PolicyStat ID 14331009

Last Approved	9/15/2023	Area	Medical Policy
Effective	10/27/2023	Lines Of Business	All Lines of Business
Next Review	9/14/2024		

COVID-19 Treatment

PURPOSE

The purpose of this policy is to provide information on the use of Remdesivir, as well as other therapies outlined in the U.S. Food and Drug Administration's Emergency Use Authorization, for the treatment of individuals with COVID-19.

Note: Per the FDA, the ending of the COVID-19 PHE will not impact FDA's ability to authorize treatments for emergency use. Existing EUAs for products will remain in effect, and the agency may continue to issue new EUAs if the situation meets the criteria to do so.

DEFINITIONS

COVID-19: COVID-19 is a respiratory disease caused by SARS-CoV-2, a new coronavirus discovered in 2019. The virus is thought to spread mainly from person to person through respiratory droplets produced when an infected person coughs, sneezes, or talks. Some people who are infected may not have symptoms. For people who have symptoms, illness can range from mild to severe. Adults 65 years and older and people of any age with underlying medical conditions are at higher risk for severe illness.

Mechanical Ventilation: An artificial respiration using a mechanical ventilator to support the delivery of oxygen to the lungs when breathing has ceased, is failing, or is inadequate.

ECMO: Treatment providing respiratory and circulatory support for a patient that involves pumping blood from the body and through a membrane oxygenator to exchange carbon dioxide for oxygen and a heat exchanger to cool or warm the blood before returning it to the body.

Emergency Use Authorization (EUA): Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), when the Secretary of HHS declares that an emergency use authorization is appropriate, FDA may authorize unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN (chemical, biological, radiological, and nuclear) threat agents when certain criteria are

met, including there are no adequate, approved, and available alternatives. The HHS declaration to support such use must be based on one of four types of determinations of threats or potential threats by the Secretary of HHS, Homeland Security, or Defense.

PROCEDURE

Remdesivir may be considered medically necessary for the treatment of COVID-19 when all of the following criteria are met:

- The individual has a confirmed COVID-19 diagnosis, and;
- The medication will be administered in an inpatient setting, and;
- The individual is at least 12 years of age or older, AND weighs at least 40kg (see EUA for additional information for individuals under 12 years of age), and;
- The individual has an eGFR greater than 30 ml/min; and
- The individual will receive a loading dose of 200 mg, followed by a maintenance dose of 100 mg/day for the remainder of the treatment, and;
- The treatment duration should not exceed 5 days for individuals not requiring mechanical ventilation and/or ECMO, and should not exceed 10 days for individuals requiring mechanical ventilation and/or ECMO.

The use of Remdesivir for any other indications other than those listed above, or in the EUA by the FDA, is considered not medically necessary, and therefore non-covered.

The use of Ivermectin, Quercetin, chloroquine phosphate, and hydroxychloroquine sulfate is considered experimental and investigational, and therefore non-covered, because safety and efficacy cannot be established by peer reviewed literature and/or the U.S Food and Drug Administration (FDA).

The Health Plan will follow all treatment guidelines outlined by the FDA in their COVID-19 EUA. To navigate to the list of drugs under the EUA, scroll down below the "EMERGENCY" image, and then select "Drugs and Non-Vaccine Biological Products" which will jump down to the list of drugs.

The use of any of the drugs outside the guidelines listed in the EUA is considered experimental and investigational, and therefore non-covered, because safety and efficacy cannot be established by peer reviewed literature and/or the U.S Food and Drug Administration (FDA).

CODING

Procedure codes for Remdesivir:

HCPCS Code	DESCRIPTION
J0248	Injection, remdesivir, 1 mg

ICD-10 PCS	DESCRIPTION
XW033E5	Introduction of Remdesivir Anti-infective into Peripheral Vein, Percutaneous Approach, New Technology Group 5

ICD-10 PCS	DESCRIPTION
XW043E5	Introduction of Remdesivir Anti-infective into Central Vein- Percutaneous Approach, New Technology Group 5

Procedure codes for other therapies included in the EUA:

CPT CODE	DESCRIPTION
M0220	Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40kg) with no known sars-cov-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available covid-19 vaccine is not recommended due to a history of severe adverse reaction to a covid-19 vaccine(s) and/ or covid-19 vaccine component(s), includes injection and post administration monitoring. **Note: This product isn't currently authorized.**
M0221	Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40kg) with no known sars-cov-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available covid-19 vaccine is not recommended due to a history of severe adverse reaction to a covid-19 vaccine(s) and/ or covid-19 vaccine component(s), includes injection 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. **Note: This product isn't currently authorized.**
M0222	Intravenous injection, bebtelovimab, includes injection and post administration monitoring. **Note: This product isn't currently authorized.**
M0223	Intravenous injection, bebtelovimab, includes injection 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. **Note: This product isn't currently authorized.**
M0240	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab, includes infusion or injection and post administration monitoring, subsequent repeat doses. **Note: This product isn't currently authorized.**
M0241	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab, includes infusion or injection, 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, subsequent repeat doses **Note: This product isn't currently authorized.**
M0243	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab, includes infusion or injection, and post administration monitoring **Note: This product isn't currently authorized.**
M0244	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab, includes infusion or injection 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

CPT CODE	DESCRIPTION
	the COVID-19 public health emergency **Note: This product isn't currently authorized.**
M0245	Intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring **Note: This product isn't currently authorized.**
M0247	Intravenous infusion, sotrovimab, includes infusion and post administration monitoring **Note: This product isn't currently authorized.**
M0248	Intravenous infusion, sotrovimab, 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 **Note: This product isn't currently authorized.**
M0249	Intravenous infusion, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and older) with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) only, includes infusion and post administration monitoring, first dose
M0250	Intravenous infusion, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and older) with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) only, includes infusion and post administration monitoring, second dose
Q0220	Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40kg) with no known sars-cov-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available covid-19 vaccine is not recommended due to a history of severe adverse reaction to a covid-19 vaccine(s) and/or covid-19 vaccine component(s), 300 mg. **Note: This product isn't currently authorized.**
Q0222	Injection, bebtelovimab, 175 mg **Note: This product isn't currently authorized.**
Q0240	Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring, subsequent repeat doses **Note: This product isn't currently authorized.**
Q0243	Injection, casirivimab and imdevimab, 2400 mg **Note: This product isn't currently authorized.**
Q0244	Injection, casirivimab and imdevimab, 1200 mg **Note: This product isn't currently authorized.**
Q0245	Injection, bamlanivimab and etesevimab, 2100 mg **Note: This product isn't currently authorized.**
Q0247	Injection, sotrovimab, 500 mg **Note: This product isn't currently authorized.**
Q0249	Injection, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and older) with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) only, 1 mg

A code being listed above does not guarantee approval or payment for a specific COVID-19 treatment.

ICD-10 Diagnosis Codes

ICD-10	DESCRIPTION
U07.1	COVID-19

PLACE OF SERVICE

- Per the procedural criteria above, the place of service for Remdesivir is inpatient only.
- The place of service for the other therapies is per the guidelines in the EUA.

REFERENCES

Gilead Sciences, Inc. Veklury (remdesivir) injection, for intravenous use. Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; October 2020.

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U.S. Food and Drug Administration(FDA). Revocation of Emergency Use Authorization for Emergency Use of Chloroquine Phosphate and Hydroxychloroquine Sulfate. June 15, 2020. Accessed January 6, 2022. https://www.fda.gov/media/138945/download

Centers for Medicare and Medicaid Services (CMS). COVID-19 Vaccines and Monoclonal Antibodies. Last modified July 27, 2023. Accessed August 17, 2023. https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies

POLICY HISTORY:

Date	Summary of Changes
1/18/2022	Added chloroquine phosphate, and hydroxychloroquine sulfate to E/I treatments. Removed list of additional EUA drugs, added directions for navigating the EUA website. Removed J3490, and added J0248, M0220, and Q0220. Added payment statement to coding section.
2/18/2022	Added M0222, M0223, Q0222.
9/28/2022	Annual Review: Added M0221 and post-payment audit statement. Added: "Note: This product isn't currently authorized" to several codes per the EUA and CMS. Updated references. Ensured all links are working.
8/23/2023	Annual Review: Updated drugs that are not currently authorized per the EUA. Added a "Note" to the Purpose section about the end of the PHE. Corrected typos. Reviewed links and updated references. Add-on payment information for Medicare removed as it ends September 30, 2023.

POST-PAYMENT AUDIT STATEMENT:

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by THP at any time pursuant to the terms of your provider agreement.

DISCLAIMER:

This policy is intended to serve as a guideline only and does not constitute medical advice, any guarantee of payment, plan pre-authorization, an explanation of benefits, or a contract. This policy is intended to address medical necessity guidelines that are suitable for most individuals. Each individual's unique clinical situation may warrant individual consideration based on medical records. Individual claims may be affected by other factors, including but not necessarily limited to state and federal laws and regulations, legislative mandates, provider contract terms, and THP's professional judgment. Reimbursement for any services shall be subject to member benefits and eligibility on the date of service, medical necessity, adherence to plan policies and procedures, claims editing logic, provider contractual agreement, and applicable referral, authorization, notification, and utilization management guidelines. Unless otherwise noted within the policy, THP's policies apply to both participating and non-participating providers and facilities. THP reserves the right to review and revise these policies periodically as it deems necessary in its discretion, and it is subject to change or termination at any time by THP. THP has full and final discretionary authority for its interpretation and application. Accordingly, THP may use reasonable discretion in interpreting and applying this policy to health care services provided in any particular case.

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All Revision Dates

9/15/2023, 10/25/2022, 5/4/2022, 12/30/2021, 11/29/2021