Therapies for COVID-19

WA.PHAR.127

Background:

This policy describes the requirements that facilities, providers, and pharmacies must abide by to receive and use the COVID-19 therapies listed in this policy for the treatment of COVID-19. For general information about COVID-19, see HCA's Information about novel coronavirus (COVID-19) webpage.

A pharmacist may prescribe, administer, and bill for COVID-19 therapies for the treatment of mild to moderate COVID-19 when there is a standing order or a collaborative practice agreement in place. Pharmacies may bill for COVID-19 therapies for the treatment of mild to moderate COVID-19 .

The administration of these products must be billed as a HIPPA 837 transaction using the pharmacy billing taxonomy of 193200000X.

This policy applies to HCA fee-for-service and contracted managed care organizations.

Billing information for Professional and Facility Claims:

Reimbursement information and billing guidance

The COVID-19 therapies and their specific administration codes listed, are covered by Apple Health (Medicaid) for the treatment of COVID-19.

Please see the COVID-19 fee schedule for rates and effective dates.

When billing COVID monoclonal antibodies in an OPPS setting, use revenue code 0636. This is effective retroactively to 1/1/2022.

Outpatient hospital facility

CMS established modifier "PN" (Non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital) to identify and pay non-excepted items and services billed on an institutional claim. For COVID-19 therapy treatment, non-excepted off-campus provider-based departments of a hospital are required to report this modifier on each claim line with a HCPCS for non-excepted items and services.

Medical necessity

Drug	Medical Necessity
Tocilizumab	Tocilizumab may be considered medically necessary when prescribed for the treatment of coronavirus disease 2019 in hospitalized adults who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO), in accordance with the National Institutes of Health (NIH) COVID-19 Treatment Guidelines and DOH requirements.
Remdesivir (Veklury)	Remdesivir may be considered medically necessary when prescribed for the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients (28 days of age and older and weighing at least 3 kg) with positive results of direct severe acute respiratory syndrome 2 (SARS-CoV-2) viral testing, in accordance with the National Institutes of Health (NIH) COVID-19 Treatment Guidelines and DOH Requirements, who are: • Hospitalized; **OR** • Not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.
Nirmatrelvir+ritonavir (Paxlovid)	Nirmatrelvir+ritonavir may be considered medically necessary when prescribed for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age or older weighing at least 40 kg) with positive results of direct SARS-CoV-2, and who are at high risk for progression to severe COVID-19, including hospitalization or death in accordance with the Emergency Use Authorization (EUA), National Institutes of Health (NIH) COVID-19 Treatment Guidelines, and DOH requirements.
Molnupiravir (Lagevrio)	Molnupiravir may be considered medically necessary when prescribed for the treatment of mild to moderate COVID-19 in adults with positive results of direct SARS-CoV-2, and who are at high risk for progression to severe COVID-19, including hospitalization or death in accordance with the Emergency Use Authorization (EUA), National Institutes of Health (NIH) COVID-19 Treatment Guidelines, and DOH requirements.
Baricitinib (Olumiant)	Baricitinib may be considered medically necessary when prescribed for the treatment of coronavirus disease 2019 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO, in accordance with the National Institutes of Health COVID-19 Treatment Guidelines and DOH requirements.
Vilobelimab (Gohibic)	Vilobelimab may be considered medically necessary when prescribed for the treatment of COVID-19 in hospitalized adults within 48 hours of receiving invasive mechanical ventilation or extracorporeal membrane oxygenation in accordance with the Emergency Use Authorization (EUA), National Institutes of Health (NIH) COVID-19 Treatment Guidelines, and DOH requirements.

Clinical policy:

Clinical Criteria	
Mild to moderate COVID-19 at high risk for progressing to severe COVID-19 or hospitalization Molnupiravir Nirmatrelvir+ritonavir Remdesivir	Healthcare providers must document in the patient's medical record that the patient/caregiver has been: 1. For products authorized under EUA, communicated information consistent with and provided the respective Fact Sheet for Patients, Parents, and Caregivers prior to administering the medication; **AND** 2. Informed of alternatives prior to receiving these medications; **AND** 3. For products authorized under EUA, informed that these medications are unapproved drugs that are authorized for use under Emergency Use Authorization; **AND** 4. For molnupiravir, alternative COVID-19 treatment options authorized by the FDA are not accessible or clinically appropriate. 5. Patient will be monitored for at least 1 hour after infusion or injection is complete.
COVID-19 in hospitalized adults and pediatric children Baricitinib Tocilizumab Remdesivir *Vilobelimab* (Adults Only)	Healthcare providers must document in the patient's medical record that the patient/caregiver has been: 1. Informed of alternatives prior to receiving these medications. 2. For products authorized under EUA, communicated information consistent with and provided the "" prior ti administering the medication; **AND** 3. Informed of alternatives prior to receiving these medications; **AND** 4. For products authorized under EUA, informed that these medications are unapproved drugs that are authorized for use under Emergency Use Authorization.

Dosage and quantity limits

Drug	Dose and Quantity Limits
Tocilizumab	• Patients less than 30 kg: 12 mg/kg, max 2 infusions • Patients at or above 30 kg: 8 mg/kg, max 800 mg per infusion, max 2 infusions
Remdesivir	Loading dose: • 3 kg to less than 40 kg: 5 mg/kg • 40 kg and higher: 200 mg Maintenance: • 3 kg to less than 40 kg: 2.5 mg/kg • 40 kg and higher: 100 mg
Nirmatrelvir+ritonavir	• 300 mg nirmatrelvir + 100 mg ritonavir twice daily for 5 days
Molnupiravir	• 800 mg every 12 hours for 5 days
Baricitinib	• 4 mg once daily for 14 days or until hospital discharge, whichever comes first

Vilobelimab	• 800 mg on days 1, 2, 4, 7, 15, and 22 as long as the patient is hospitalized. Max 6 doses.

Coding:

HCPCS Code	*Description*
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
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
J0248	Injection, remdesivir, 1 mg when administered in an outpatient setting

Providers

1. In accordance with the DOH requirements, healthcare providers must communicate to patients or parents/caregivers, as age appropriate, information consistent with the "Nirmatrelvir+ritonavir Fact Sheet for Patients, Parents, and Caregivers," "Molnupiravir Fact Sheet for Patients, Parents, and Caregivers," or "Vilobelimab Fact Sheet for Patients, Parents, and Caregivers" (and provide a copy of the Fact Sheet) prior to the patient receiving the medication, including:
   • The patient or parent/caregiver has the option to accept or refuse nirmatrelvir+ritonavir, molnupiravir, or vilobelimab.

   • The significant known and potential risks and benefits of nirmatrelvir+ritonavir, molnupiravir and vilobelimab and the extent to which such potential risks and benefits are unknown.

   • Information on available alternative treatments and the risks and benefits of those alternatives, including clinical trials.

   • Patients treated with remdesivir, nirmatrelvir+ritonavir, or molnupiravir should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high touch" surfaces, and frequent handwashing) according to CDC guidelines.

2. • The prescribing health care provider and/or provider's designee are/is responsible for mandatory reporting of all medication errors and serious adverse events potentially related to tocilizumab treatment within 7 calendar days from the onset of the event. These reports are to be submitted to FDA MedWatch. See "Fact Sheet for Healthcare Providers Emergency Use Authorization (EUA) for Paxlovid," "Fact Sheet for Healthcare Providers Emergency Use Authorization (EUA) for Molnupiravir," or "Fact Sheet for Healthcare Providers Emergency Use Authorization (EUA) for Vilobelimab" for respective reporting requirements.
   • Actemra subcutaneous injection is **NOT** authorized for the treatment of COVID-19 patients.

- Actemra for COVID-19 is **NOT** authorized to be used outside the hospital (i.e. for non-hospitalized patients).

References

1. Apple Health (Medicaid) Monoclonal Antibody Treatment for COVID-19 clinical policy. Washington State Health Care Authority. https://www.hca.wa.gov/assets/billers-and-providers/apple-health-monoclonal-antibody-treatment-COVID-19-clinical-policy.pdf
2. Information About Novel Coronavirus. Washington State Health Care Authority. https://www.hca.wa.gov/information-about-novel-coronavirus-covid-19.
3. Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) for Molnupiravir. https://www.fda.gov/media/155054/download. Accessed 3/29/2023.
4. Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) for Paxlovid. https://www.fda.gov/media/155050/download. Accessed 3/29/2023.
5. Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) for Gohibic. InflaRx GmbH. Jena, Germany. Accessed 7/18/2022. https://www.fda.gov/media/166824/download
6. Fact Sheet for Patients, Parents, and Caregivers Emergency Use Authorization (EUA) of Molnupiravir for the treatment of Coronavirus Disease 2019 (COVID-19). https://www.fda.gov/media/155055/download. Accessed 1/4/2022.
7. Fact Sheet for Patients, Parents, and Caregivers Emergency Use Authorization (EUA) of Paxlovid for Coronavirus Disease 2019 (COVID-19). https://www.fda.gov/media/155051/download. Accessed 3/29/2023.
8. Frequently Asked Questions on the Emergency Use Authorization for Paxlovid for Treatment of COVID-19. https://www.fda.gov/media/155052/download. Accessed 3/29/2023.
9. Frequently Asked Questions on the Emergency Use Authorization for Gohibic (Vilobelimab) injection for Treatment of COVID-19. https://www.fda.gov/media/166826/download. Accessed 7/18/2023.
10. Fact Sheet for Patients and Caregivers Emergency Use Authorization (EUA) of Gohibic for Coronavirus Disease 2019 (COVID-19). https://www.fda.gov/media/166821/download. Accessed 7/18/2023.Frequently Asked Questions on the Emergency Use Authorization for Molnupiravir for Treatment of COVID-19. https://www.fda.gov/media/155056/download. Accessed 3/29/2023.
11. Interim Guidance on Duration of Isolation and Precautions for Adults with COVID-19. https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html.
12. The COVID-19 Treatment Guidelines Panel's Statement on Therapies for High-Risk, Nonhospitalized Patients with Mild to Moderate COVID-19. https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-therapies-for-high-risk-nonhospitalized-patients/. Accessed 3/29/2023.
13. Gottlieb R, Vaca C, Paredes R, et al. Early Remdesivir to Prevent Progression to Severe COVID-19 in Outpatients. N Engl J Med 2022; 386:305-315.
14. Veklury Prescribing Information. Gilead Sciences. Foster City, CA. 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/214787s011lbl.pdf.
15. Actemra Prescribing Information. Genentech. San Francisco, CA. 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125472s049lbl.pdf.
16. Olumiant Prescribing Information. Lilly USA. Indianapolis, IN. 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/207924s007lbl.pdf.

History

Date	Action and Summary of Changes
7/18/2023	Updated policy to include: • Added vilbelimab
4/24/2023	Updated policy to include:

	• Added baricitinib for hospitalized patients Removed tixagevimab+cilgavimab as emergency use authorization was revoked.
12/16/2022	Removed bebtelovimab as emergency use authorization was revoked.
9/14/2022	Removed the following statement: • As of 1/1/21 claims billed with the PN modifier are paid at 46% EAPG rates. Providers are subject to post pay review. If it found that modifier PN should have been used at the time of billing, recoupment of payment may occur.
8/19/2022	Updating policy to include statement: • Providers should not bill for products received free through the USG-purchased inventory. Providers should only bill Medicaid for commercially purchased products.
5/10/2022	Updating policy to include: • FDA label update for remdesivir
4/12/2022	Updating policy to include: Updated clinical policy and billing codes to reflect products (casirivimab+imdevimab, bamlanivimab+etesevimab and sotrovimab) that are no longer authorized
3/23/2022	Updating policy to include: • Updated dosage and quantity limits for tixagevimab+cilgavimab Updated billing codes
2/24/2022	Updating policy to include: Updated FDA label for bebtelovimab
1/28/2022	Updating policy to include: • Updated FDA label for remdesivir Updated EUA for remdesivir
1/18/2022	Updating policy to include: • Use of Paxlovid and molnupiravir for mild to moderate COVID-19. • Use of Evusheld for pre-exposure prophylaxis. • Use of remdesivir for hospitalized patients with suspected or laboratory confirmed COVID-19. • Use of remdesivir for non-hospitalized patients from recent NIH treatment guidelines. Updated: • Hyperlinks, provider requirements, and HCPCS codes. • Bamlanivimab+etesevimab dosing. Title of policy from “Monoclonal antibody for treatment of COVID-19” to “Therapies for COVID-19”.
9/22/2021	Updating policy to include use of casirivimab + imdevimab and bamlanivimab + etesevimab for post-exposure prophylaxis. Updating policy to include tocilizumab. Updated hyperlinks, provider requirements, and HCPCS codes. Added resource information for subcutaneous administration of casirivimab + imdevimab. Added information for providers for limitations of authorized use.
7/1/2021	Updating policy to include sotrovimab
4/20/2021	Removed bamlanivimab as emergency use authorization was revoked.
3/2/2021	Updating policy to include bamlanivimab + etesevimab

12/18/2020	New policy