509.448.2067
support@snfcb.com
December 4, 2020 (Updated 2.18.21)

COVID-19 Monoclonal Antibody Treatment Facts and Guidance

BACKGROUND

Monoclonal antibodies are laboratory-made proteins that mimic the immune system's ability to fight off harmful pathogens such as viruses. Three investigational monoclonal antibody therapies are currently available for the treatment of mild-to-moderate COVID-19 cases in adults and pediatric patients with positive COVID-19 test results who are at high risk for progressing to severe COVID-19 and/or hospitalization. ***These treatments are administered via infusion and in settings where health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.***

CURRENT AVAILABILITY

The U.S. Food and Drug Administration (FDA) issued the first of the two emergency use authorizations (EUAs) for the investigational monoclonal antibody therapy, Bamlanivimab, on November 9, 2020 and the second for the investigational monoclonal antibody therapy, Casirivimab and Imdevimab, (administered together) on November 21, 2020. A third treatment, Bamlanivimab and Estesevimab, received EUA on February 9, 2021. ***These treatments should be prepared according to their EUA's in the links above and administered by a qualified healthcare professional.***

CERTIFIED PROVIDERS

If you're enrolled in Medicare under these institutional or non-institutional provider types, you don't need to take any action to administer and bill the COVID-19 shot, either through individual claims or roster bill, without enrolling as a mass immunizer.

Institutional	Non-Institutional
Hospital Hospital Outpatient Department Skilled Nursing Facility (includes Parts A and B)* Critical Access Hospital End-Stage Renal Disease Facility Home Health Agency Hospice Comprehensive Outpatient Rehabilitation Facility Federally Qualified Health Center** Rural Health Clinic*** Indian Health Services Facility	Physician Doctor of Medicine or Doctor of Osteopathy Doctor of Dental Surgery or Dental Medicine Doctor of Podiatric Medicine Doctor of Optometry Doctor of Chiropractic Non-Physician Clinic/Group Practice Pharmacy (enrolled as Part B) Mass Immunizer (roster bill only)

*A SNF may either administer the vaccine directly to a resident who's in a covered Part A stay or under arrangement pursuant to which the SNF pays an outside immunizer to administer the vaccine. In both these situations the SNF must bill Medicare. However, during the public health emergency, Medicare enrolled immunizers *who are not under arrangement with the SNF* are allowed to vaccinate Medicare SNF residents and bill directly to get reimbursed from Medicare. See the recent enforcement discretion notice (PDF) for more information. For a resident in a noncovered stay, either the SNF or the immunizer not under arrangement may bill for the shot.

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COVERAGE

During the COVID-19 public health emergency (PHE), Medicare will cover and pay for these infusions. Medicare national average payment rate for the administration will be approximately $309.60 (geographical adjustments may factor actual reimbursement rates). This payment rate is based on one hour of infusion and post-administration monitoring in the hospital outpatient setting.

Medicare will not pay for the COVID-19 monoclonal antibody products that providers receive for free, payments are only made for the infusion itself, in these circumstances. The Centers for Medicare and Medicaid (CMS) states they intend to address potential refinements to payment for COVID-19 monoclonal antibody infusions and their administration through future notice and comment rulemaking.

People with Medicare pay no cost sharing for these COVID-19 monoclonal antibody infusion therapy products: No copayment/coinsurance, No deductible.

Complete details on (including but not limited to) authorized use, limitations, dosing, administration instructions, storage, side effects and reporting requirements for each treatment are available on CMS's website, here: https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion

STATE GUIDANCE

Depending on your specific state's Department of Health Guidance, it may be within the scope of practice for the appropriately prepared and competent registered nurse (RN) and licensed practical nurse (LPN) to provide and manage infusion therapy under the direction of authorized health care practitioners. It is recommended the RN or LPN use the Interactive Scope of Practice Decision Tree to determine if an activity is within their legal and individual scope of practice.

Vascular and non-vascular access devices are commonly used in inpatient, outpatient, community-based and in-home/hospice care settings. Phlebotomy and laboratory/diagnostic testing often coincides with access to vascular and non-vascular procedures and medication administration including venous, peripheral, and central, arterial, intraosseous, and intraspinal (epidural, intrathecal and ventricular).

State nursing law dictates if it does or does not prohibit the RN or LPN from placing or managing infusion device, performing infusion therapy, performing phlebotomy or radiological procedures to aid insertion of a device (such as ultrasound or fluoroscopy) within their legal and individual scope of practice under the direction of an authorized health care practitioner in any setting.

It is not within the scope of practice in any state for the RN or LPN to start a vascular or non-vascular access device or administer an infusion without an order from an authorized health care practitioner. Please verify if your state's nursing law and rule requires a specific certification or training course. The organization or employer may require specific training or certification. Organizational policies and procedures may be more restrictive than law and rule and limit nursing scope of practice. The RN and LPN remains individually accountable and responsible for the nursing care they provide.

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DOCUMENTATION

In all billing scenarios, providers should have documentation that supports that the terms of the EUA are met, including that it is being used for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) for a patient that is at high risk for progressing to severe COVID-19 and/or hospitalization. The documentation should also include the name of the practitioner who ordered or made the decision to administer the infusion, even in cases where claims for these services are submitted on roster bills.

BILLING GUIDANCE

In order to facilitate efficient administration CMS is exercising discretion of the SNF Consolidated Billing rule and allowing Medicare-enrolled providers including, but not limited to, infusion centers, and home health agencies to bill directly to Part B on a single claim for COVID-19 monoclonal antibody administration or submit claims on a roster bill and receive direct reimbursement from the Medicare program for the administration.

Health care providers who furnish these services to enrollees in a Medicare Advantage (MA) Plan should submit claims for these monoclonal antibodies to treat COVID-19 that are covered by Part B, in accordance with Section 3713 of the CARES Act to Original Medicare for all patients enrolled in Medicare Advantage in 2020 and 2021. If the patient is on a Medicaid stay without Part B benefits contact your state Medicaid program.

Providers who have conducted COVID-19 testing or provided treatment for uninsured individuals with a COVID-19 diagnosis on or after February 4, 2020 can begin the process to file claims for reimbursement for testing and treating the uninsured via the Health Resources and Services Administration's (HRSA) COVID-19 Uninsured Program Portal, here: https://coviduninsuredclaim.linkhealth.com/ For more information on the HRSA Uninsured Program, please visit: https://www.hrsa.gov/CovidUninsuredClaim

CMS created 6 new billing HCPCS, unique to each infusion product and its administration. Please reference the chart below for HCPCS details and corresponding effective dates.

Code	CPT Short Descriptor	Labeler Name	Vaccine/Procedure Name	Average Payment Allowance	Effective Dates
Q0239	bamlanivimab-xxxx	Eli Lilly	Injection, bamlanivimab, 700mg	$0.010*	11/10/2020 – TBD
M0239	bamlanivimab-xxxx infusion	Eli Lilly	Intravenous infusion, bamlanivmab-xxx, includes infusion and post administration monitoring	$309.60	11/10/2020 – TBD
Q0243	casirivimab and imdevimab	Regeneron	Injection, casirivimab and imdevimab 2400mg	$0.010*	11/21/2020 – TBD
M0243	casirivi and imdevi infusion	Regenerom	Intravenous infusion, casiriviman and imdevimab, includes infusion and post administration monitoring	$309.60	11/21/2020 – TBD
Q2045	Bamlanivimab and etesevima	Eli Lilly	Injection, bamlanivimab and etesevimab, 2100mg	$0.010*	02/09/2021 – TBD
M0245	Bamlan and etesev infusion	Eli Lilly	Intraveneous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring	$309.60	02/09/2021 - TBD

* Since it is anticipated that providers, initially, will not incur a cost for the product, CMS will update the payment allowance at a later date. Providers should not bill for the product if they received it for free

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MEDICARE UB-04 FOR NURSING FACILITIES

- For skilled residents under a Medicare Part A use type of bill 22X.
- For non-skilled residents with Medicare B use type of bill 23X.
- Bill with Revenue code 0771 for the administration code and check for the maximum reimbursement rate for your geographic location. [Medicare pays at the lower of billed or allowable amount]
- If your software requires, use revenue code 0636 for the appropriate drug with a payment amount of $0.01 when the drug has been supplied for no cost.
- Use a condition code A6 for 100% payment with no cost sharing.
- For Medicare Advantage beneficiaries only, add a condition code 78.
- Appropriate diagnosis codes are Z23 Encounter for immunization and U071 COVID-19