NHIA TALK INFUSION WEBINAR

Providing and Billing for Home Infusion of COVID-19 Monoclonal Antibodies

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12pm EST

Brought to you by
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Today' Speakers

Connie Sullivan
President & CEO

Bill Noyes,
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Agenda

- Introduction and Review of CMS Rate Changes for COVID-19 Monoclonal Antibody Therapies
- Advocacy Updates
- Qualifying Patients and Ordering COVID-19 Monoclonal Antibodies
- NHIA COVID-19 mAB Data Sharing Program
- Enrollment and Reimbursement

NHIA Advocacy

- HHS/ASPR
- SPEED Program
- Data
  - Demographics
  - Utilization
  - Geographic
  - Outcomes

Medicare

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Site of Care[1]	Payable by Medicare	Expected Patient Cost-Sharing
Inpatient Hospital	✓	No patient cost-sharing
Outpatient Hospital or "Hospital without Walls[2]"	✓	No patient cost-sharing
Outpatient Physician Office/ Infusion Center	✓	No patient cost-sharing[3]
Nursing Home *(See third bullet in Key Facts on CMS enforcement discretion)*	✓	No patient cost-sharing
Home or Residence	✓	No patient cost-sharing

Expected Payment to Providers: Key Facts

- Medicare payment for monoclonal antibody products to treat COVID-19 is **similar across sites of care**, with some small differences.
- Medicare **pays for the administration** of monoclonal antibody products to treat COVID-19. For example, beginning on May 6, 2021, Medicare will pay approximately $450 in most settings, or approximately $750 in the beneficiary's home or residence, for the administration of certain monoclonal antibody products[4] to treat COVID-19. For monoclonal antibody products to treat COVID-19 that are administered before May 6, 2021, the Medicare payment rate in all settings is approximately $310.
- CMS will exercise **enforcement discretion** to allow Medicare-enrolled immunizers working within their scope of practice and subject to applicable state law to **bill directly and receive direct reimbursement from the Medicare program for administering monoclonal antibody treatments** to Medicare Part A Skilled Nursing Facility residents.
- Medicare will pay the provider for these monoclonal antibody products **when they are purchased by the provider**. Medicare won't pay if the product is given to the provider for free by, for example, a government entity.
- When purchased by the provider, Medicare

NATIONAL HOME INFUSION FOUNDATION
MARCH / APRIL • 2021

NHIF Research Supplement

Discharge Reasons of Patients Receiving Home-Based Outpatient Parenteral Antimicrobial Therapy

Danell J. Haines, PhD
Ryan Garst, PharmD, MBA, BCSCP
Connie Sullivan, BSPharm
Jennifer Charron, RN, MSN, MBA, VA-BC

A Home Infusion Program for Administration of Bamlanivimab in High-Risk Settings

Connie Sullivan, BSPharm
Ryan Garst, PharmD, MBA, BCSCP
Jennifer Charron, RN, MSN, MBA, VA-BC
Danell J. Haines, PhD

Special thanks to the following provider organizations who participated in the home infusion program for administration of bamlanivimab in high-risk settings and shared the patient outcomes and other data used in the creation of this report.

Align Vital Care
Amber Specialty
Amerimed Infusion Pharmacy
Amerita
ARJ Infusion Services, Inc.
Big Sky IV Care
Burnham's Vital Care
CAIS Inc.
CarePro Home Infusion
ContinuumRx
Community Pharmacy Services
Complete Infusion Care
Cure Stat RX Home Infusion & Specialty Pharmacy
Deliverit Pharmacy Infusion & Specialty
Delta Medical Infusion
Druid City Vital Care
Empire Home Infusion
First Option Home Infusion Pharmacy
IV League
Kaup Pharmacy
National Infusion Services
New England Life Care
North Mississippi Vital Care
NuCara Infusion Center/NuCara Pharmacy
Oakstead Infusion-Vital Care
Option Care Health
Owens Infusion
Poudre Infusion
Premier Infusion Care
Pruit Pharmacy Services
Quick RX Pharmacy
Red River Pharmacy of Jonesboro-Vital Care
Red River Pharmacy of Little Rock-Vital Care
Red River Pharmacy Services-Vital Care
Red River Vital Care of Tyler
Regioncare Home Infusion
Rivers Edge Pharmacy
Saint Mary's Mercy Health Home Infusion
Soleo Health
Thomas Jefferson University
Upstate Home Care
UW Health Care Direct
Vital Care of Las Cruces
Wellspan Infusion

Clinical Qualification of Patients

Patients must meet conditions of FDA EUA	• Fact Sheet for HC Providers: Casirivimab/Imdevimab • Fact Sheet for HC Providers: Bamlanivimab/Etesevimab
Must be 12 years of age and weight at least 40 kg	• Use for treatment of mild to moderate COVID-19 in adults and pediatric patients • Must be administered within 10 days of symptom onset
Must report all serious ADR's	• FDA MedWatch • Must provide Fact Sheet for Patients and Caregivers

High-Risk Definition

High risk is defined as patients who meet at least one of the following criteria:

- Have a body mass index (BMI) ≥35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are ≥65 years of age
- Are ≥55 years of age AND have:
  - cardiovascular disease, OR
  - hypertension, OR
  - chronic obstructive pulmonary disease/other chronic respiratory disease.

High risk pediatric patients that are 12 – 17 years of age AND have:

- BMI ≥85th percentile for their age and gender based on CDC growth charts, OR
- Sickle cell disease, OR
- Congenital or acquired heart disease, OR
- Neurodevelopmental disorders, for example, cerebral palsy, OR
- A medical-related technological dependence, for example tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR
- Asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.

COVID-19 mAB Federal Requirements

Direct Ordering

- All mAB products are to be ordered directly from Amerisource Bergen
- Must order Etesevimab separately to pair with unused Bamlanivimab
- No Amerisource account required
- Online Order Form

Teletracking

- Weekly reporting required on *Wednesday's* per Federal government
- Registration
  - Email hhs-protect@Teletracking.com
  - Add additional team members
- Enter Data Weekly
  - On Hand Quantity
  - # of courses used (administered) in the last week

NHIA COVID-19 mAB Data Sharing Program

- Why?
  - Data from the Bamlanivimab pilot was instrumental in the CMS rate change to $750.00 per infusion in the home
  - Home infusion data will be critical to CMMI for Part D Demonstration Program
- What?
  - Collection of clinical outcomes data on patients receiving COVID-19 mAB treatment in the home setting
  - Provides utilization data for home infusion in rural and underserved populations
- How?
  - Sign Program Participation Agreement
  - Submit agreement to nhifdata@nhia.org
  - Data will be de-identified
  - Participation in the program: Providers will be listed on website

Home Infusion Provider Map

NHIA COVID-19 Data Collection Tool

DPC Code												
Drug Administered	Referring Physician	Patient Age	Patient Ethnicity	Patient Race	Gender	Date of COVID-19 Symptom Onset	Date of Infusion	Infusion Time	Adverse Event	Adverse Event Intervention	If Adverse Event "Other," please list here	Post-Infusion Follow-Up (7-days)
Bamlanivimab/Etesevimab	Primary Care	72	African American/Black	Non-Hispanic/Latino	Male	5/1/21	5/5/21	27 min	None	None	N/A	Patient Stable

Other Tools and Resources for Home Infusion Providers

- Fact Sheets for Healthcare Providers
- Billing and Resource Coding Guide
- Sample Home Infusion mAB Order Form
- Direct Ordering and Teletracking Information
- NHIA COVID-19 mAB Data Sharing Program
- Scientific Resources
- General Information on COVID-19 Monoclonal Therapies
- Outpatient Therapeutics Mini-series
- Weekly ASPR Stakeholder
  - Email COVID19Therapeutics@hhs.gov

Enrollment & Reimbursement Considerations

Who Can Bill for COVID-19 Treatments

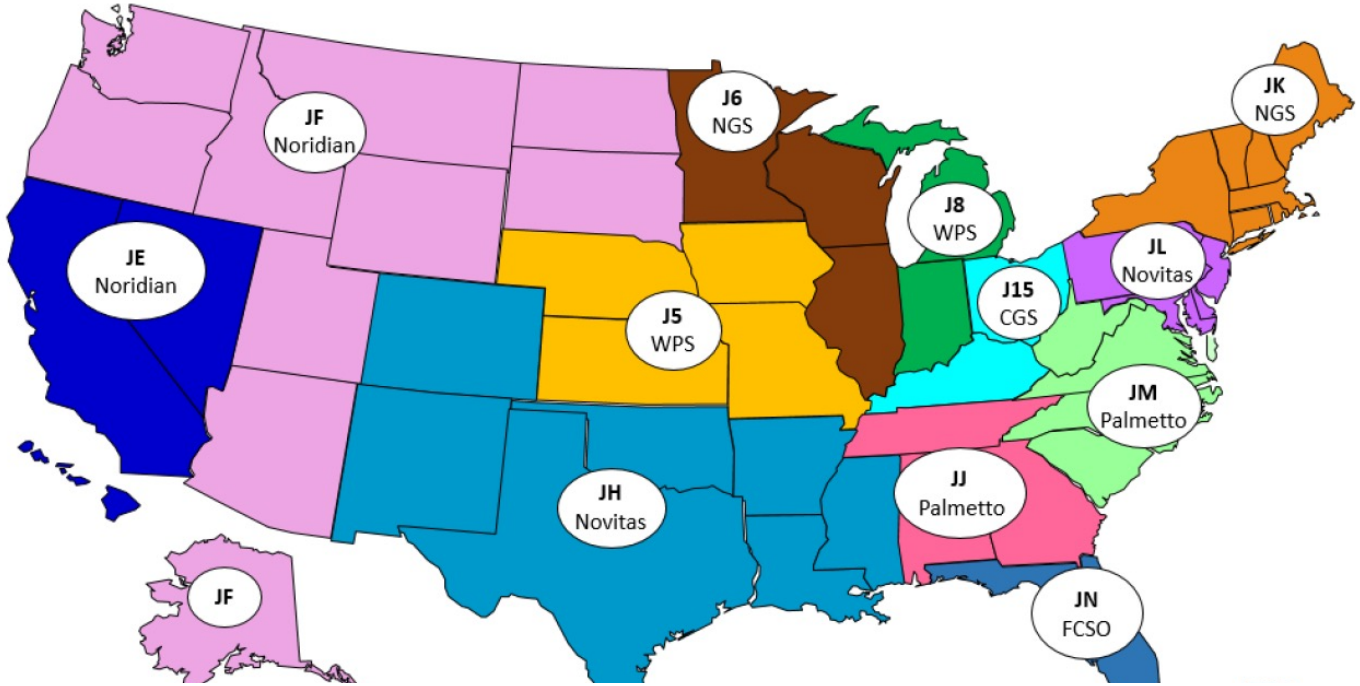
Health care providers administering COVID-19 monoclonal antibodies will follow the same enrollment process as those administering the COVID-19 vaccines.

Provider enrollment information:

https://www.cms.gov/medicare/covid-19/enrollment-administering-covid-19-vaccine-shots

Must be enrolled properly to bill to A/B MAC

A/B MAC Jurisdictions
as of June 2019



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 • Non-Physician • Clinic/Group Practice • Pharmacy (enrolled as Part B) • Mass Immunizer (roster bill only)

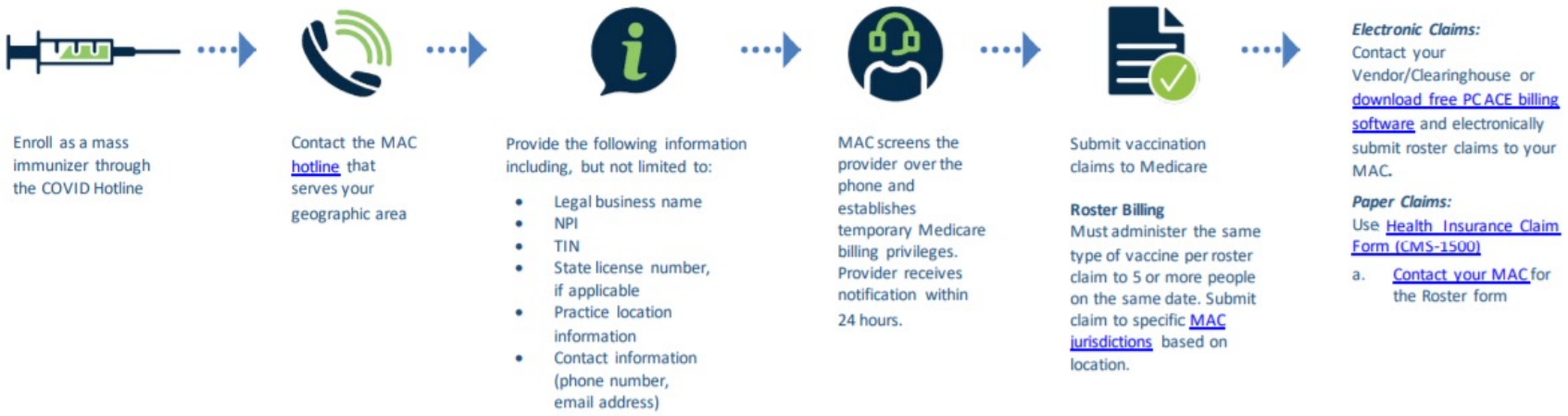
If you're enrolled in Medicare under these provider types and you want to bill for administering COVID-19 treatments, you must also separately enroll as a mass immunizer. Enrolling over the phone as a mass immunizer is easy and quick — call your MAC-specific enrollment hotline (PDF) and give your valid Legal Business Name (LBN), National Provider Identifier (NPI), Tax Identification Number (TIN), practice location and state license, if applicable.

Institutional	Non-Institutional	Durable Medical Equipment (DME)
• Outpatient Physical Therapy • Occupational Therapy • Speech Pathology Services • Histocompatibility Laboratory • Religious Non-Medical Health Care Institution	• Independent Clinical Laboratory • Ambulance Service Supplier • Independent Diagnostic Testing Facility • Intensive Cardiac Rehabilitation Supplier • Mammography Center • Medicare Diabetes Prevention Program Suppliers • Portable X-ray Supplier • Radiation Therapy Center • Opioid Treatment Program • Organ Procurement Organization • Home Infusion Therapy Supplier	• Durable Medical Equipment Supplier • Pharmacy (enrolled as DME supplier

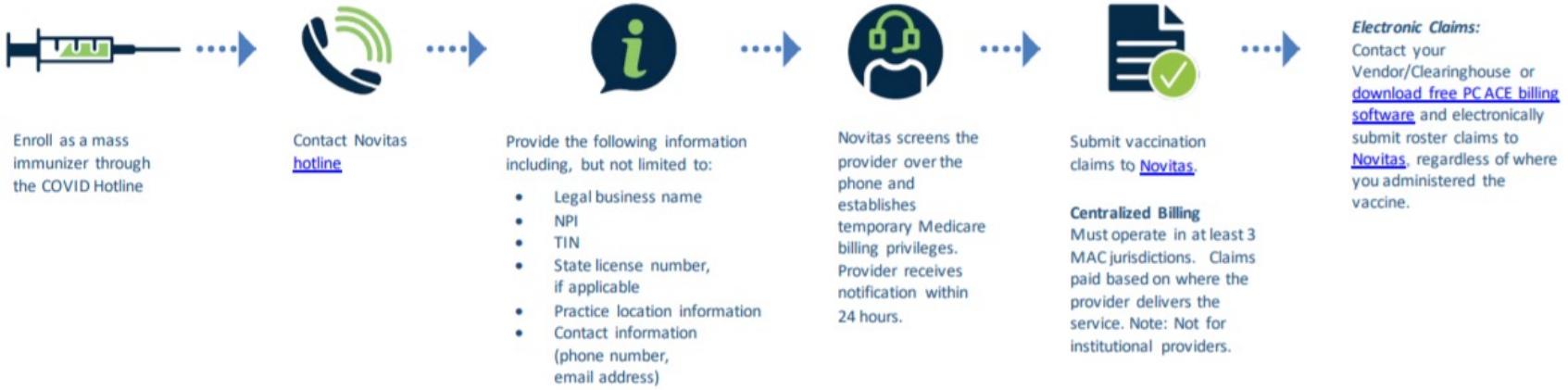
https://www.cms.gov/files/document/covid-19-mac-webpages-and-hotlines.pdf

3 Provider is Not Currently Enrolled in Medicare

3a Enroll in Medicare as Mass Immunizer to Roster Bill *(e.g. Senior Center)*



3b Enroll in Medicare as a Mass Immunizer to Centralize Bill *(e.g. Pharmacy)*



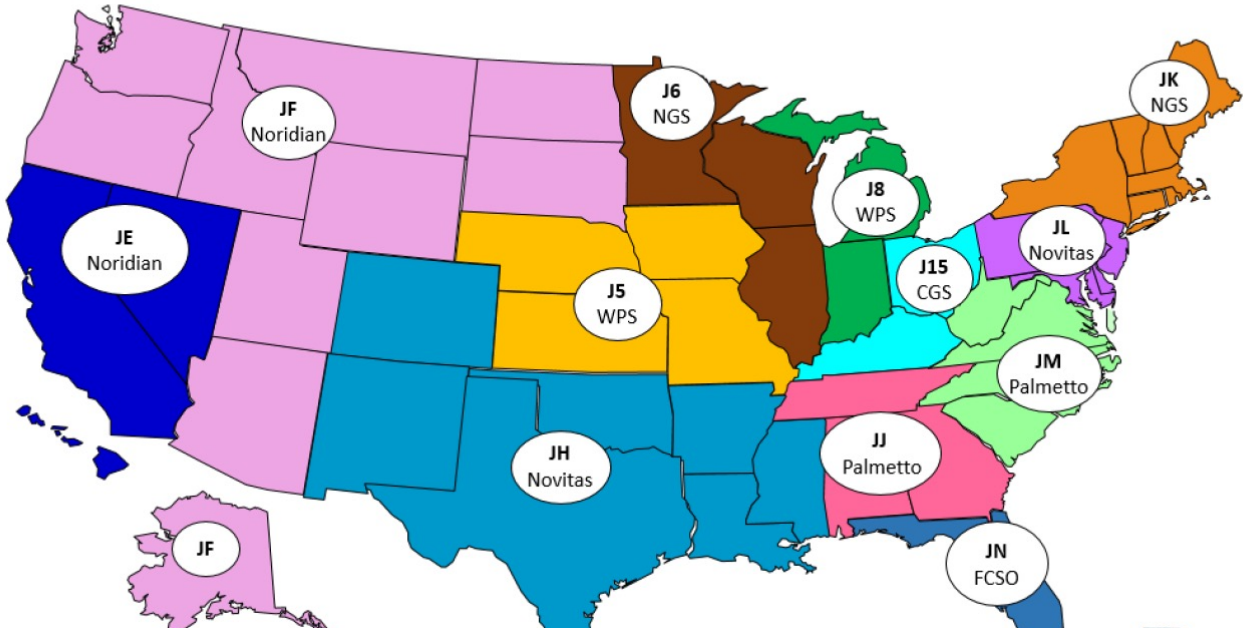
Hotline tips:

The provider would call the A/B MAC that services their geographic area. Or if the provider will be centralized billing they would call the Novitas hotline.

Do not call the National Supplier Clearinghouse (NSC).

Mass Immunizer Hotline Enrollment

A/B MAC Jurisdictions
as of June 2019



Enrollment Hotlines

- CGS, J15 – (855) 769-9920
- FCSO, JN – (855) 247-8428
- NGS, J6&JK – (888) 802-3898
- Noridian, JE&JF – (866) 575-4067
- Novitas, JH&JL – (855) 247-8428
- Palmetto, JJ&JM – (833) 820-6138
- WPS, J5&J8 – (844) 209-2567

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

Hotline Enrollment is Temporary

- Medicare billing privileges established via the Medicare Provider Enrollment Hotline are being granted on a provisional basis as a result of the public health emergency declaration and are temporary. Upon the lifting of the COVID-19 PHE declaration, providers and suppliers, will be asked to submit a complete CMS-855 enrollment application in order to establish full Medicare billing privileges. Failure to respond to the MAC's request within 30 days of the notification, will result in the deactivation of your temporary billing privileges. No payments can be made for services provided while your temporary billing privileges are deactivated.

Billing for COVID Treatments

Currently Enrolled as Other Eligible Provider *(e.g. Physician/Non-Physician, Hospital, Clinic/Group Practice)*

No Enrollment
Action Needed

Submit vaccination claims to Medicare
(Two options)

1. Roster Billing
Must administer the same type of vaccine per roster claim to 5 or more people on the same date. Submit claim to specific MAC jurisdictions based on location.

Institutional Claims (e.g. Hospital)

Electronic Claims:
Use Direct Data Entry
a. Option 02, Claims Attachment
b. Option 87, Roster Bill Entry

Paper Claims:
Use CMS-1450 (UB-04)
a. Contact your MAC for the roster form

Professional Claims (e.g. Physician)

Electronic Claims:
Contact your Vendor/Clearinghouse or download free PC ACE billing software and electronically submit roster claims to your MAC.

Paper Claims:
Use Health Insurance Claim Form (CMS-1500)
a. Contact your MAC for the roster form

2. Claim-by-Claim Billing

https://www.cms.gov/files/document/covid-19-vaccine-enrollment-scenario-1.pdf

Billing for COVID Treatments

Currently Enrolled Mass Immunizer *(e.g. Pharmacy)*

No Enrollment
Action Needed

Submit vaccination claims to Medicare
(Two options)

1. Centralized Billing
Must operate in at least 3 MAC jurisdictions. Claims paid based on where the provider delivers the service. Submit claim to Novitas.

2. Roster Billing
Must administer the same type of vaccine per roster claim to 5 or more people on the same date. Submit claim to specific MAC jurisdictions based on location.

Electronic Claims:
Contact your Vendor/Clearinghouse or download free PC ACE billing software and electronically submit roster claims to your MAC.

Paper Claims: Not Applicable for Centralized Billing Claims
Use Health Insurance Claim Form (CMS-1500)

b. Contact your MAC for the roster form

Health care providers can bill for the administration of the monoclonal antibody infusion on a single claim for COVID-19 monoclonal antibody administration or submit claims on a roster bill, in accordance with the FDA EUA.

https://www.cms.gov/files/document/covid-19-vaccine-enrollment-scenario-1.pdf

CMS Increases Medicare Payment for Infusion of COVID-19 Monoclonal Antibodies

The Centers for Medicare and Medicaid Services announced on May 6, 2021 that it would increase the Medicare payment rate for administering monoclonal antibodies to treat COVID-19, regardless of where the treatment is administered. The national average payment rate was increased from $310 to $450 for most care settings, although CMS increased home infusion rates to $750 to support providers' efforts to prevent the spread of COVID-19. **The payment rate for home infusion service will apply to care administered in a beneficiary's permanent residence or temporary lodging, such as a hotel, cruise ship, hostel, or homeless shelter.**

CMS Increases Medicare Payment for Infusion of COVID-19 Monoclonal Antibodies

The administration explained that the new national payment rate for home infusion of monoclonal antibodies takes into account the increased costs associated with the “one-on-one nature” of home care and was established based on stakeholder feedback on the costs associated with providing home infusion services in a safe and timely manner. CMS also announced it had updated toolkits for providers, states, and insurers to assist the health care system swiftly implement the new Medicare payment rates.

Place of Service

CMS will establish a higher national payment rate of $750 when monoclonal antibodies are administered in the beneficiary's **home**, including the beneficiary's permanent residence or **temporary lodging** (e.g., hotel/motel, cruise ship, hostel, or **homeless shelter**).

- Home (12)
- Temporary lodging (16)
- Homeless shelter (4)

Place of Service?

NHIA has asked CMS about other sites of care that may be considered for the higher “home” payment amount.

- Prison/correctional facility (09)
- Assisted living facility (13)
- Group home (14)
- Skilled nursing facility (31) during and/or outside of a Part A stay
- Custodial care facility (33)
- Hospice (34)
- Residential substance abuse treatment facility (55)
- Inpatient psychiatric facility (51)

New Codes for Administration in Home

[3] These rates will be geographically adjusted for many providers. For providers and suppliers with payments that are geographically adjusted by the methodology used by the Medicare Physician Fee Schedule (MPFS), files with the geographically adjusted payment rates for monoclonal antibody administration are included in the "Additional Resources".

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

HCPCS Code	CPT Short Descriptor	Labeler Name	Vaccine/Procedure Name	Payment Allowance for Claims with DOS on or after 05/6/2021	Payment Allowance for Claims with DOS through 05/5/2021
M0243	Casirivi and imdevi infusion	Regeneron	Intravenous infusion, casirivimab and imdevimab includes infusion and post administration monitoring	$450.00[3]	$309.600[3]
M0244	Casirivi and imdevi infus hm	Regeneron	Intravenous infusion, casirivimab and imdevimab includes infusion and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the covid-19 public health emergency.	$750.00[3]	Code not active during this time period
M0245	Bamlan and etesev infusion	Eli Lilly	intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring	$450.00[3]	$309.600[3]
M0246	Bamlan and etesev infus home	Eli Lilly	Intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the covid-19 public health emergency.	$750.00[3]	Code not active during this time period

Tips for Coding Claims

- Health care providers should not include the monoclonal antibody codes on the claim when the product is provided for free.
- **No patient copayment/coinsurance or deductible** for COVID-19 treatments
- Bill Original Medicare even for those with Medicare Advantage
- Mass Immunizers should use:
  - Place of Service 60 - Mass immunization center
  - Diagnosis Z23 - Encounter for immunization
  - Also Diagnosis U07.1 - COVID-19, virus identified (lab confirmed)

Billing and Documentation for Monoclonal Antibody COVID-19 Infusion Administration

- Health care providers can bill for the administration of the monoclonal antibody infusion on a single claim for COVID-19 monoclonal antibody administration or submit claims on a roster bill, in accordance with the FDA EUA.
- CMS expects that health care providers will maintain appropriate medical documentation that supports the medical necessity of the service.
  - This includes 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.

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

This EUA is for the use of the unapproved product bamlanivimab for the treatment of mild to moderate COVID-19 in adults 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 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization [see Limitations of Authorized Use]. High risk is defined as patients who meet at least one of the following criteria:

- Have a body mass index (BMI) ≥35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are ≥65 years of age
- Are ≥55 years of age AND have
  - o cardiovascular disease, OR
  - o hypertension, OR
  - o chronic obstructive pulmonary disease/other chronic respiratory disease
- Are 12 – 17 years of age AND have
  - o BMI ≥85th percentile for their age and gender based on CDC growth charts, OR
  - o sickle cell disease, OR
  - o congenital or acquired heart disease, OR
  - o neurodevelopmental disorders, for example, cerebral palsy, OR
  - o a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR
  - o asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.

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