COVID-19: Coverage of Monoclonal Antibody Injections by Pharmacy Providers

To comply with the 9th Amendment of the Public Readiness and Emergency Preparedness (PREP) Act, the Michigan Department of Health and Human Services (MDHHS) will provide reimbursement to Medicaid-enrolled pharmacy providers for the administration of Emergency Use Authorization (EUA) monoclonal antibody (mAb) COVID-19 injections in accordance with the Food and Drug Administration (FDA) EUA authorization of those products, and for beneficiary populations authorized by the FDA. This policy is effective immediately.

Billing guidance/instructions from MDHHS for the billing of pharmacist administered COVID-19 monoclonal antibodies are included in the attached bulletin, HASA 22-02.

Additional Resources for Providers
Information on FDA EUA drugs, devices and biological products for COVID-19 prevention and treatment can be found at https://www.cms.gov/monoclonal.

Information on Monoclonal Antibodies for COVID-19, including billing for treatment or post-exposure prophylaxis, can be found on the CMS website at https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion.

MDHHS Michigan Department of Health & Human Services

Health and Aging Services Administration

BULLETIN

HASA

Language Corrected on 3-25-2022

Bulletin Number: HASA 22-02

Distribution: All Providers

Issued: February 18, 2022

Subject: COVID-19 Response: Coverage of U.S. Food & Drug Administration (FDA) Emergency Use Authorization (EUA) COVID-19 Monoclonal Antibody Injections by Pharmacy Providers

Effective: As Indicated

Programs Affected: Medicaid, Healthy Michigan Plan, Emergency Services Only (ESO), Maternity Outpatient Medical Services (MOMS), Children's Special Health Care Services (CSHCS)

To comply with the 9th Amendment of the Public Readiness and Emergency Preparedness (PREP) Act, the Michigan Department of Health and Human Services (MDHHS) will provide reimbursement to Medicaid-enrolled pharmacy providers for the administration of Emergency Use Authorization (EUA) monoclonal antibody (mAb) COVID-19 injections in accordance with the Food and Drug Administration (FDA) EUA authorization of those products, and for beneficiary populations authorized by the FDA. This policy is effective immediately.

The purpose of this policy is to increase timely access to care in providing available treatments for the prevention and treatment of COVID-19. Allowing pharmacists to order and administer COVID-19 mAb therapeutics for treatment and prevention will significantly expand patient access to needed treatments and prophylaxis, particularly in medically underserved areas.

Provider Qualifications

Medicaid-enrolled pharmacy providers administering injections of EUA monoclonal antibody products for the treatment or post-exposure prophylaxis (PEP) of COVID-19, or for the pre-exposure prophylaxis (PrEP) of COVID-19 must:

- Follow the same enrollment process as those administering the COVID-19 vaccines. Provider enrollment information can be found on the Centers for Medicare & Medicaid Services (CMS) website at: www.cms.gov/medicare/covid-19/enrollment-administering-covid-19-vaccines.
- Adhere to all other requirements of the MDHHS FDA EUA policy, established in Bulletin MSA 20-81 and the MDHHS Medicaid Provider Manual unless otherwise indicated by CMS.
- Adhere to all other requirements of the MDHHS Coverage of COVID-19 Vaccine Services where applicable, as established in Bulletin MSA 20-75.
- Remain in compliance with all other Department rules and regulations for vaccine administration.

Pharmacy Reimbursement for Administration of EUA mAb COVID-19 Injections

For the duration of the federally declared COVID-19 Public Health Emergency (PHE), Medicaid will cover the administration of FDA EUA mAb COVID-19 injections. The effective date and coverage parameters will be consistent with their respective FDA EUA status provisions.

During the PHE, when EUA mAb COVID-19 drug products for COVID-19 treatment are procured and purchased by the federal government, they will be made available to Medicaid-enrolled pharmacy providers at no cost. Medicaid will not reimburse providers for EUA mAb COVID-19 injection drug products that are federally purchased or supplied for free. Providers may bill the cost of the EUA mAb COVID-19 injection drug products as $0.00. During the federally declared PHE period, including any extensions, reimbursement for the administration services of the EUA mAb COVID-19 injection will be temporarily increased to 100% of Medicare rates for equivalent services.

Consistent with billing guidance described in bulletin MSA 20-81, EUA mAb COVID-19 injection administration is covered for Medicaid beneficiaries according to reimbursement rates published on the MDHHS website at www.michigan.gov/medicaidproviders >> Billing & Reimbursement >> Provider Specific Information. Additional pertinent coverage parameters are accessible via the Medicaid Code and Rate Reference tool within the Community Health Automated Medicaid Processing System (CHAMPS).

Any pharmacy-specific COVID-19 mAb injection billing instructions will be published at michigan.magellanrx.com/provider and also incorporated into the Pharmacy Claims Processing Manual at michigan.magellanrx.com/provider >> Documents >> Manuals.

Documentation Requirements

Medicaid-enrolled pharmacies must verify the administration of EUA mAb COVID-19 injections are supported by documentation to ensure terms of the applicable EUA are met. (Refer to the FDA EUA site listed below for COVID-19 therapies.)

The administration of EUA mAb COVID-19 injections must be evaluated for the safety and efficacy of treatment for the beneficiary to support medical necessity.

Additional Resources for Providers

Information on FDA EUA drugs, devices and biological products for COVID-19 prevention and treatment can be found at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

Information on Monoclonal Antibodies for COVID-19, including billing for treatment or post-exposure prophylaxis, can be found on the CMS website at https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion

Public Comment

The public comment portion of the policy promulgation process is being conducted concurrently with the implementation of the change noted in this bulletin. Any interested party wishing to comment on the change may do so by submitting comments to Vicki Goethals via e-mail at GoethalsV@michgian.gov.

Please include "COVID-19 Response: Coverage of U.S. Food & Drug Administration (FDA) Emergency Use Authorization (EUA) COVID-19 Monoclonal Antibody Injections by Pharmacy Providers" in the subject line.

Comments received will be considered for revisions to the change implemented by this bulletin.

Manual Maintenance

Retain this bulletin until the information is incorporated into the MDHHS Medicaid Provider Manual.

Questions

Any questions regarding this bulletin should be directed to Provider Inquiry, Department of Health and Human Services, P.O. Box 30731, Lansing, Michigan 48909-8231, or e-mailed to ProviderSupport@michigan.gov. When you submit an e-mail, be sure to include your name, affiliation, NPI number, and phone number so you may be contacted if necessary. Typical Providers may phone toll-free 800-292-2550. Atypical Providers may phone toll-free 800-979-4662.

An electronic copy of this document is available at www.michigan.gov/medicaidproviders >> Policy, Letters & Forms.

Approved

Kate Massey, Director
Health and Aging Services Administration