New Jersey Vaccine Coordinator Toolkit

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To health!
NJHA
New Jersey Hospital Association

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INTRODUCTION

As vaccine recipients' most-trusted source of information on vaccines, vaccination coordinators play a critical role in managing the flow, administration, logistics and operations of smooth-running vaccine efforts. This toolkit is aimed to support vaccination coordinators in this role.

Vaccination administration is being conducted through a phasing method with widespread availability rapidly expanding to all individuals. Currently, individuals ages 12 and older who live, work or study in New Jersey are eligible for the COVID-19 vaccine. The New Jersey Department of Health is tracking on its website current data on confirmed cases, vaccinations administered and latest updates specific to New Jersey. Be sure to visit NJ COVID-19 information hub https://covid19.nj.gov/pages/vaccine often for the latest news and updates.

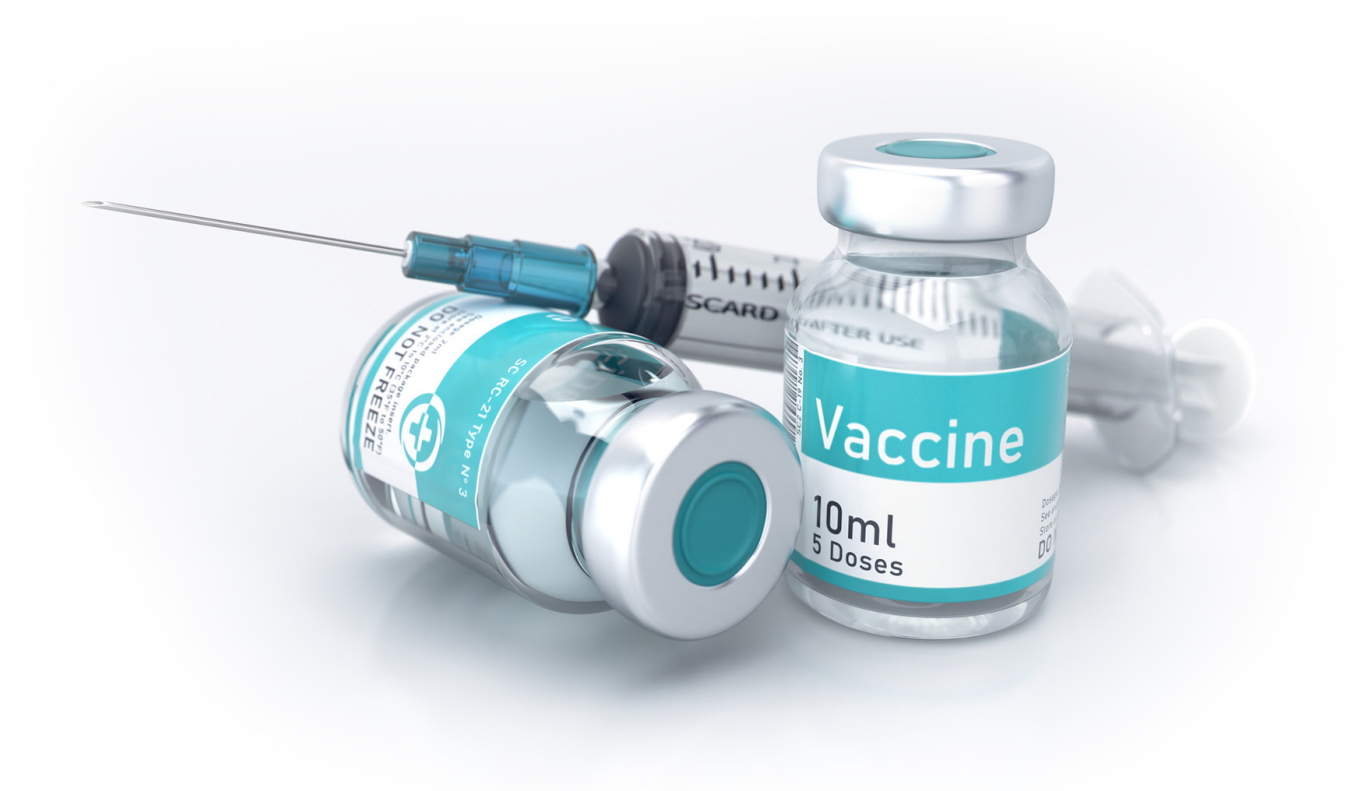
In addition, the Centers for Disease Control and Prevention (CDC) published a companion guide to assist state, tribal, local or territorial immunization programs and other immunization partners in planning for vaccination of these populations.

Although several vaccines are in clinical trial, three COVID-19 vaccines have been authorized under an Emergency Use Authorization (EUA) issued by the U.S. Food and Drug Administration (FDA) and recommended by the Advisory Committee on Immunization Practices (ACIP).

	Pfizer-BioNTech	Moderna	Janssen/J&J
Most Recent Letter of EUA (PDF)	Pfizer-BioNTech COVID-19 Vaccine (Reissued 2/25/2021) Date of first issuance: 12/11/2020	Moderna COVID-19 Vaccine Amendment Amendment: 04/2021 Moderna COVID-19 Vaccine (Reissued 2/25/2021) Date of first issuance: 12/18/2020	Janssen COVID-19 Vaccine Amendment Amendment: 04/23/2021 Janssen COVID-19 Vaccine Date of first issuance: 02/27/2021
Authorized Use	For the prevention of 2019 Coronavirus Disease (COVID-19) for individuals 12 years of age and older	For the prevention of Coronavirus Disease 2019 (COVID-19) for individuals 18 years of age and older	For the prevention of Coronavirus Disease 2019 (COVID-19) for individuals 18 years of age and older
Vaccine Type	mRNA	mRNA	Viral Vector
# of doses	2, 21 days apart	2, 28 days apart	1
Most common side effects	Tiredness, Headache, Muscle pain, Chills, Fever, Nausea More common with second dose	Tiredness, Headache, Muscle pain, Chills, Fever, Nausea More common with second dose	Tiredness, Headache, Muscle pain, Chills, Fever, Nausea More common in people 18–59 years old compared to people 60 years and older.

RESEARCH IS CONTINUING ON THE NEED FOR AND TIMING OF COVID-19 BOOSTER DOSES.

- NJDOH: COVID-19 Vaccination Site
  https://www.nj.gov/health/cd/topics/covid2019_vaccination.shtml
- NJDOH: COVID-19 Provider Vaccination Checklist
  https://www.nj.gov/health/cd/documents/topics/NCOV/COVID19_provider_checklist.pdf
- NJDOH: LIVE Data COVID-19 Dashboard/Stats
  https://covid19.nj.gov/index.html#live-updates
- FDA: Vaccines
  https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#vaccines
- FDA: COVID Vaccine News and Updates
  https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines#news
- FDA: Leaders on Vaccine
  https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines#leaders
- Early Evidence of the Effect of SARS-CoV-2 Vaccine
  https://www.nejm.org/doi/full/10.1056/NEJMc2102153



I. COVID VACCINATION COORDINATOR EDUCATION/TRAINING/OUTREACH

Healthcare professionals play critical roles in proper vaccine storage, handling, preparation and administration, and they must be prepared to respond to vaccine recipients' questions and concerns. It is important to receive the training needed to effectively meet the demands of these roles. Training must be ongoing as new COVID-19 vaccines become available, as vaccine recommendations evolve and as improvements to the vaccination process are added.

NJHA's COVID Vaccination Outreach Toolkit, developed in partnership with the Vaccination Communication Work Group established by NJHA's Road Ahead Steering Committee, compiles research and resources for ongoing vaccination outreach and awareness across New Jersey's communities, including tools focused on vaccine-hesitant groups. In addition to resources from NJHA and public health agencies, this toolkit includes an addendum linking to materials developed and shared by NJHA members in their commitment to advancing COVID-19 vaccination in their communities.

- **NJHA COVID-19 Vaccination Outreach Toolkit**
  http://www.njha.com/media/635176/NJHA-COVID-19-Vaccination-Outreach-Toolkit.pdf

Other Resources

The COVID-19 Vaccine Education and Equity Project is led by the Alliance for Aging Research, Healthy Women and the National Caucus and Center on Black Aging. With support from Pfizer, Inc. and Johnson and Johnson, it provisions additional efforts to build trust and confidence in authorized and approved COVID-19 vaccines. Through this project, leading organizations representing patients, caregivers and families, diverse communities, healthcare workers, older Americans, veterans, frontline workers and scientists have come together to provide information about the clinical trials process, regulatory review, distribution of and access to COVID-19 vaccines in a way that promotes equity and trust. Educational webinars, tools and consumer resources in multiple languages are available online.

- **CDC: Healthcare Professional Vaccine Training and Education**
  https://www.cdc.gov/vaccines/covid-19/training-education/index.html
- **NJDOH: List of COVID-19 Healthcare Provider Education**
  https://www.nj.gov/health/cd/documents/topics/NCOV/COVID_vax_HCP_education.pdf
- **COVID-19 Vaccine Education and Equity Project**
  https://covidvaccineproject.org/

II. VACCINE ADMINISTRATION

COVID-19 vaccines are administered intramuscularly as either a two-dose series or single dose.

Vaccine	Dose	Dose volume	Number doses/series	Interval between doses
Pfizer-BioNTech	30 µg	0.3 ml	2	3 weeks (21 days)
Moderna	100 µg	0.5 ml	2	1 month (28 days)
Janssen	5×10^{10} viral particles	0.5 ml	1	N/A

Vaccine Documentation

Vaccination providers enrolled in the COVID-19 Vaccination Program are required to:

- **Document vaccine administration in their medical record systems within 24 hours of administration.**
- **Report administration data to the relevant system (i.e., NJIIS) for their jurisdiction as soon as practicable and no later than 72 hours after administration.**
- **Report inventory daily using Vaccines.gov. In some jurisdictions, providers may report vaccine inventory to the jurisdiction's IIS for the jurisdiction to upload into Vaccines.gov. If you have questions about the process for your jurisdiction, please contact your jurisdiction's immunization program.**
- **Report the following to the Vaccine Adverse Event Reporting System (VAERS)** https://vaers.hhs.gov/index.html:
  - Vaccine administration errors
  - Serious adverse events
  - Multisystem inflammatory syndrome
  - Cases of COVID-19 that result in hospitalization or death after the recipient has received COVID-19 vaccine.

There are additional requirements for COVID-19 vaccination providers besides documentation (e.g., providing the Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers to vaccine recipients). Please refer to your COVID-19 vaccination provider agreement for all provider requirements.

Vaccine Storage and Handling

All vaccination providers participating in the COVID-19 Vaccination Program must store and handle COVID-19 vaccines under proper conditions to maintain the cold chain. The Advisory Committee on Immunization Practices (ACIP) recently added an addendum to the 2021 Vaccine Storage and Handling Toolkit https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf to include these specifications.

New from FDA on storage of the Pfizer vaccine: FDA In Brief: FDA Authorizes Longer Time for Refrigerator Storage of Thawed Pfizer-BioNTech COVID-19 Vaccine Prior to Dilution, Making Vaccine More Widely Available | FDA

Proper Disposal of Vaccination Supplies

The U.S. Department of Health and Humans Services, in conjunction with the FDA Office of Criminal Investigations and FBI Office of the Private Sector, has placed increased emphasis on proper product disposal as concerns rise on tampering and potential use. https://content.govdelivery.com/attachments/USFDA/2021/03/15/file_attachments/1723684/LIR-COVID%20Vaccine%20Disposal%202021%2003%2003.pdf

To reduce instances of vaccine fraud by improper disposal, providers may adopt the following:

- Make sure all individuals handling vaccines are familiar with proper disposal guidelines
- Tear or shred empty boxes containing vaccine vials
- Return any ultra-low temperature packaging as instructed
- Verify that tamper-proof seals are intact before opening new vaccine vial containers
- Discard used syringes and empty vials in designated sharps disposal containers
- Be on the lookout for any unauthorized personnel attempting to access medical waste
- Do not leave vaccine vials, syringes, container boxes or other packaging unsecured or unattended
- Do not keep or share empty vials, containers or packaging as “souvenirs”
- Do not accept vaccine vials which are individually shipped or delivered as pre-filled syringes.

III. ROLE OF NJIIS

Vaccination Sites throughout the State

The New Jersey Immunization Information System (NJIIS) is a free, confidential, population-based online system that collects and consolidates vaccination data for New Jersey's children and adults.

New Jersey-based vaccination sites are available for individuals who live, work or study in New Jersey. There are a number of ways for people to schedule their appointments:

- The New Jersey Vaccine Scheduling System is a centralized state-run system. Users may register at any time, whether they are eligible now or are registering in advance of when they are eligible to receive the vaccine. The system generates automatic notification when a registrant is eligible for the vaccine and again when a vaccination appointment is available.
- The state provides telephone support at 1-855-568-0545 for those without internet access and to provide additional assistance for those who may have difficulty with online scheduling. The appointment call center is available 8 a.m. to 8 p.m.
- The state's Vaccine Appointment Finder assists individuals in searching for sites with available appointments.

IV. ELDER CARE FACILITIES AND SERVICES

COVID-19 vaccination in long term care settings was accomplished through the federal long term care pharmacy partnership, directed by the CDC between December 2020 through March 2021. Through this program nearly 90 percent of long term care residents and approximately half of the staff became fully vaccinated. Access to vaccine continues to be challenging due to storage and handling requirements as well as the pause on the Janssen vaccine. Currently, long term care pharmacies that serve facilities are the primary vaccine source for residents and staff although staff can readily access vaccine in their communities. The percent of fully vaccinated long term care staff still lags behind the resident vaccination rate as it does in other parts of the healthcare delivery system. Efforts are underway to promote awareness and education among these staff members.

Given the terrible toll that COVID-19 has exacted on the frail elderly, the vaccination process is a significant positive development with cases and deaths dramatically falling in the weeks since vaccinations began. But, there is more to do.

The resources provided from the CDC specific to vaccination in long term care settings, as well as the information about vaccine hesitancy among long term care staff, are designed to inform and support efforts to continue to vaccinate the frail elderly and those who care for them. More information on the pharmacy partnership can be found online at https://www.cdc.gov/vaccines/covid-19/long-term-care/pharmacy-partnerships-access.html. Additional NJDOH-specific resources can be found online at https://www.nj.gov/health/ltc/documents/Long-Term_Care_ToolKit_508.pdf

Federal Resources

- Interim Final Rule - COVID-19 Vaccine Immunization Requirements for Residents and Staff
  https://www.cms.gov/files/document/qso-21-19-nh.pdf
- COVID-19 Vaccine Policies & Guidance
  https://www.cms.gov/COVIDvax
- Importance of COVID-19 Vaccination for Residents of Long-term Care Facilities
  https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/LTCF-residents.html
- Long-Term Care Facility Toolkit: Preparing for COVID-19 Vaccination at Your Facility
  https://www.cdc.gov/vaccines/covid-19/toolkits/long-term-care/index.html
- COVID-19 Data Tracker: Federal Pharmacy Partnership for Long-Term Care (LTC) Program
  https://covid.cdc.gov/covid-data-tracker/#vaccinations-ltc
- Long-Term Care Facility Toolkit: Preparing for COVID-19 Vaccination at Your Facility
  https://www.cdc.gov/vaccines/covid-19/toolkits/long-term-care/index.html

Webinars/Recordings

- COVID-19 Vaccine Education and Equity Project: Overcoming barriers to COVID-19 vaccine confidence in long-term care employees
  https://covidvaccineproject.org/news/webinar-recording-overcoming-barriers-to-covid-19-vaccine-confidence-in-long-term-care/
- AMA EdHub JN Learning: Vaccinating Nursing Home and Long-term Care Facility Residents for Coronavirus
  https://edhub.ama-assn.org/jn-learning/audio-player/18588221

Articles

- KHN: COVID cases plummet among nursing homes staffers despite vaccine hesitancy
  https://khn.org/news/article/covid-cases-plummet-among-nursing-home-staffers-despite-vaccine-hesitancy/
- KHN: Vaccine hesitancy vs. vaccine refusal: Nursing home staffers say there's a difference
  https://khn.org/news/article/vaccine-hesitancy-vs-vaccine-refusal-nursing-home-staffers-say-theres-a-difference/
- McKnight's Senior Living: Long-term care staff vaccine hesitancy: Safety, efficacy, newness, distrust top factors
  https://www.mcknightsseniorliving.com/home/news/long-term-care-staff-vaccine-hesitancy-safety-efficacy-newness-distrust-top-factors/
- NPR: Vaccine hesitancy among long-term care facility workers
  https://www.npr.org/2021/01/31/962638218/vaccine-hesitancy-among-long-term-care-facility-workers
- NY Times: Getting to Yes: A Nursing Home's Mission to Vaccinate Its Hesitant Staff
  https://www.nytimes.com/2021/03/28/health/nursing-home-covid-19-vaccine.html#click=https://t.co/BR8Xe5aFVg

V. FUNDING

On March 15, 2021, the Centers for Medicare & Medicaid Services (CMS) increased the Medicare payment amount for administering the COVID-19 vaccine. The increase will support actions taken by providers designed to increase the number of vaccines they can furnish each day, including establishing new or growing existing vaccination sites, conducting patient outreach and education and hiring additional staff. The exact payment rate for administration of each COVID-19 vaccine will depend on the type of entity that furnishes the service and will be geographically adjusted based on where the service is furnished.

Coverage of COVID-19 Vaccines

As a condition of receiving free COVID-19 vaccines from the federal government, vaccine providers are prohibited from charging patients any amount for administration of the vaccine. To ensure broad and consistent coverage across programs and payers, the toolkits have specific information for several programs, including:

- **Medicare.** Beneficiaries with Medicare pay nothing for COVID-19 vaccines and there is no applicable copayment, coinsurance or deductible.
- **Medicare Advantage (MA).** For calendar years 2020 and 2021, Medicare will pay providers directly for the COVID-19 vaccine (if they do not receive it for free) and its administration for beneficiaries enrolled in MA plans. More information is available at https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment.

- **Medicaid.** State Medicaid and CHIP agencies must provide vaccine administration with no cost sharing for nearly all beneficiaries during the public health emergency (PHE) and at least one year after it ends. Through the American Rescue Plan Act signed by President Biden on March 11, 2021, the COVID vaccine administration will be fully federally funded. The law also provides an expansion of individuals eligible for vaccine administration coverage. There will be more information provided in upcoming updates to the Medicaid toolkit at: https://www.medicaid.gov/state-resource-center/downloads/covid-19-vaccine-toolkit.pdf.
- **Private Plans.** CMS and the Departments of Labor and Treasury require most private health plans and issuers to cover the COVID-19 vaccine and its administration, both in-network and out-of-network, with no cost sharing during the public health emergency (PHE).
- **Uninsured.** For individuals who are uninsured, providers may submit claims for reimbursement for administering the COVID-19 vaccine to individuals without insurance through the Provider Relief Fund. Information on the COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment and Vaccine. Administration for the Uninsured Program is available at https://www.hrsa.gov/CovidUninsuredClaim.

More information regarding the CDC COVID-19 Vaccination Program Provider Requirements is available at: https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html.

Reimbursement for COVID-19 Administration Fees

The U.S. Department of Health and Human Services, through the Health Resources and Services Administration (HRSA), announced a new program covering costs of administering COVID-19 vaccines to patients enrolled in health plans that either do not cover vaccination fees or cover them with patient cost-sharing. Since providers cannot bill patients for COVID-19 vaccination fees, the COVID-19 Coverage Assistance Fund (CAF), addresses an outstanding compensation need for providers on the front lines vaccinating underinsured patients.

- HHS Launches New Reimbursement Program for COVID-19 Vaccine Administration Fees not Covered by Insurance.https://www.hhs.gov/about/news/2021/05/03/hhs-launches-new-reimbursement-program-for-covid19-vaccine-adminsitration-fees-not-covered-by-insurance.html

VI. CODING COVID VACCINES

ICD-10-PCS (Inpatient) and CPT (outpatient/charges) codes have been created for the administration of COVID-19 vaccinations and therapeutic treatments. CMS and other insurers have announced that for hospitalized patients, there will be no cost to the patient for COVID-19 treatments and vaccines. Hospitals/facilities will be reimbursed separately from the DRG rate (Diagnosis Related Group) assigned during coding for any COVID related treatment. Assigning the codes support the administration of the vaccine and therapeutics making the processing of claims more efficient.

Below you will find a list of the codes created for use as a result of the pandemic to date. As new vaccine candidates become available or are being considered for use, new codes will be created.

In the CPT code set, the American Medical Association (AMA) has created a new vaccine coding structure for COVID-19 vaccine candidates in CPT. The new structure is different from that of other CPT vaccine codes due to the rapid development of new vaccines. This structure is a way to track both the specific vaccine being administered and the dose received.

For more information, see https://www.cms.gov/medicare/covid-19/coding-covid-19-vaccine-shots.

COVID Vaccines

Inpatient - ICD-10-PCS Codes	
XW013S6	Introduction of COVID-19 vaccine dose 1 into subcutaneous tissue, percutaneous approach, new technology group 6
XW013T6	Introduction of COVID-19 vaccine dose 2 into subcutaneous tissue, percutaneous approach, new technology group 6
XW013U6	Introduction of COVID-19 vaccine into subcutaneous tissue, percutaneous approach, new technology group 6
XW023S6	Introduction of COVID-19 vaccine into subcutaneous tissue, percutaneous approach, new technology group 6
XW023T6	Introduction of COVID-19 vaccine into subcutaneous tissue, percutaneous approach, new technology group 6
XW023U6	Introduction of COVID-19 vaccine into muscle, percutaneous approach, new technology group 6

Outpatient - CPT Codes	
91300	**Pfizer** (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)
	CODE ALSO THE ADMINISTRATION OF THE VACCINE 0001A (FIRST DOSE) and 0002A (SECOND DOSE)
91301	**Moderna** (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)
	CODE ALSO THE ADMINISTRATION OF THE VACCINE 0011A (FIRST DOSE) and 0012A (SECOND DOSE)
91303	**Janssen (Johnson & Johnson)** (Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-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)
	CODE ALSO THE ADMINISTRATION OF THE VACCINE 0031A

Monoclonal Antibodies

Inpatient - ICD-10-PCS Codes	
XW013H6	Introduction of other new technology monoclonal antibody into subcutaneous tissue, percutaneous approach, new technology group 6
XW033H6	Introduction of other new technology monoclonal antibody into peripheral vein, percutaneous approach, new technology group 6
XW043H6	Introduction of other new technology monoclonal antibody into central vein, percutaneous approach, new technology group 6
XW013K6	Introduction of leronlimab monoclonal antibody into subcutaneous tissue, percutaneous approach, new technology group 6
XW033E6	Introduction of etesevimab monoclonal antibody into peripheral vein, percutaneous approach, new technology group 6

Inpatient - ICD-10-PCS Codes	
XW043E6	Introduction of etesevimab monoclonal antibody into central vein, percutaneous approach, new technology group 6
XW033F6	Introduction of bamlanivimab monoclonal antibody into peripheral vein, percutaneous approach, new technology group 6
XW043F6	Introduction of bamlanivimab monoclonal antibody into central vein, percutaneous approach, new technology group 6
XW033G6	Introduction of REGN-COV2 monoclonal antibody into peripheral vein, percutaneous approach, new technology group 6
XW043G6	Introduction of REGN-COV2 monoclonal antibody into central vein, percutaneous approach, new technology group 6
XW033L6	Introduction of CD24Fc immunomodulator into peripheral vein, percutaneous approach, new technology group 6
XW043L6	Introduction of CD24Fc immunomodulator into central vein, percutaneous approach, new technology group 6

Other Therapeutics

Inpatient - ICD-10-PCS Codes	
XW0DXM6	Introduction of baricitinib into mouth and pharynx, external approach, new technology group 6
XW0G7M6	Introduction of baricitinib into upper GI, via natural or artificial opening, new technology group 6
XW0H7M6	Introduction of baricitinib into lower GI, via natural or artificial opening, new technology group 6
XW013F5	Introduction of Other New Technology Therapeutic Substance into Subcutaneous Tissue, Percutaneous Approach, New Technology Group 5
XW033E5	Introduction of Remdesivir Anti-infective into Peripheral Vein, Percutaneous Approach, New Technology Group 5

Inpatient - ICD-10-PCS Codes	
XW033F5	Introduction of Other New Technology Therapeutic Substance into Peripheral Vein, Percutaneous Approach, New Technology Group 5
XW033G5	Introduction of Sarilumab into Peripheral Vein, Percutaneous Approach, New Technology Group 5
XW033H5	Introduction of Tocilizumab into Peripheral Vein, Percutaneous Approach, New Technology Group 5
XW043E5	Introduction of Remdesivir Anti-infective into Central Vein, Percutaneous Approach, New Technology Group 5
XW043F5	Introduction of Other New Technology Therapeutic Substance into Central Vein, Percutaneous Approach, New Technology Group 5
XW043G5	Introduction of Sarilumab into Central Vein, Percutaneous Approach, New Technology Group 5
XW043H5	Introduction of Tocilizumab into Central Vein, Percutaneous Approach, New Technology Group 5
XW0DXF5	Introduction of Other New Technology Therapeutic Substance into Mouth and Pharynx, External Approach, New Technology Group 5
XW13325	Transfusion of Convalescent Plasma (Nonautologous) into Peripheral Vein, Percutaneous Approach, New Technology Group 5
XW14325	Transfusion of Convalescent Plasma (Nonautologous) into Central Vein, Percutaneous Approach, New Technology Group 5

VII. THERAPEUTICS

EUA Issuance

Pursuant to section 564 of the FD&C Act, effective March 27, 2020, HHS declared justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic. The following EUAs have been issued for use of monoclonal antibodies therapies.

Date of First EUA issuance	Most Recent Letter of EUA (PDF)	Authorized Use
03/12/2021	Propofol-Lipuro 1% (344KB)	To maintain sedation via continuous infusion in patients greater than age 16 with suspected or confirmed COVID-19 who require mechanical ventilation in an ICU setting. 2
02/09/2021	Bamlanivimab and Etesevimab (344KB) (Reissued 2/25/2021)	For the treatment of mild-to-moderate COVID-19 in adult and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kilograms (about 88 pounds), and who are at high risk for progressing to severe COVID-19 and/or hospitalization.
11/21/2020	REGEN-COV (Casirivimab and Imdevimab) (232KB) (Reissued 2/3/2021 and 2/25/2021)	Casirivimab and imdevimab to be administered together for the treatment of mild to moderate coronavirus disease 2019 (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.
11/19/2020	Baricitinib (Olumiant) in Combination with remdesivir (Veklury) (322KB)	For emergency use by healthcare providers for the treatment of suspected or laboratory-confirmed COVID-19 in hospitalized adults and pediatric patients 2 years of age or older requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
11/09/2020	Bamlanivimab (339KB) (reissued 2/9/2021 and 3/2/2021)	For the treatment of mild-to-moderate COVID-19 in adult and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kilograms (about 88 pounds), and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

Date of First EUA issuance	Most Recent Letter of EUA (PDF)	Authorized Use
08/23/2020	COVID-19 convalescent plasma (284KB) (Reissued 2/23/2021 and 3/9/2021)	For the treatment of hospitalized patients with Coronavirus Disease 2019 (COVID-19)
05/01/2020	Remdesivir for Certain Hospitalized COVID-19 Patients (423KB) (Reissued 8/28/2020, 10/1/2020, and 10/22/2020)	For emergency use by licensed healthcare providers for the treatment of suspected or laboratory-confirmed 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

EUA Resources

- **Article: FDA Combating COVID-19 with Therapeutics**
  https://www.fda.gov/media/136832/download
- **FDA: Drug and Biological Therapeutic Products**
  https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-andpolicy-framework/emergency-use-authorization#coviddrugs
- **Authorizations of Emergency Use of Certain Drug and Biological Products During the COVID-19 Pandemic; Availability**
  https://www.federalregister.gov/documents/2021/02/19/2021-03429/authorizations-ofemergency-use-of-certain-drug-and-biological-products-during-the-covid-19-pandemic
- **FDA Adverse Event Reporting System (FAERS) Public Dashboard**
  https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-systemfaers/fda-adverse-event-reporting-system-faers-public-dashboard

In response to the COVID-19 pandemic, FDA launched the FAERS Public Dashboard for COVID-19 emergency use authorization (EUA) products. The COVID-19 EUA FAERS Public Dashboard provides weekly updates of adverse event reports submitted to FAERS for drugs and therapeutic biological products used under EUA in COVID-19. The intention of this tool is to expand access of FAERS data to the general public to search for information related to human adverse events reported to the FDA by the pharmaceutical industry, healthcare providers and consumers.

Payment announcement/allotment

All antibody (mAb) therapeutics are currently allocated through the authorized distributor, AmerisourceBergen (ABC), via a direct order process. To place an order for product, sites must establish an account with ABC and do the following:

- **Provide ABC with a board of pharmacy license or physician letter of authorization**
- **Attest to their designated class of trade and administering the authorized product according to the terms of the FDA issued EUA**
- **Complete ABC Direct Bill Account questionnaire**
- **Provide utilization data via either TeleTracking or NHSN.**

Product can be ordered based on established minimum amounts. Subsequent orders are subject to a maximum amount based on previous orders and site utilization. ABC will invoice sites directly upon shipment of product. NJDOH will be informed of therapies ordered for awareness.

- **Overview of Direct Order Process for COVID-19 Therapeutics.**
  https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/Overview%20of%20direct%20order%20process%20Fact%20Sheet-508.pdf
- **To order online, sites can use this direct link to ABC:**
  https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8

As mentioned, sites using monoclonal therapies are required to report through HHS Protect, TeleTracking, or CDC's National Healthcare Safety Network (NHSN) depending on facility type. Registration is required through HHS and reporting is due weekly. Below is more information on the process for tracking utilization of COVID-19 therapeutics:

- **Process for Tracking Utilization of COVID-19 Therapeutics**
  Direct link: https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/COVID19-therapeutics-teletracking.aspx
  PDF: http://champsonline.org/assets/files/EmergencyPreparedness/EPDocs/TeleTracking-SOP.pdf
- **TeleTracking Portal**
  https://help.cl-teletracking.com/en-us/c19/Therapeutics/Content/Home.htm