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## **BULLETIN 21-09**

Date: March 22, 2021

To: All Health Carriers

Re: COVID-19 State of Emergency: Coverage of Costs Associated With the Administration of Certain Monoclonal Antibody Therapies for COVID-19

On March 5, 2020, Governor Larry Hogan issued a Proclamation declaring a State of Emergency and finding that a Catastrophic Health Emergency exists in the State of Maryland. The Proclamation was most recently renewed on March 18, 2021.

On November 9, 2020, the U.S. Food and Drug Administration (“FDA”) issued an emergency use authorization (“EUA”) for the investigational monoclonal antibody therapy bamlanivimab for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progressing to severe COVID-19 and/or hospitalization. On November 21, 2020, the FDA issued an EUA for casirivimab and imdevimab to be administered together for the treatment of mild-to-moderate COVID-19 in the same set of high-risk adult and pediatric patients. The issuance of an EUA does not constitute FDA approval of a product. The EUA means that the FDA has determined that the therapies may be effective in treating patients with mild or moderate COVID-19; that the known and potential benefits of the therapies outweigh the known and potential risks; and that there are no adequate, approved, and available alternative treatments.

The United States Government has purchased a limited number of doses of these therapeutics and has provided them to the states for distribution to health care providers for patient use. The medication itself is provided by the federal government at no cost. However, there are costs associated with the administration of the therapeutics at infusion facilities and other approved settings. In December, 2020, the Centers for Medicare & Medicaid Services noted that coverage for these therapeutics varies among health plans subject to the Affordable Care Act’s market reforms and could be subject to exclusion on the ground that the treatment is experimental.

COVID-19 continues to pose a threat to Marylanders and it is critical that when therapeutics are made available without charge by the government that administration costs do not become a barrier to their use when medically appropriate and within the scope of the EUA. The Commissioner is aware that major health insurers in the State have not taken the position that these particular

therapeutics are excluded from coverage as experimental and are currently covering the administration of these therapeutics without cost sharing. It is important, however, that the ability of insured individuals to access these treatments without incurring the cost of administration in whole or in part not be dependent on their health plan.

In consideration of the above, and pursuant to § 2-115 of the Insurance Article and COMAR 31.1.02.05 and 06, the Commissioner hereby invokes her emergency powers to activate the provisions of COMAR 31.01.02.06A(8), F and M, which allow the Commissioner to require a health carrier to waive any cost-sharing, including copayments, coinsurance, and deductibles, for treatment for a specified illness and to make a claims payment for treatment for a specified illness that the health carrier has denied as experimental.

Consistent therewith, and effective immediately:

1. a health carrier is prohibited from denying a claim or authorization request for coverage for the administration of monoclonal antibody therapies, including Bamlanivimab and the combination of Casirivimab and Imdevimab, on the ground that such therapy or treatment modality is experimental or investigational; and
2. a health carrier must waive any cost-sharing, including copayments, coinsurance, and deductibles, for the administration of monoclonal antibody therapies, including Bamlanivimab and the combination of Casirivimab and Imdevimab;

provided, with respect to each of (1) and (2), that the EUA issued by the FDA is in effect and the administration of the drug complies with the terms of the EUA.

The Maryland Insurance Administration (MIA) also reminds carriers of their obligation under § 15-113(d) of the Insurance Article to provide health care practitioners with a description of their coding guidelines that are applicable to the services billed by a health care practitioner in that specialty, and to update this information in advance of a change. Providing health care practitioners with timely and appropriate coding guidelines is particularly important to help avoid unnecessary delays or denials of claims for new and emerging therapies. The MIA strongly encourages health carriers to follow CMS coding guidance for new therapies in order to facilitate claim filing and payment.

In addition, the MIA will closely monitor any prior authorization requirements imposed by health carriers with respect to the administration of these therapies to assure that appropriate treatment is not being unduly delayed.

These regulations shall be in effect along with those activated in Bulletins 20-05, 20-36, and 21-05 until the emergency declaration is lifted or the Commissioner issues a Bulletin deactivating the regulations at issue.

Questions about this Bulletin may be directed to the Life & Health Unit of the Maryland Insurance Administration at 410-468-2170.



KATHLEEN A. BIRRANE.  
Commissioner