New Policy -
COVID-19 Treatments: Monoclonal Antibody and Convalescent Plasma

December 17, 2020

We recently developed a policy to address COVID-19 treatments, specifically monoclonal antibody (Bamlanivimab, casirivimab, and imdevimab) and convalescent plasma. HAP will cover bamlanivimab and casirivimab/imdevimab in accordance with most current Emergency Use Authorization (EUA) issued by the Food and Drug Administration (FDA) and for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of these products, unless the authorization is terminated or revoked sooner.

For details on covered codes, coverage criteria and exclusions, please see the attached policy.

Status: Published

COVID-19 Treatments: Monoclonal Antibody and Convalescent Plasma

DESCRIPTION

Monoclonal antibody:
Bamlanivimab, casirivimab, and imdevimab are all monoclonal antibodies. An antibody is a protein that the body makes to fight off viruses and other foreign substances. Monoclonal antibodies are man-made antibodies produced in a laboratory that can mimic the human immune system response to infection. Each of these three drugs are designed to block viral attachment and entry into human cells, thus neutralizing the virus that causes COVID-19. Benefit of treatment with monoclonal antibodies, including bamlanivimab and combination Casirivimab and imdevimab , have not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation. Casirivimab and imdevimab must be given together, while bamlanivimab is given by itself. They are investigational drugs, meaning they are not currently FDA-approved, but are authorized for emergency use for the treatment of mild to moderate COVID-19.

Convalescent Plasma:
COVID-19 convalescent plasma is human plasma collected from individuals whose plasma contains anti-SARS-CoV-2 antibodies, and who meet all donor eligibility requirements and qualifications. An Emergency Use Authorization (EUA) for the emergency use of COVID-19 convalescent plasma for the treatment of hospitalized patients with Coronavirus Disease 2019 (COVID-19) was issued August 23, 2020 by the FDA. The FDA states that adequate and well-controlled randomized trials remain necessary for a definitive demonstration of COVID-19 convalescent plasma efficacy and to determine the optimal product attributes and appropriate patient populations for its use. Given that the clinical evidence supporting the EUA was not obtained from prospective, well-controlled randomized clinical trials (RCTs), additional RCTs are needed. COVID-19 convalescent plasma should not be considered a new standard of care for the treatment of patients with COVID-19.

Coding for Monoclonal Antibody COVID-19 Infusion

M0239	Intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring
M0243	Intravenous infusion, casirivimab and imdevimab includes infusion and post administration monitoring
Q0239	Injection, bamlanivimab-xxxx, 700 mg
Q0243	Injection, casirivimab and imdevimab, 2400 mg

Convalescent Plasma related codes

P9017	Fresh frozen plasma (single donor), frozen within 8 hours of collection, each unit
P9071	Plasma (single donor), pathogen reduced, frozen, each unit
P9099	Blood component or product not otherwise classified

COVERAGE CRITERIA

HAP will cover bamlanivimab and casirivimab/imdevimab in accordance with most current Emergency Use Authorization (EUA) issued by the Food and Drug Administration (FDA) and for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of these products, unless the authorization is terminated or revoked sooner.

Monoclonal Antibody-Bamlanivimab:

1. Bamlanivimab, is a monoclonal antibody therapy which is covered consistent with the FDA-Emergency Use Authorization for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients with ALL the following:
    a. Have positive results of direct SARS-CoV-2 viral testing
    b. Who are 12 years of age and older weighing at least 40 kg
    c. Who are at high risk* for progressing to severe COVID-19 and/or hospitalization.
2. Treatment with Bamlanivimab is covered as a single dose provided within 10 days of symptom onset consistent with the EUA recommendation.
    a. Bamlanivimab dose 700 mg
3. 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).
    a. May be used in Members hospitalized for reasons other than COVID-19, so long as the terms and conditions of authorization are met.

4. FACT SHEET FOR HEALTH CARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF BAMLANIVIMAB. **http://pi.lilly.com/eua/bamlanivimab-eua-factsheet-hcp.pdf**

Monoclonal Antibody- Casirivimab and Imdevimab:

1. Casirivimab and Imdevimab, is a combination monoclonal antibody therapy which is covered consistent with the FDA-Emergency Use Authorization for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients with ALL the following:
    a. Have positive results of direct SARS-CoV-2 viral testing
    b. Who are 12 years of age and older weighing at least 40 kg
    c. Who are at high risk* for progressing to severe COVID-19.
2. Casirivimab and Imdevimab must be administered together by intravenous infusion.
3. Treatment with Casirivimab and Imdevimab combination therapy is covered as single dose provided within 10 days of symptom onset consistent with the EUA recommendation.
    a. Casirivimab dose 1.2 g and Imdevimab dose 1.2 g
4. Casirivimab and imdevimab, administered together, 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).
    a. May be used in Members hospitalized for reasons other than COVID-19, so long as the terms and conditions of authorization are met.
5. FACT SHEET FOR HEALTH CARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF CASIRIVIMAB AND IMDEVIMAB. **https://www.fda.gov/media/143892/download**

***High Risk Criteria for Progressing to severe COVID-19 and/or hospitalization is defined as those Members who meet at least ONE of the following:**

1. Have a body mass index (BMI) ≥35
2. Have chronic kidney disease
3. Have diabetes
4. Have immunosuppressive disease
5. Are currently receiving immunosuppressive treatment
6. Are ≥65 years of age
7. Are ≥55 years of age AND have ONE of the following:
    a. Cardiovascular disease
    b. Hypertension
    c. Chronic obstructive pulmonary disease/other chronic respiratory disease.
8. Are 12 – 17 years of age AND have ONE of the following:
    a. BMI ≥85th percentile for their age and gender based on CDC growth charts
        i. **https://www.cdc.gov/growthcharts/clinical_charts.htm**
    b. Sickle cell disease
    c. Congenital or acquired heart disease
    d. Neurodevelopmental disorders, for example, cerebral palsy
    e. A medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)
    f. Asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.

Convalescent Plasma:

1. Convalescent Plasma is covered for HAP/AHL Members consistent with the FDA Emergency Use Authorization recommendations for the treatment of hospitalized patients with COVID-19.
2. FACT SHEET FOR HEALTH CARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF COVID-19 CONVALESCENT PLASMA FOR TREATMENT OF COVID-19 IN HOSPITALIZED PATIENTS. **https://www.fda.gov/media/141478/download**

Convalescent Plasma DONOR Information:

1. Convalescent Plasma must be obtained per EUA recommendations from a Donor that meets eligibility requirements as outlined by the FDA which include ALL the following:
    a. Donor has evidence of COVID-19 documented by laboratory testing meeting ONE of the following:
        i. Individuals who had symptoms of COVID-19 and a positive test result from a diagnostic test approved, cleared, or authorized by FDA.
        ii. Individuals who did not have a prior positive diagnostic test and/or never had symptoms of COVID-19 may be qualified to donate if they have had reactive (positive) results in two different tests approved, cleared, or authorized by FDA to detect SARS-CoV-2 antibodies.
    b. Donor has complete resolution of symptoms at least 14 days before the donation. A negative result for COVID-19 by a diagnostic test is not necessary to qualify the donor.
    c. Male donors, female donors who have never been pregnant, or female donors who have been tested since their most recent pregnancy and results interpreted as negative for HLA antibodies.
    d. Donor who has NOT received an investigational COVID-19 vaccine because of the uncertainty regarding the quality of the immune response produced by such investigational vaccines.

For all services:

1. Coverage of services is based on the Member's subscriber documents. Please refer to those resources for information regarding eligibility for coverage, network or provider requirements. If the Member has coverage for the services discussed in this policy, then the medical criteria applies.
2. Some services require pre-authorization by a HAP Medical Director or designee, please refer to the Procedure reference list for specific code information.
3. Medicaid Providers should refer to:
    a. The Michigan Medicaid Provider Manual for coverage criteria, located at: **http://www.mdch.state.mi.us/dch-medicaid/manuals/MedicaidProviderManual.pdf**
    b. The Michigan Medicaid Fee Schedule located at: **http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html**

EXCLUSIONS

1. Monoclonal antibody infusions including **Bamlanivimab, Casirivimab and imdevimab** are not covered when Emergency Use Authorization recommendations are not met, such as but not limited to the following:
    i. Members who are hospitalized due to COVID-19
    ii. Members who require oxygen therapy due to COVID-19
    iii. Members 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.
    iv. Members who are younger than 12 years of age or weigh less than 40 kg
    v. Members who have already received a dose of bamlanivimab or another antibody directed against SARS-CoV-2 virus for the current infection.
    vi. The combined use of antibody therapy; with exception of casirivimab and imdevimab which are dosed together.
2. HAP will not reimburse for the COVID-19 monoclonal antibody products that providers receive for free.

REFERENCES:

1. **Monoclonal Antibody**:
    a. CMS. Monoclonal Antibody COVID-19 Infusion. Center for Medicare & Medicaid services. Page Last Modified: 11/20/2020. **https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion**
    b. **BAMLANIVIMAB**:
        i. FACT SHEET FOR HEALTH CARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF BAMLANIVIMAB. Literature issued November 2020. Eli Lilly and Company, Indianapolis, IN 46285, USA. Copyright © 2020, Eli Lilly and Company. **http://pi.lilly.com/eua/bamlanivimab-eua-factsheet-hcp.pdf**
        ii. FDA. Frequently Asked Questions on the Emergency Use Authorization for Bamlanivimab. U.S. Department of Health and Human Services. Updated 11/19/2020. **https://www.fda.gov/media/143605/download**
    c. **Casirivimab + Imdevimab**:
        i. FACT SHEET FOR HEALTH CARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF CASIRIVIMAB AND IMDEVIMAB. **https://www.fda.gov/media/143892/download**
        ii. FDA. Frequently Asked Questions on the Emergency Use Authorization of Casirivimab + Imdevimab. U.S. Department of Health and Human Services. 11/21/2020. **https://www.fda.gov/media/143894/download**
2. **Convalescent Plasma**:
    a. FACT SHEET FOR HEALTH CARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF COVID-19 CONVALESCENT PLASMA FOR TREATMENT OF COVID-19 IN HOSPITALIZED PATIENTS. **https://www.fda.gov/media/141478/download**
    b. Food & Drug Administration. Investigational COVID-19 Convalescent Plasma. U.S. Department of Health and Human Services. November 16, 2020. **https://www.fda.gov/media/136798/download**
    c. Food & Drug Administration. Recommendations for Investigational COVID-19 Convalescent Plasma. U.S. Department of Health and Human Services. November 16, 2020. **https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma**
3. **Coding for COVID Monoclonal Antibodies**:
    a. CMS. COVID-19 Vaccines and Monoclonal Antibodies. Center for Medicare & Medicaid services. Page Last Modified: 12/02/2020. **https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies**

This Benefit policy discusses the medical criteria for covered services. Coverage of services for Members is based on the Member's subscriber documents and are subject to all terms and conditions including specific exclusions and limitations. This type of document includes the following: Subscriber contract and associated riders; Member Benefit Guide; or an Evidence of Coverage document (for Medicare Advantage Members).

HAP HMO/POS and AHL EPO/PPO Members:

If there is a discrepancy between this policy and coverage described in the subscriber documents, the Member's subscriber documents will apply.

ASO Members:

Coverage as discussed in this policy may not apply to employer groups that are self-funded (referred to as an ASO group [Administrative Services Only]). Each ASO group determines the coverage available to their members which is found in the ASO Benefit Guide and associated riders. If a member has coverage for the type of service covered by this policy, then the medical criteria as discussed in this policy applies to those services.

Medicare Advantage Plan Members:

Coverage is based on Medicare (CMS) regulations and guidelines which include the NCDs (National Coverage Decision) and LCDs (Local Coverage Decision) for our area. When no coverage determination has been made by CMS, then this policy will apply.

Medicaid Plan Members:

For Medicaid/Healthy Michigan Plan members coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: **http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html**. If there is a discrepancy between this policy and the Michigan Medicaid Provider

Manual located at: **http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html**, the Michigan Medicaid Provider Manual will apply.

EFFECTIVE DATE

12/09/2020

REVISED DATE

12/09/2020

REVIEWED DATE

12/02/2020