a particular patient who has tested positive for coronavirus disease 2019 (COVID-19) is infected with a viral variant prior to initiation of treatment, there is an increased risk of treatment failure when bamlanivimab is administered alone. As such, based on the totality of scientific evidence available, the Agency has concluded that the known and potential benefits of bamlanivimab administered alone no longer outweigh the known and potential risks for the product. Therefore, the Agency has determined that the criteria for issuance of an EUA are no longer met and has revoked EUA 90 for bamlanivimab administered alone for the treatment of COVID-19.

Additional information is available through CMS:

https://www.cms.gov/files/document/covid-medicare-monoclonal-antibody-infusion-program-instruction.pdf

COVID-19 Vaccine Codes

On Friday, December 18, 2020 the FDA approved the Moderna COVID-19 vaccine for use under an Emergency Use Authorization (EUA). This vaccine joins the Pfizer product which was provided EUA on December 11, 2020.

Under the CARES Act, Medicare will provide beneficiaries COVID-19 vaccine administration with no cost-sharing to beneficiaries under Part B coverage. Initially, providers will not incur a cost for the drug product as they will be distributed through government agencies. Providers should not bill for the drug when they receive it at no cost. CMS states it will establish COVID-19 drug product allowances, which will be based on reasonable costs (or, for physician offices, 95% of Average Wholesale Prices), later.

Per the The Medicare Claims Processing Manual Chapter 32 - Billing Requirements for Special Services section 67.2 providers should not bill for drugs when they receive it at no cost.

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c32.pdf#

67.2 – Institutional Billing for No Cost Items
(Rev. 4013, Issued: 03-30-18, Effective: 01-01-09, Implementation: 06-29-18)

In anticipation of the EUA approval of the COVID-19 vaccine that is currently in development by AstraZeneca and the University of Oxford, the AMA CPT® code set for the vaccine product and administration. Like both the Pfizer and Moderna vaccines, administration code will be reported based whether it is the first or the second dose. The effective date for these codes will follow the EUA approval (continues next page).

Vaccine Code	CPT Long Descriptor	Mfr Vaccine / Procedure	MCR Allowed	Effective Date
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 *(PARA note: Report administration code 0001A or 0002A)*	Pfizer-Biontech Covid-19 Vaccine	$0.01	12/11/2020
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 *(PARA note: Report administration code 0011A or 0012A)*	Moderna Covid-19 Vaccine	$0.01	12/18/2020

91302*	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free, 5x1010 viral particles/0.5mL dosage, for intramuscular use *(PARA note: Report administration code 0021A or 0022A)*	AstraZeneca Covid-19 Vaccine	$0.01	**TBD**
91303	Severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free, 5x1010 viral particles/0.5mL dosage, for intramuscular use *(PARA note: Report administration code 0031A)*	Jennsen Covid-19 Vaccine	$0.01	02/26/2020

***** Initially, providers will not incur a cost for the drug product as they will be distributed through government agencies. Providers should not bill for the drug when they receive it at no cost. CMS will update the payment allowance later.

COVID-19 Vaccine Administration Codes

Effective immediately after the FDA approves vaccinations with an Emergency Use Authorization, providers may report the COVID-19 administration code based on the type of vaccine and the which dose is provided.

Johnson & Johnson Janssen COVID-19 Vaccine:

After a short pause on from April 13, 2021 to April 23, 2021 the FDA and CDC again recommends the Janssen COVID-19 vaccine for individuals 18 years old and older.

As with other vaccines, the most common side effects are pain at the injection site, muscle aches, nausea, and headaches. Those side effects generally last one to two days.

The Janssen COVID-19 vaccine was paused after several immunized individuals developed thrombosis-thrombocytopenia syndrome (TTS). While both the FDA and CDC will continue to investigate risk with all COVID-19 vaccines, they recommend all practitioners administering the Janssen vaccine review the Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccine Providers) and the Fact Sheet for Recipients which are revised with the risk about the syndrome.

Fact Sheet for Healthcare Providers Administering Vaccine (Vaccine Providers)

https://www.fda.gov/media/146304/download

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA) OF THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Janssen COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

Fact Sheet for Recipients and Caregivers

https://www.fda.gov/media/146305/download

FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Janssen COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of receiving the Janssen COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

CMS announced on March 15, 2021 COVID-19 vaccine administration payment rates will increase to (geographically adjusted) $40 each dose. The increased rates, which go into effect for dates of service on or after March 15, 2021, are expected to increase the number of vaccines administered daily by helping to establish new or expand current vaccination sites, hire additional staff, and provide community education.

https://www.cms.gov/newsroom/press-releases/biden-harris-administration-increases-medicare-payment-life-saving-covid-19-vaccine

Code	CPT Long Descriptor	Mfr Vaccine/ Procedure Name	Payment Allowance	Effective Date	Payment Allowance after Date of Service 03/15/2021
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**	**Pfizer**-Biontech Covid-19 Vaccine Administration – **First Dose**	$ 16.94	12/11/2020	$40.00*
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**	**Pfizer**-Biontech Covid-19 Vaccine Administration – **Second Dose**	$ 28.39	12/11/2020	$40.00*

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**	**Moderna** Covid-19 Vaccine Administration – **First Dose**	$ 16.94	12/18/2020	$40.00*
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**	**Moderna** Covid-19 Vaccine Administration – **Second Dose**	$ 28.39	12/18/2020	$40.00*
0021A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free, 5x1010 viral particles/0.5mL dosage; **first dose**	**AstraZeneca** Oxford Covid-19 Vaccine Administration – **First Dose**	$ 16.94	TBD	TBD
0022A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free, 5x1010 viral particles/0.5mL dosage; **second dose**	**AstraZeneca** Oxford Covid-19 Vaccine Administration – **Second Dose**	$ 28.39	TBD	TBD
0031A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free, 5x1010 viral particles/0.5mL dosage, **single dose**	**Janssen** Covid-19 Vaccine Administration	$28.39	02/26/2020	$40.00*

**Payment is geographically adjusted based on where the vaccine service is furnished.*

Billing and Coding for Vaccines

Vaccines and Administration Codes					
Service	**Description**	**Rev Code**	**Condition Code(s)**	**Dx Notes**	**Dosing Info**
Pfizer					
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 **(DO NOT REPORT IF PROVIDED FREE OF COST)**	0636	**A6** - 100% Medicare Payment For patients who have Medicare Advantage Plans, bill services to traditional Medicare and report **78** - New coverage not implemented by Medicare Advantage	**Z23** - Encounter for immunization	21 Days
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**	0771			
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**	0771			
Moderna					
Service	**Description**	**Rev Code**	**Condition Code(s)**	**Dx Notes**	**Dosing Info**
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 **(DO NOT REPORT IF PROVIDED FREE OF COST)**	0636	**A6** - 100% Medicare Payment For patients who have Medicare Advantage Plans, bill services to traditional Medicare and report **78** - New coverage not implemented by Medicare Advantage	**Z23** - Encounter for immunization (Continued next page)	21 Days
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**	0771			

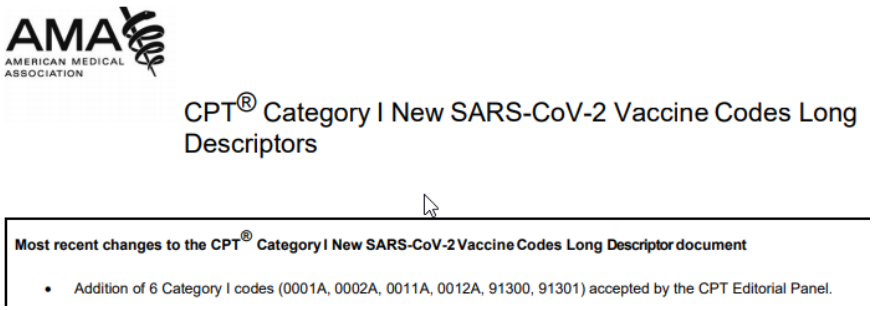
Moderna (continued from prior page)					
Service	**Description**	**Rev Code**	**Condition Code(s)**	**Dx Notes**	**Dosing Info**
0012A	Immunization administration by intramuscular injection of Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative-free, 100 mcg/0.5mL dosage; **second dose**	0771			
Janssen					
91303	Severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free, 5x1010 viral particles/0.5mL dosage, for intramuscular use **(DO NOT REPORT IF PROVIDED FREE OF COST)**	0636	**A6** - 100% Medicare Payment For patients who have Medicare Advantage Plans, bill services to traditional Medicare and report **78** - New coverage not implemented by Medicare Advantage	**Z23** - Encounter for immunization	Single Dose
0031A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free, 5x1010 viral particles/0.5mL dosage, single dose	0771			

(Continued)

AstraZeneca (Currently not approved in the United States)					
91302	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free, 5x1010 viral particles/0.5mL dosage, for intramuscular use **(DO NOT REPORT IF PROVIDED FREE OF COST)**	0636	**A6** - 100% Medicare Payment For patients who have Medicare Advantage Plans, bill services to traditional Medicare and report **78** - New coverage not implemented by Medicare Advantage	**Z23** - Encounter for immunization	28 Days
0021A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free, 5x1010 viral particles/0.5mL dosage; **first dose**	0771			
0022A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free, 5x1010 viral particles/0.5mL dosage; **second dose**	0771			

The AMA provides instructions for coding administration of the COVID-19 vaccines through the following document:

https://www.ama-assn.org/system/files/2020-11/covid-vaccine-long-descriptors.pdf


AMA
AMERICAN MEDICAL ASSOCIATION

CPT® Category I New SARS-CoV-2 Vaccine Codes Long Descriptors

Most recent changes to the CPT® Category I New SARS-CoV-2 Vaccine Codes Long Descriptor document

- Addition of 6 Category I codes (0001A, 0002A, 0011A, 0012A, 91300, 91301) accepted by the CPT Editorial Panel.

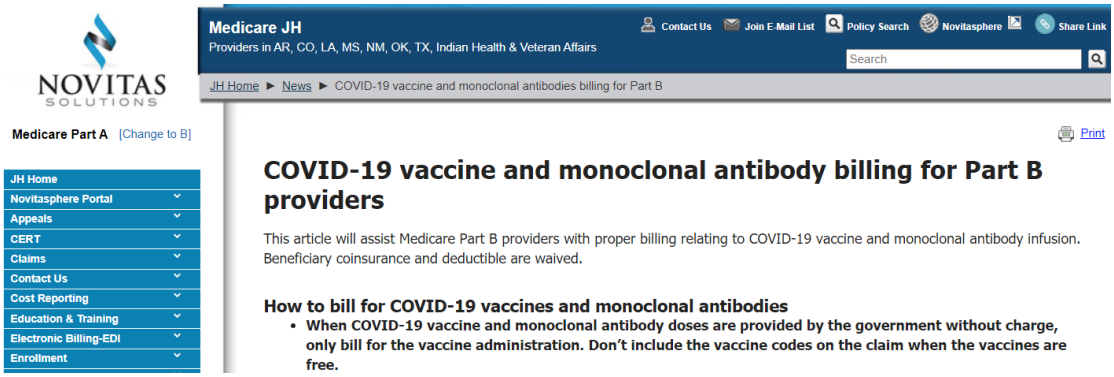
RHCs and FQHCs cannot bill COVID-19 for COVID-19 vaccines on a claim form. If the patient is there for another reason, the RHC or FQHC should exclude the cost of the vaccines. It will be settled on a cost report.

A listing of payment rates by each type of Medicare provider can be found in the Medicare FAQ link.

Medicare Provider	Vaccine Payment	Vaccine Administration Payment
Hospitals – Outpatient Departments	Reasonable Costs*	Separately payable based on established rate for code. Not subject to OPPS.
Hospitals – Inpatients	Reasonable Costs*	Separately payable based on established rate for code.
Critical Access Hospitals (CAHs)	101% of Reasonable Costs	101% of Reasonable Costs
Rural Health Centers (RHCs)	Paid through the cost report	Paid through the cost report

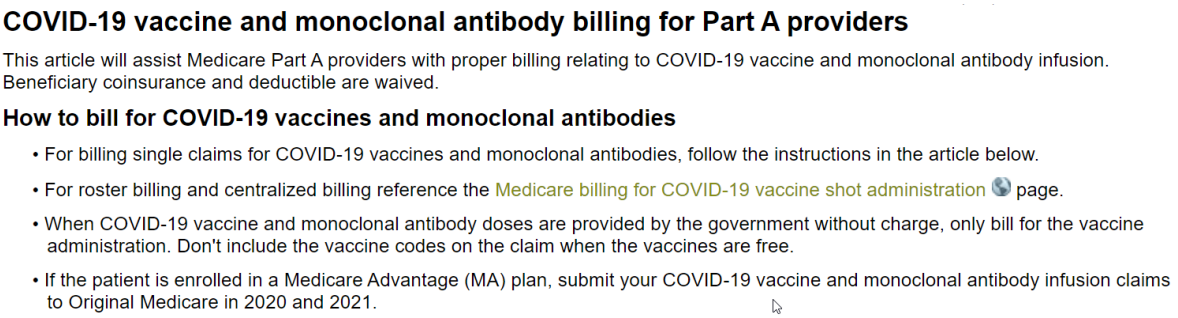
Medicare MAC Novitas JH provides billing information for Part B providers:

https://www.novitas-solutions.com/webcenter/portal/MedicareJH/pagebyid?contentId=00243903



Another MAC, First Coast Service Options, has a webpage devoted to billing for COVID-19 vaccines and monoclonal antibodies for Part A providers:

https://medicare.fcso.com/Billing_news/0479121.asp



CMS created a resource page to provide COVID-19 vaccine policies and guidance for providers, state programs, and beneficiaries:

https://www.cms.gov/covidvax

Condition Codes during the PHE

Condition Code A6 – During the PHE, Medicare will cover monoclonal infusions and COVID-19 vaccines at no expense to the beneficiary under the COVID-19 vaccine program. Report Condition code A6 for 100% payment from Medicare.

> Per UB-04 Manual: "This code identifies that pneumococcal pneumonia and influenza vaccine services are reimbursed under special Medicare program provisions and Medicare deductible and coinsurance requirements do not apply."

Condition Code DR – The Disaster Related (DR) Condition code is an informational billing indicator to assist Medicare in collecting information on when services were permissible due to a waiver.

While CMS will not reject a claim that falls outside of their revised instructions, on November 9, 2020, CMS provided a table to clarify when a provider should include condition code DR on an institutional claim. The MLN Matters publication link and an excerpt are provided below:

https://www.cms.gov/files/document/se20011.pdf

MLN Matters SE20011 Related CR N/A

Waiver/Flexibility	Summary	CR	DR
Services provided by the hospital in the patient's home as a provider-based outpatient department when the patient is registered as a hospital outpatient.	During the COVID-19 PHE, hospitals may furnish clinical staff services in the patient's home as a provider-based outpatient department and bill and be paid for these services as Hospital Outpatient Department (HOPD) services when the patient is registered as a hospital outpatient. Hospitals should bill as if the services were furnished in the hospital, including appending the PO modifier for excepted items and services and the PN modifier for non-excepted services. The DR condition code should also be appended to these claims.		X

Condition Code 78 – Medicare has also advised that when administering monoclonal antibody infusions and COVID-19 vaccines to a Medicare Advantage plan patient, the claim should be submitted to traditional Medicare. Report to Medicare Condition Code 78 New coverage not implemented by Medicare Advantage.

> Per UB-04 Manual: "Billing is for a newly covered service for which the managed care plan/HMO does not pay."

Condition Codes 90 and 91 – On October 29, 2020, the National Uniform Billing Committee (NUBC) created condition codes 90 and 91 for services and treatment provided under Expanded Access Approved Services (EA) or Emergency Use Authorization (EUA.)

https://www.nubc.org/nubc-announces-new-condition-codes-effective-february-1-2021

NUBC announces new condition codes effective February 1, 2021

The new condition codes are as follows:

90	Expanded Access Approval (Effective 2/1/21)	Service provided as part of an Expanded Access approval.
91	Emergency Use Authorization (Effective 2/1/21)	Service provided as part of an Emergency Use Authorization.

For claims **received** (not based on date of service, admission date, or discharge date) on or after February 1, 2021 Medicare instructs providers to append **Condition Code 90** to claims with Expanded Access Approved (EA) services. The EA program, sometimes referred to as "compassionate use," authorizes investigational drugs, biologicals, or medical devices for treatments outside of clinical trials when no other therapy or treatment is available for patients with diseases or conditions that are serious or life-threatening. The treatment offered under an EA have not been approved by the FDA and may or may not be effective in treatment.

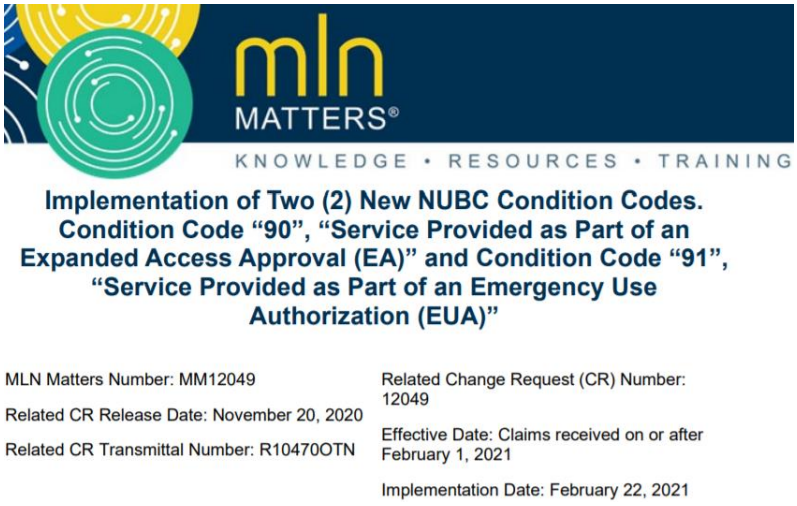
For claims **received** (not based on date of service, admission date, or discharge date) on or after February 1, 2021 Medicare instructs providers to append **Condition Code 91** to claims with treatment provided as part of an Emergency Use Authorization (EUA). EUA therapy or treatments are approved by the FDA during the Public Health Emergency when no alternative treatments are available. These treatments haven't been granted full FDA approval. Examples of recent therapies approved by the FDA under EUA are monoclonal antibody drugs Regeneron combo Casirivimab and Imdevimab, Bamlanivimab, pediatric Remdesivir and convalescent plasma.

The FDA list of Medical Countermeasures the FDA approved under an EUA is available at this link:

https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

On November 20, 2020. CMS released MLN Matters MM12049:

https://www.cms.gov/files/document/mm12049.pdf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Implementation of Two (2) New NUBC Condition Codes. Condition Code "90", "Service Provided as Part of an Expanded Access Approval (EA)" and Condition Code "91", "Service Provided as Part of an Emergency Use Authorization (EUA)"

MLN Matters Number: MM12049
Related CR Release Date: November 20, 2020
Related CR Transmittal Number: R10470OTN

Related Change Request (CR) Number: 12049
Effective Date: Claims received on or after February 1, 2021
Implementation Date: February 22, 2021

Condition Code DR/Modifier CR –

CMS has instructed providers to report these codes when care is provided under one of the Section 1135 waivers to address the Public Health Emergency. These codes do not affect payment. They are not necessary on Medicare telehealth services.

When all services or items billed on the claim are related to a COVID-19 waiver, Condition Code DR is used by institutional providers and Modifier CR is for both institutional and non-institutional providers.

On August 26, 2020, CMS revised its document that discusses the use of these modifiers and condition code DR in MLN SE20011 "Medicare Fee-for-Service (FFS) Response to the Public Health Emergency on the Coronavirus (COVID-19)."

https://www.cms.gov/files/document/se20011.pdf

Medicare Fee-For-Service (FFS) Response to the Public Health Emergency on the Coronavirus (COVID-19)

MLN Matters Number: SE20011 Revised
Article Release Date: August 26, 2020
Related CR Transmittal Number: N/A

Related Change Request (CR) Number: N/A
Effective Date: N/A
Implementation Date: N/A

Modifiers

Modifier CR –

The Catastrophe Related (CR) modifier is an informational billing indicator to assist Medicare in collecting information on when services were permissible due to a waiver.

While CMS will not reject a claim that falls outside of their revised instructions, on November 9, 2020, CMS provided a table to clarify when a provider should include modifier CR on institutional and non-institutional claims. The MLN Matters publication link and an excerpt are provided below:

https://www.cms.gov/files/document/se20011.pdf

Waiver/Flexibility	Summary	CR	DR
Care for Excluded Inpatient Psychiatric Unit Patients in the Acute Care Unit of a Hospital	Allows acute care hospitals with excluded distinct part inpatient psychiatric units to relocate inpatients from the excluded distinct part psychiatric unit to an acute care bed and unit as a result of a disaster or emergency.		X
Housing Acute Care Patients in the IRF or Inpatient Psychiatric Facility (IPF) Excluded Distinct Part Units	Allows acute care hospitals to house acute care inpatients in excluded distinct part units, such as excluded distinct part unit IRFs or IPFs, where the distinct part unit's beds are appropriate for acute care inpatients.		X

Modifier CS –

Effective March 18, 2020, under the under the Families First Coronavirus Response Act (FFCRA), Medicare will waive cost-sharing liability for certain evaluation and management services related to COVID-19 testing. The services must result either in an order or administration of COVID-19 testing or were provided to determine the need for a COVID-19 test. The evaluation and management may be provided either in person or through telehealth services. Append modifier CS to COVID-19 specimen collection C9803 or other evaluation and management codes, such as ED visits (9928x) to ensure cost-sharing is waived, unless the testing is neither for suspected exposure or symptoms (i.e. presurgery testing, travel, and return to work testing.)

On August 27, 2020, CMS clarified the correct use of modifier CS by providing a list of HCPCS codes that are appropriate for waiving cost-sharing for physicians, hospitals, and RHC's/FQHC's when providing medically necessary COVID-19 related Medicare Part B services. CMS waives beneficiary coinsurance and deductible amounts for these services when **Modifier CS** is appended. CMS will return claims containing modifier CS on procedure codes that are not listed.

CMS provides separate lists of CS-eligible HCPCS code for three categories of medical providers.

- Physicians/Non-physician Practitioners
- Hospital OPPS Outpatient Departments
- RHCs and FQHCs

The document instructs Critical Access Hospitals to use the lists applicable to their billing method (Method I or Method II.)

https://www.cms.gov/outreach-and-educationoutreachffsprovpartprogprovider-partnership-email-archive/2020-08-27-mlnc#_Toc49329805

Claims, Pricers & Codes

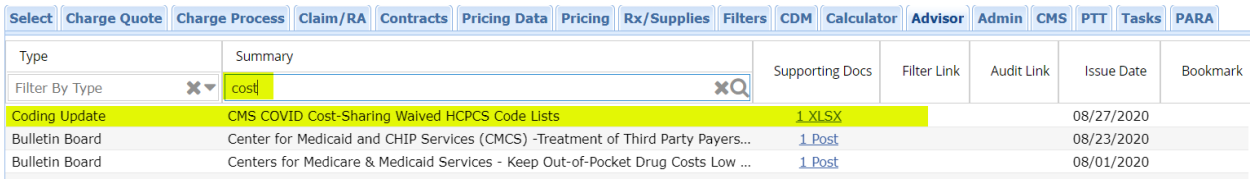
COVID-19: Waive Cost-Sharing for These HCPCS Codes

The Families First Coronavirus Response Act waives cost-sharing under Medicare Part B (coinsurance and deductible amounts) for COVID-19 testing-related services through the end of the public health emergency. In April, CMS provided evaluation and management categories for applicable medical visits. We are now specifying HCPCS procedure codes for this cost-sharing waiver for:

1. Physicians/Non-Physician Practitioners (ZIP)
2. Hospital Outpatient Departments paid under the Outpatient Prospective Payment System (PDF)
3. Rural Health Clinics and Federally Qualified Health Centers (ZIP)
4. Critical Access Hospitals (CAHs) use the Outpatient list; Method II CAHs use the Outpatient and Physicians/Non-Physician Practitioners lists as applicable

Use the Cost Sharing (CS) modifier on applicable claim lines to identify the service as subject to this cost-sharing wavier. If you use the CS modifier with HCPCS codes that are not on the list, we will return the claim.

The CMS spreadsheet is available in the Advisor tab of the PARA Data Editor – enter "Cost" in the summary field for quick access:



Commercial Insurers

Coverage and billing requirements on COVID-19 vary based on the insurance plan. To avoid denials and payment delays, providers are encouraged to consult the plan involved prior to billing. The website link on the next page, compiled by AHIP, offers links to various insurance plan COVID-19 webpages:

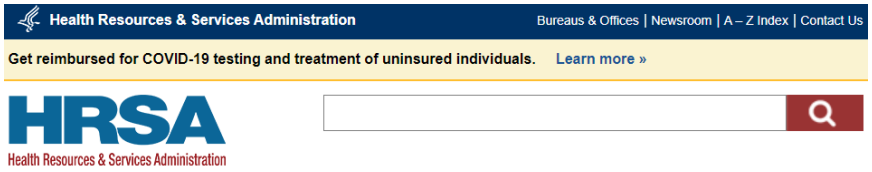
https://www.ahip.org/health-insurance-providers-respond-to-coronavirus-covid-19/

Uninsured COVID-19

Providers who have tested or provided services to uninsured (and in some cases undocumented) patients with a COVID-19 diagnosis after February 4, 2020 may enroll to file claims for reimbursement under the HHS COVID-19 Uninsured Program.

The program covers qualified expenses for COVID-19 outpatient and inpatient services and covers COVID-19 vaccinations.

https://www.hrsa.gov/coviduninsuredclaim



HRSA requires specific coding requirements for claim submission.

https://www.hrsa.gov/coviduninsuredclaim/frequently-asked-questions

Is the COVID-19 Uninsured Program considered to be a health plan and therefore subject to Health Insurance Portability and Accountability Act (HIPAA) requirements?

No. The HRSA COVID-19 Uninsured Program is a claims reimbursement program for health care providers which does not meet the definition of a "health plan" as defined in section 1171(5) of the Social Security Act and in 45 C.F.R. § 160.103 in that the program has no relationship with individuals that would legally obligate the program to pay claims for some or all of the health care provided to those individuals. Therefore, the program is not subject to HIPAA requirements.

The HRSA COVID-19 Uninsured Program does not provide coding guidance to providers. Rather, the program provides billing guidance to allow providers to identify and submit only claims eligible for reimbursement under this program, which is exclusively for reimbursing providers for COVID-19 testing of uninsured individuals and treatment for uninsured individuals when COVID-19 is the primary reason for treatment, or for vaccine administration to uninsured individuals. HRSA has developed the following guidance for claims reimbursement submission:

- For dates of service or discharges on or after April 1, 2020, providers will use primary diagnosis U07.1 to indicate COVID-19 is the primary reason for treatment except for pregnancy for which providers will use O98.5 as primary diagnosis and U07.1 as the secondary diagnosis.

(continued next page)

- For dates of services or discharges prior to April 1, 2020, there is no equivalent diagnosis to indicate COVID-19 is the primary reason for treatment. To address this issue, HRSA has established separate guidance for this program to use B97.29 as the primary diagnosis when COVID-19 is the primary reason for treatment except for pregnancy for which providers would use O98.5 as the primary diagnosis and B97.29 as the secondary diagnosis (similar to how U07.1 is used).

HRSA recognizes that the use of B97.29 as the primary diagnosis as described above is different from the ICD-10-CM Official Coding Guidelines – Supplement for Coding encounters related to COVID-19 Coronavirus Outbreak. However, as previously stated, HRSA's COVID-19 Uninsured Program is not a health plan.

COVID-19 Funeral Assistance Program

As part of the Coronavirus Response and Relief Supplemental Appropriations Act of 2021 and the American Rescue Plan Act of 2021, FEMA may aid with funeral expenses that occurred after **January 20, 2020**. Applications opened on **April 12, 2021**, to "ease of some of the financial stress and burden caused by the virus."

Applicants will need to provide a death certificate that indicates the patient died because of coronavirus while in the United States or U.S. territories. The patient did not have to be a United States citizen, non-citizen, or qualified alien.

The COVID-19 Funeral Assistance Line Number:
844-684-6333|TTY: 800-462-7585

A U.S. citizen, non-citizen, or qualified alien who incurred funeral and related expenses will need to provide receipts or contracts showing the responsible party. Expenses may include but are not limited to:

- Transfer of remains
- Marker or headstone
- Clergy or officiant services
- Cremation or burial costs
- Funeral ceremony arrangements
- Funeral home equipment or staff
- Costs associated with producing and certifying death certificates
- Transportation of up to persons to identify the deceased individual
- Casket or urn

Additionally, applicants will be asked for the following information, so FEMA suggest preparing these before calling:

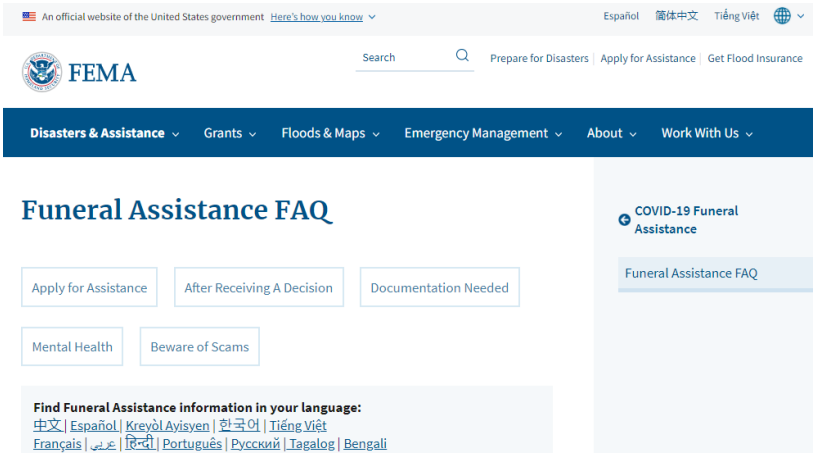
- Deceased individual's SSN, date of birth, where the individual passed away
- Information on donations, grants, or other funeral assistance received
- Routing and account number for the applicant for direct deposit of funds

Qualified individuals may apply for assistance for more than one person who died from coronavirus. Financial assistance is limited to a max of $9,000 per funeral and a maximum of $35,500 per application per state, and life insurance proceeds are not considered a duplication of Funeral Assistance benefits. Pre-planned and pre-paid burials or funerals are not eligible for reimbursement.

FEMA will not accept online applications but has set up a toll-free phone number for questions and complete an application with an agent. A caller may experience busy signals as FEMA works through technical issues, but, currently, there is no deadline to apply.

FEMA offers a FAQ page at the following site:

https://www.fema.gov/disasters/coronavirus/economic/funeral-assistance/faq



References:

Congress.gov –

American Rescue Plan Act of 2021

https://www.congress.gov/bill/117th-congress/house-bill/1319

Consolidated Appropriations Act, 2021

https://www.congress.gov/bill/116th-congress/house-bill/133/text

COVID-19 MAC Webpages, Hotlines, and PC-ACE Software

CMS has updated its PC-ACE software with anticipated availability of COVID-19 vaccines. Providers who intend to administer vaccines or monoclonal antibody infusions or roster bill, should download and install the newest release of PC-ACE from the applicable MAC.

https://www.cms.gov/files/document/covid-19-mac-hotlines.pdf

COVID-19 MAC Webpages, Hotlines, and PC-ACE Software

Only contact the COVID-19 Hotline for the Medicare Administrative Contractor (MAC) that serves your geographic area.

Medicare Administrative Contractor (links to webpages)	States and Territories per MAC Jurisdiction	Toll-free Hotline Telephone Number	Hotline Hours of Operation, Monday – Friday	PC-ACE Download (links to software)
CGS Administrators, LLC (CGS)	**Part A/B:** J15: Kentucky, Ohio **Home Health & Hospice:** J15: Colorado, Delaware, District of Columbia, Iowa, Kansas, Maryland, Missouri, Montana, Nebraska, North Dakota, Pennsylvania, South Dakota, Utah, Virginia, West Virginia, Wyoming	1-855-769-9920	7:00 am – 4:00 pm CT	J15 – Part A J15 – Part B J15 – HH&H
First Coast Service Options Inc. (FCSO)	JN: Florida, Puerto Rico, U.S. Virgin Islands	1-855-247-8428	8:30 am – 4:00 pm ET	ABILITY | PC-ACE

CMS COVID-19 Resources

Billing and coding guidance is available within the "Frequently Asked Questions to Assist Medicare Providers" on the CMS "Current Emergencies" website on the next page:

https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page

COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing

The FAQs in this document supplement the previously released FAQs: 1135 Waiver FAQs, available at https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/MedicareFFS-EmergencyQsAs1135Waiver.pdf.

We note that in many instances, the general statements of the FAQs referenced above have been superseded by COVID-19-specific legislation, emergency rules, and waivers granted under section 1135 of the Act specifically to address the COVID-19 public health emergency (PHE). The policies set out in this FAQ are effective for the duration of the PHE unless superseded by future legislation.

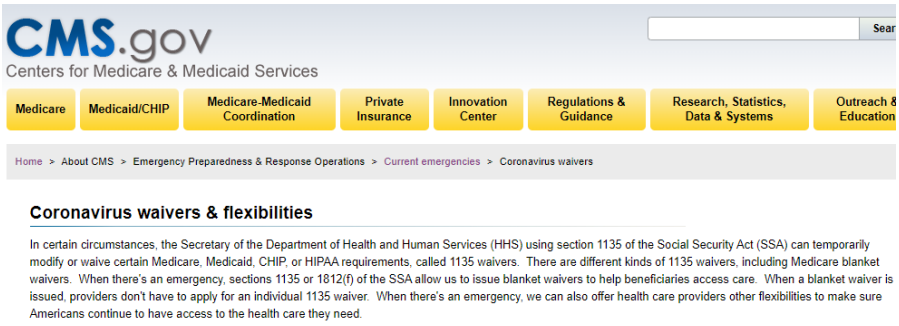
CMS Toolkit on COVID-19 Vaccine: Health Insurers and Medicare Advantage Plans

https://www.cms.gov/files/document/COVID-19-toolkit-issuers-MA-plans.pdf

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

Coronavirus Waivers & Flexibilities:

https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers



CMS Podcasts and Transcripts:

https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/PodcastAndTranscripts