

**INFORMATIONAL LETTER NO. 2207-MC-FFS-CVD**

**DATE:** January 8, 2021

**TO:** Iowa Medicaid Hospital, Physician MD, Physician DO, Podiatrist, Optometrist, Rural Health Clinic (RHC), Clinic, Community Mental Health Center (CMHC), Psychologist, Certified Nurse Midwife, Certified Registered Nurse Anesthetist (CRNA), Clinical Social Worker, Federally Qualified Health Center (FQHC), Nurse Practitioner (NP), Behavioral Health and Physician Assistant Providers, Area Education Agency (AEA), and Local Education Agency (LEA), Nursing Facilities/Skilled Nursing Facilities (NF/SNF), Pharmacies

**APPLIES TO:** Managed Care (MC) and Fee-for-Service (FFS), and Coronavirus Disease (CVD)

**FROM:** Iowa Department of Human Services (DHS), Iowa Medicaid Enterprise (IME)

**RE:** COVID-19 Vaccines and Monoclonal Antibodies

**EFFECTIVE:** See Specific Direction Identified in the Narrative and Tables Below

The purpose of this informational letter is to inform and update providers regarding the release of COVID-19 vaccines and Monoclonal Antibodies to treat COVID-19. Information regarding billing and coding for administration fees is included below.

**COVID-19 Vaccines**

The Food and Drug Administration (FDA) has released two vaccines under an emergency use authorization (EUA). These vaccines are being purchased by the federal government and distributed to states and territories. To receive free supplies of the COVID-19 vaccines, pharmacies, retail clinics, providers, and any other site of care receiving and administering COVID-19 vaccine must sign an agreement with the U.S. government. Based on this agreement, all providers must:

- Vaccinate individuals regardless of whether they have health insurance coverage or what type of coverage they have, and are prohibited from balance billing or otherwise charging vaccine recipients.

- Provide EUA Fact Sheets on the vaccine and vaccination cards to individuals immunized.
- Providers must administer the vaccine in accordance with the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP) requirements.
- Meet vaccine storage and recordkeeping requirements.
- Record in the vaccine recipient's record and report required information to the relevant state, local, or territorial public health authority within 24 hours of administering a dose of COVID-19 vaccine.

Information on how to complete the CDC COVID-19 Vaccination Program Provider Agreement is available on the Iowa Department of Public Health (IDPH) website at <https://idph.iowa.gov/Emerging-Health-Issues/Novel-Coronavirus/Vaccine/Information-for-Vaccine-Providers> in the "COVID-19 Vaccine Provider Enrollment Letter".

The IDPH COVID-19 Vaccine Information for Vaccine Providers webpage contains the most current information specific to Iowa about the available vaccines, frequently asked questions (FAQs), factsheets, instructions for reporting administration data, job aids, videos, and more.

Of note, vaccine distribution is occurring outside of the Vaccine for Children (VFC) program. A provider does not need to be enrolled in the VFC program to administer a COVID-19 vaccine to children eligible for the VFC program.

Distribution of the COVID-19 vaccine in Iowa is occurring through the State and local public health departments. Coordinate with local public health officials to determine when vaccine will be available in your area.

### **Vaccine Priority Groups**

The COVID-19 vaccines will be distributed by priority groups. The IDPH Infectious Disease Advisory Council (IDAC) provides recommendations in developing COVID-19 vaccine distribution and therapy guidance. Iowa specific vaccine priority recommendations based on the ACIP recommendations can be found at <https://idph.iowa.gov/Emerging-Health-Issues/Novel-Coronavirus/IDAC>.

### **COVID-19 Vaccine Orders**

The Iowa Department of Public Health has issued a Vaccine Shortage Order. The order is available on the IDPH webpage at <https://idph.iowa.gov/Emerging-Health-Issues/Novel-Coronavirus/Vaccine/Information-for-Vaccine-Providers>. Additionally, a Statewide Standing Order for COVID-19 Vaccination was issued on December 14, 2020 and then updated December 30, 2020 by Dr. Caitlin Pedati, MD, MPH, FAAP. Dr. Pedati is the Medical Director and State Epidemiologist at IDPH. Dr. Pedati is an enrolled Medicaid provider. The standing order will be updated regularly as vaccine priority groups are refined and additional vaccines become available. The standing

order is available through State and local public health for providers that receive allocations of the COVID-19 vaccine.

### **COVID-19 Vaccine Medicaid Billing and Rates**

At this time, there is no charge for the vaccine as it is being acquired and distributed by the federal government. The IME will pay for COVID-19 vaccine administration. **The IME will pay for COVID-19 vaccine administration at the Medicare rate of \$16.94 for the initial dose and \$28.39 for the second dose.** Both COVID-19 vaccines currently approved consist of a two-dose series. **For any single dose COVID-19 vaccines released in 2021, the IME will provide payment at the Medicare rate of \$28.39 to administer the vaccine.** Roster billing will not be available for providers.

Providers should submit Medicaid member claims for vaccine administration to the member's MCO or through the FFS program as applicable to the member and according to the provider's corresponding fee schedule and provider type. All claims for vaccine administration will be processed as electronic transactions through the medical benefit and not pharmacy point of sale (POS). Providers must use the appropriate administration codes for the specific vaccine and specific dose being administered.

**Please note:** The vaccine administration code and National Drug Code (NDC) must also appear on the claim. No reimbursement will be paid for the vaccine while the vaccine is being provided by the federal government.

### **Pharmacy Providers**

COVID-19 vaccines administered by a pharmacy require the National Provider Identifier (NPI) of the ordering provider, rendering provider and billing provider.

- The ordering provider NPI = Standing Order Medical Director NPI or that of the physician on the physician-pharmacy vaccine protocol.
- The rendering provider NPI = NPI of the pharmacy
- The billing provider NPI = NPI of the pharmacy

### **Important Documentation Requirements for Pharmacies**

The [September 3, 2020](https://www.hhs.gov/sites/default/files/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf)<sup>1</sup> and [October 20, 2020](https://www.hhs.gov/sites/default/files/prep-act-authorization-pharmacies-administering-covered-countermeasures.pdf)<sup>2</sup> authorizations of the Health and Human Services (HHS) COVID-19 Public Readiness and Emergency Preparedness (PREP) Act provide that, in order to be covered by the PREP Act liability immunity for ordering or administering COVID-19 vaccinations, qualified state-licensed pharmacists, state-authorized pharmacy interns, and qualified pharmacy technicians must satisfy a number of requirements. The billing pharmacy must document that all of those requirements have been fulfilled. The documentation is subject to audit and potential

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<sup>1</sup> <https://www.hhs.gov/sites/default/files/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf>

<sup>2</sup> <https://www.hhs.gov/sites/default/files/prep-act-authorization-pharmacies-administering-covered-countermeasures.pdf>

recoupment if the pharmacy fails to adequately document that it has fulfilled the requirements of the act.

The pharmacy shall document all PREP Act requirements:

- The vaccine must be FDA-authorized or FDA-licensed. The pharmacist must identify the vaccine sufficiently in the patient record to confirm that the vaccine was FDA authorized or FDA licensed.
- For each qualified state-authorized pharmacy intern, qualified pharmacy technician, and qualified pharmacist involved in the administration of COVID-19 vaccines, the pharmacy shall keep a record evidencing that the participant is qualified.<sup>3</sup>
- If the vaccination is administered by a qualified state-authorized pharmacy intern or qualified pharmacy technician, it must be ordered by the supervising qualified pharmacist. The patient record must identify the state-authorized pharmacy intern or qualified pharmacy technician administering the vaccination. The patient record must identify the ordering supervising qualified pharmacist.
- If the vaccine is administered by a qualified pharmacy technician, the supervising qualified pharmacist must be readily and immediately available to the immunizing qualified pharmacy technician. The patient record must identify the qualified pharmacy technician administering the vaccine and the readily available supervising qualified pharmacist.
- The vaccination must be ordered and administered according to the CDC's ACIP's COVID-19 vaccine recommendation(s) as indicated by the patient record.
- The qualified pharmacist must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines. For each qualified pharmacist involved in the administration of vaccines, the pharmacy shall keep a record identifying the pharmacist, the training program completed by the qualified pharmacist, the dates of the training program, and any other information necessary to ensure that the training program meets the requirements of this provision.

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<sup>3</sup> A qualified state-authorized pharmacy intern is a pharmacy intern who is authorized by the state or State board of pharmacy. To be a "qualified pharmacy technician," pharmacy technicians working in states with licensure and/or registration requirements must be licensed and/or registered in accordance with state requirements; pharmacy technicians working in states without licensure and/or registration requirements must have a Certified Pharmacy Technician (CPhT) certification from either the Pharmacy Technician Certification Board or National Healthcareer Association. a "qualified pharmacist" means those pharmacists who satisfy the requirements listed in Section V(d) of the Third Amendment. See 85 Fed. Reg. at 52140 (Aug. 24, 2020). <https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf>

- The qualified pharmacy technician or state-authorized pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines. For each qualified pharmacy technician or state-authorized pharmacy intern involved in the administration of vaccines, the pharmacy shall keep a record identifying the qualified pharmacy technician or state-authorized pharmacy intern, the training program completed by the technician or intern, the dates of the training program, and any other information necessary to ensure that the training program meets the requirements of this provision.
- The qualified pharmacist, qualified pharmacy technician, or state-authorized pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation. For each qualified pharmacist, qualified pharmacy technician, or state-authorized pharmacy intern involved in the administration of vaccines, the pharmacy shall keep a copy of their certificate in basic cardiopulmonary resuscitation and any other information necessary to ensure that the pharmacist, technician, or intern have met the requirements of this provision.
- The qualified pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each state licensing period. For each qualified pharmacist involved in the administration of vaccines, the pharmacy shall keep a record that the pharmacist has completed a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each state licensing period, including identifying the education completed, the dates of the education, and any other information necessary to ensure that the continuing education meets the requirements of this provision.
- The qualified pharmacy technician must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during the relevant state licensing period(s). For each qualified pharmacy technician involved in the administration of vaccines, the pharmacy shall keep a record that the pharmacist has completed a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each state licensing period, including identifying the education completed, the dates of the education, and any other information necessary to ensure that the continuing education meets the requirements of this provision.
- The qualified pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the state or local immunization information system (vaccine registry), complying with requirements related to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine. These requirements also apply when the pharmacist is supervising the administration of a COVID-19 vaccination by a qualified pharmacy technician or state-authorized pharmacy intern. The pharmacist shall document all of the foregoing in the patient record.

- The qualified pharmacist, qualified pharmacy technician, or state-authorized pharmacy intern must, if the patient is 18 years of age or younger, inform the patient and the adult caregiver accompanying the patient of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate, and document the foregoing in the patient record.
- The qualified pharmacist must comply with any applicable requirements (or conditions of use) as set forth in the CDC COVID-19 Vaccination Provider Agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s). This requirement also applies when the pharmacist is supervising the administration of a COVID-19 vaccination by a qualified pharmacy technician or state-authorized pharmacy intern.

### **NF/SNF**

If the nursing home administers the vaccine, then that administration will be considered part of their regular operations and included in regular per diem/capitated payments. If an outside entity goes into the nursing home to administer the vaccine (i.e. a pharmacy chain, home health, local public health, etc.), then that entity may bill for the vaccine administration costs. Medicare and private insurance will be the primary payers in this case. Medicaid is the payer of last resort if the individual is only covered by Medicaid.

### **RHC/FQHC**

Administration of COVID-19 vaccines are considered part of the encounter rate determined for these entities. No changes will occur to these billing processes for COVID-19 vaccine administration.

**For all Medicaid members with Medicare or private insurance, Medicare or the private insurance should be billed for vaccine administration fees. Medicaid is the payer of last resort.**

If a physician or non-physician practitioner sees a Medicaid member for the sole purpose of administering a vaccine, the provider may not routinely bill for an Evaluation and Management (E/M) visit. However, physicians and non-physician practitioners can bill for an E/M service furnished on the same day as a vaccine when the practitioner performs a medically necessary and significant, separately identifiable E/M visit in addition to the vaccine administration. Additionally, providers may not balance bill Medicaid beneficiaries amounts additional to the amount paid by the IME.

### **No Co-Payments**

There are no co-payments for COVID-19 vaccine administration, including no co-payments for a physician office visit at which the vaccine is administered.

### **No Prior Authorization (PA)**

There is no prior authorization for the COVID-19 vaccine administration.

### **COVID-19 Vaccine Administration Billing for Uninsured**

Providers administering the vaccine to people without health insurance or whose insurance does not provide coverage of the vaccine, can request reimbursement for the administration of the COVID-19 vaccine through the Health Resources & Services Administration (HRSA) COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment, and Vaccine Administration for the Uninsured Fund, see <https://www.hrsa.gov/CovidUninsuredClaim>.<sup>4</sup>

### **COVID-19 Vaccine CPT Codes**

The Centers for Medicare & Medicaid Services (CMS) has released CPT codes for the COVID-19 vaccines. These codes are manufacturer and dose specific. As additional vaccine codes become available, IME will relay that information. The codes for the COVID-19 vaccines identified below were made effective December 1, 2020, however IME will not reimburse claims billed with service dates prior to the vaccine's EUA approval date.

**The following table lists the vaccine and vaccine administration codes for COVID-19:**

Vaccine Code	Vaccine Administration Code	Vaccine Manufacturer	Vaccine Names	Dosing Interval
<b>91300</b> (Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/.3mL dosage, diluent reconstituted, for intramuscular use)	0001A: 1 <sup>st</sup> dose	Pfizer, Inc.	Pfizer-BioNTech COVID-19 Vaccine	21 days
	0002A: 2 <sup>nd</sup> dose			
<b>91301</b> (Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease	0011A: 1 <sup>st</sup> dose	Moderna, Inc.	Moderna COVID-19 Vaccine	28 days

<sup>4</sup> Coverage and Reimbursement of COVID-19 Vaccines, Vaccine Administration, and Cost Sharing under Medicaid, the Children's Health Insurance Program, and Basic Health Program. Centers for Medicare and Medicaid Services. December 17, 2020. <https://idph.iowa.gov/Emerging-Health-Issues/Novel-Coronavirus/Vaccine/Information-for-Vaccine-Providers>

[COVID-19] vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/.5mL dosage, diluent reconstituted, for intramuscular use)	0012A: 2 <sup>nd</sup> dose			
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### **Monoclonal Antibody Treatments**

Currently there are two monoclonal antibody treatments authorized for emergency use by the FDA. The IME added these treatments to the fee schedule with an effective date that corresponds with their EUA date. The drugs are currently being provided at no charge by the federal government. The IDPH is coordinating distribution of the monoclonal antibodies.

Providers should only charge for the infusion of the antibodies at a rate of \$309.60 for procedure codes M0239 and M0243. If a physician or non-physician practitioner sees a Medicaid member for the sole purpose of administering a COVID-19 monoclonal antibody treatment, the provider may not routinely bill for an E/M visit. However, physicians and non-physician practitioners can bill for an E/M service furnished on the same day as a COVID-19 monoclonal antibody treatment when the practitioner performs a medically necessary and significant, separately identifiable E/M visit in addition to the vaccine administration.



The following table lists the Monoclonal antibody treatment and administration codes:

Procedure Code	Description	Effective Date
Q0239	Injection, bamlanivimab-xxxx, 700 mg	November 10, 2020
M0239	Intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring	November 10, 2020
Q0243	Injection, casirivimab and imdevimab, 2400 mg	November 21, 2020
M0243	Intravenous infusion, casirivimab and imdevimab, includes infusion and post administration monitoring	November 21, 2020

Providers should submit Medicaid member claims for monoclonal antibody infusion to the member's MCO or through the FFS program as applicable to the member. Claims for monoclonal antibody treatments will be processed through the medical benefit and not pharmacy (POS). Providers must use the appropriate administration codes for the specific monoclonal antibody treatment and associated infusion code.

**Please note:** The monoclonal antibody treatment code must also appear on the claim. No reimbursement will be paid for the monoclonal antibody medication(s) while these drugs are provided by the federal government.

#### **No Co-Payments**

There are no co-payments for COVID-19 monoclonal antibody infusion, including no co-payments for a physician office visit at which the infusion is administered.

#### **No Prior Authorization (PA)**

There is no prior authorization for the COVID-19 monoclonal antibody infusion.