Reimbursement Policy

<table>
<thead>
<tr>
<th>Title:</th>
<th>Drug Treatment and Vaccinations for COVID-19</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy Number:</td>
<td>RP-PF-450X</td>
</tr>
<tr>
<td>Application:</td>
<td>*All Medica Members</td>
</tr>
<tr>
<td>Last Updated:</td>
<td>03/09/2021</td>
</tr>
<tr>
<td>Effective Date:</td>
<td>12/31/2020</td>
</tr>
<tr>
<td>Related Policies:</td>
<td>COVID-19 Testing</td>
</tr>
</tbody>
</table>

**Disclaimer:** This reimbursement policy is intended to provide general guidance regarding Medica’s policy for the services described, and does not constitute a guarantee of payment. You are responsible for submitting accurate claims. Factors affecting claims reimbursement may include, but are not limited to, state and federal laws, regulations and accreditation requirements, along with administrative services agreements, provider contracts, and benefit coverage documents. Coding methodology and industry standards are also considered in developing reimbursement policy.

Medica routinely updates reimbursement policies, and new versions are published on this website. If you print a copy of this policy, please be aware that the policy may be updated later, and you are responsible for the information contained in the most recent online version. Medica communicates policy updates to providers via Medica’s monthly e-newsletter, Medica Connections®, as well as through Medica Provider Alerts.

All content included on the provider portion of medica.com is an extension of providers’ administrative requirements, which all Medica network providers are contractually obligated to follow.

**Summary:**
This policy was created to discuss the coverage and reimbursement guidelines around the Emergency Use Authorization of the Monoclonal Antibody Drugs for COVID-19 as well as the EUA for the COVID-19 Vaccinations.

**Policy Statement:**
The Federal Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for certain Monoclonal Antibody drugs for the treatment of the novel Coronavirus, otherwise known as COVID-19. The FDA has also issued an EUA for certain COVID-19 vaccinations. The EUA’s allow the Infusion treatments provided by Eli Lilly and Regenron Pharmaceuticals and vaccines provided by Pfizer and Moderna.

**Monoclonal Antibody Drug treatment**

**Bamlanivimab is authorized for the following use:**
- Outpatient use only *and*
- Patients who are 12 years of age and older *with*
Positive results of direct SARS-CoV-2 viral testing and  
Weighing at least 40 kilograms (about 88 pounds), and  
Are at high risk for progressing to severe COVID-19 and/or hospitalization

**Bamlanivimab is not authorized for the following:**  
- Patients Under the age of 12 years  
- Patients who are hospitalized due to COVID-19, OR  
- Patients who require oxygen therapy due to COVID-19, OR  
- Patients who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity

Bamlanivimab must be administered by intravenous (IV) infusion. Bamlanivimab may only be administered in settings in which 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.

Clinical fact sheet and dosage information can be found at [https://www.fda.gov/media/143603/download](https://www.fda.gov/media/143603/download)

**Regeneron**

On November 21, the FDA issued an EUA for a combination of two monoclonal antibodies for the treatment of mild-to-moderate COVID-19. The combination of casirivimab and imdevimab, known by the manufacturer name, Regeneron.

Regeneron is authorized for the following use:  
- Outpatient use only and  
- Patients who are 12 years of age and older with  
- Positive results of direct SARS-CoV-2 viral testing and  
- Weighing at least 40 kilograms (about 88 pounds), and  
- Are at high risk for progressing to severe COVID-19 and/or hospitalization

**Regeneron is not authorized for the following:**  
- Patients Under the age of 12 years  
- Patients who are hospitalized due to COVID-19, OR  
- Patients who require oxygen therapy due to COVID-19, OR  
- Patients who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity

Regeneron must be administered by intravenous (IV) infusion. Regeneron may only be administered in settings in which 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.
Clinical fact sheet and dosage information can be found at: https://www.fda.gov/media/143892/download

BAMLANIVIMAB AND ETESEVIMAB
On February 9, 2021, the FDA issued an EUA for the use of Bamlanivimab and etesevimab administered together for the treatment of mild to moderate coronavirus disease 2019 (COVID-19).

Bamlanivimab and etesevimab is authorized for the following use:
- Outpatient use only and
- Patients who are 12 years of age and older with
- Positive results of direct SARS-CoV-2 viral testing and
- Weighing at least 40 kilograms (about 88 pounds), and
- Are at high risk for progressing to severe COVID-19 and/or hospitalization

Bamlanivimab and etesevimab is not authorized for the following:
- Patients Under the age of 12 years
- Patients who are hospitalized due to COVID-19, OR
- Patients who require oxygen therapy due to COVID-19, OR
- Patients who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity

Bamlanivimab and etesevimab must be administered by intravenous (IV) infusion.

Bamlanivimab and etesevimab may only be administered in settings in which 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.

Clinical fact sheet and dosage information can be found at: https://www.fda.gov/media/145802/download

The FDA feels that the issuance of these monoclonal antibody therapies may help outpatients avoid hospitalization and alleviate the burden on our health care system.

Medica will follow CMS and CDC guidance and cover the administration of the COVID infusion treatments when furnished consistent with the EUA. Coverage determination is based on the member’s line of business (See Grid below)

**Note: For Medicare LOB, all cost share will be covered through 12/31/2021 but must be billed to original Medicare fee-for-service. For Commercial & IFB INN cost share will be waived through the duration of the PHE. For the Medicaid LOB all cost share will be waved until the DHS requirement is lifted.**
### COVID-19 Monoclonal Antibody Drug Treatments

<table>
<thead>
<tr>
<th>Code</th>
<th>CPT Short Descriptor</th>
<th>Labeler Name</th>
<th>Procedure Name</th>
<th>Payment Allowance</th>
<th>Effective Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q0239</td>
<td>Bamlanivimab-xxxx</td>
<td>Eli Lilly</td>
<td>Injection, bamlanivimab, 700 mg (intramuscular use)</td>
<td>$0.00</td>
<td>11/10/2020</td>
</tr>
<tr>
<td>M0239</td>
<td>Bamlanivimab-xxxx infusion</td>
<td>Eli Lilly</td>
<td>Intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring</td>
<td>$310</td>
<td>11/10/2020</td>
</tr>
<tr>
<td>Q0243</td>
<td>casirivimab and imdevimab</td>
<td>Regeneron</td>
<td>Injection, casirivimab and imdevimab, 2400 mg</td>
<td>$0.00</td>
<td>11/21/2020</td>
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<tr>
<td>M0243</td>
<td>casirivimab and imdevimab infusion</td>
<td>Regeneron</td>
<td>intravenous infusion, casirivimab and imdevimab includes infusion and post administration monitoring</td>
<td>$310</td>
<td>11/21/2020</td>
</tr>
<tr>
<td>Q0245</td>
<td>Injection, bamlanivimab and etesevimab, 2100 mg</td>
<td>Eli Lilly</td>
<td>Injection, Bamlanivimab and etesevimab, 2100 MG</td>
<td>$0.00</td>
<td>02/09/2021</td>
</tr>
<tr>
<td>M0245</td>
<td>Intravenous infusion, bamlanivimab and etesevimab</td>
<td>Eli Lilly</td>
<td>Intravenous infusion, Bamlanivimab and etesevimab, includes infusion and post administration monitoring</td>
<td>$310</td>
<td>02/09/2021</td>
</tr>
</tbody>
</table>
COVID-19 Vaccinations

The Federal Government has purchased all vaccines and is in charge of the distribution to the States. CMS will provide Medicare coverage without deductible or cost sharing for an FDA issued COVID 19 vaccine and its administration (either under an emergency use authorization (EUA) or licensed under a Biologics License Application (BLA)).

Medica will reimburse for the administration of an FDA-EUA issued and U.S. government provided COVID-19 vaccines. Reimbursement will be made in accordance with applicable state laws and federal provisions, including the CARES Act and CDC guidance, as outlined below:

- Medica will not apply a member cost share (copayment, coinsurance or deductible) for in and out-of-network providers for the administration of a COVID-19 vaccine for all non-Medicare lines of business (LOB). Cost share coverage for OON providers will remain only through the duration of the national public health emergency (PHE) period.

**Note: For Medicare LOB, all cost share will be covered through 12/31/2021 but must be billed to original Medicare fee-for-service**

- For Commercial & IFB members, Medica will cover, at no cost share to the member, items and services that are integral to the furnishing of the recommended preventive service, regardless of whether the item or service is billed separately.
- Medicare Advantage health plans: Charges for COVID-19 vaccine administration for all Medicare beneficiaries should be billed to the Center for Medicare & Medicaid (CMS) Medicare Administrative Contractor (MAC).
- For Medicare Cost Plans, Medica will waive INN vaccine administration for INN providers. All OON provider must bill Original Medicare FFS.

In-Office Visits

- If a member has a scheduled office visit and the COVID-19 vaccine is administered during that visit, Medica will reimburse for the vaccine administration at no cost share (copayment, coinsurance or deductible) for the member. Charges for the office visit and other services rendered during the visit will be adjudicated according to the member’s benefit plan.
- For Commercial & IFB, if the primary purpose of the office visit is for the delivery of the vaccine, then member cost share may not be imposed with respect to the office visit.
- For Medicare Cost Plans, standard benefits and claims processing guidelines will apply for the office visit portion of the claim for INN providers. All OON provider must bill Original Medicare FFS.
- For Medicare Advantage plans, if a member has a scheduled office visit with a health care professional and the COVID-19 vaccine is administered during that visit, the claim will need to be billed in two parts:
  - The CMS MAC should be billed for the vaccine administration.
  - Medica should be billed for the office visit and standard benefits and claims processing guidelines will apply.
Claim Submission

Providers may submit claims through the member’s medical benefit administered by Medica via our standard claims process. If the vaccine is administered through the Pharmacy, Pharmacists should submit their claims through the pharmacy administration platform. For Medicare beneficiaries, providers must submit claims to the CMS MAC.

An out-of-network provider should not bill above the CMS published rates for the administration of the vaccine. Per federal provisions a health care provider may not balance bill or impose cost share on a member for the cost of the vaccine or its administration when the U.S. government provides the vaccine. This applies for both in- and out-of-network providers.

<table>
<thead>
<tr>
<th>COVID-19 Vaccines and Administration</th>
</tr>
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<tbody>
<tr>
<td>Code</td>
</tr>
<tr>
<td>-------</td>
</tr>
<tr>
<td>91300</td>
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<tr>
<td>0001A</td>
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<tr>
<td>0002A</td>
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<td>91301</td>
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<tr>
<td>0012A</td>
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<tr>
<td>91303</td>
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</tbody>
</table>
### Definitions of *Italicized Terms:*

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>EUA</td>
<td>Emergency Use Authorization</td>
</tr>
<tr>
<td>FDA</td>
<td>Federal Drug Administration</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control</td>
</tr>
<tr>
<td>CMS</td>
<td>Centers for Medicare &amp; Medicaid Services</td>
</tr>
<tr>
<td>MAC</td>
<td>Medicare Administrative Contractor</td>
</tr>
<tr>
<td>Pfizer-Biontech Covid-19 Vaccine (91300)</td>
<td>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</td>
</tr>
<tr>
<td>Pfizer-Biontech Covid-19 Vaccine Administration</td>
<td>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</td>
</tr>
<tr>
<td>Moderna Covid-19 Vaccine (91301)</td>
<td>Severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage, for intramuscular use</td>
</tr>
<tr>
<td>Moderna Covid-19 Vaccine Administration</td>
<td>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</td>
</tr>
<tr>
<td>Janssen COVID-19 Vaccine (Johnson &amp; Johnson) 91303</td>
<td>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</td>
</tr>
<tr>
<td>Jassen COVID-19 Vaccine Administration</td>
<td>Immunization administration by intramuscular injection of 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, single dose</td>
</tr>
</tbody>
</table>
References

- Medicare Monoclonal Antibody COVID-19 Infusion Program Instruction
- Covid-19 NDC-HCPCS crosswalk
- COVID-19 Vaccination Resources at CDC
- COVID-19 CPT vaccine and immunization codes - AMA
- Quick reference guide to the coding structure for Covid-19 vaccine CPT reporting
- Bamlanivimab Emergency Use Authorization
- Casirivimab and imdevimab Emergency Use Authorization (ZIP)
- Fact Sheet for Healthcare Providers - Emergency Use Authorization of Bamlanivimab
- Fact Sheet for Healthcare Providers - Emergency Use Authorization of casirivimab and imdevimab
- COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals

Resources:

- Centers for Medicare and Medicaid Services (CMS)
- Healthcare Common Procedure Coding System (HCPCS)
- National Physician Fee Schedule (NPFS)

Effective Date: 12/31/2020

Revision Updates:

- 03/09/2021: Antibody treatment update (Bamlanivimab and etesevimab)
- 03/02/2021: Janssen (Johnson & Johnson) vaccine addition
- 01/20/2021: DHS rate update
- 12/24/2020: Policy Creation

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