Maryland
DEPARTMENT OF HEALTH

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

July 28, 2021

Dear Colleague,

As COVID-19 case rates decline as compared to the height of the pandemic, the demand for monoclonal antibodies (mAb) has also declined significantly. This communication is intended to provide an interim update on access to monoclonal antibody infusions and updates to the EUAs associated with those infusions.

Many physical infusion sites have found it necessary to shutter their operations due to little or no clinical demand over the past several weeks. The healthcare systems associated with these sites have moved the infusions to their respective emergency departments.

There are still sites offering scheduled infusions. In order to schedule an infusion at one of these sites, please refer to the list of sites and contact information in the attached referral form (Table 1).

Other sites are making infusions available in their emergency departments (Table 2). Providers who have identified a patient that is a candidate for mAb infusion should refer those patients to either an infusion center or the respective emergency department for evaluation and treatment. The providers are encouraged to contact the emergency department to provide relevant clinical information. The main access points for each hospital that provides monoclonal infusions is provided on the attached referral sheet.

Some healthcare systems are in the process of adding home monoclonal antibody infusions to their home infusion services. As more locations become available we will provide an update. In the interim, you may contact your local hospital regarding the availability of home infusions.

Key messages regarding the Emergency Use Authorization (EUA) modifications are as follows (detailed EUAs linked below)**:**

1. Bamlanivimab and etesivimab combination- due to the emergence nationally of the P.1 variant, HHS has stopped distribution of this monoclonal antibody cocktail. Providers are encouraged to use alternatives, however, the EUA has not been revoked.
2. Regeneron (REGEN-COV) formulation has been altered to 600 mg each of casirivimab and imdevimab. Providers are asked to stop the use of the 1200 mg doses of each.
3. Regeneron is now available for subcutaneous administration with 10cc of product that can be divided into four 2.5 ml subcutaneous injections. Subcutaneous injection is an alternative route of administration when intravenous infusion is not feasible and would lead to a delay in treatment.
4. An EUA has been granted for sotrovimab as now the second available monoclonal antibody. Based on similar in vitro assay data currently available, REGEN-COV and sotrovimab are likely to retain activity against the P.1 or B.1.351 variants. Healthcare providers should review the Antiviral Resistance information in Section 15 of the authorized Fact Sheets for each monoclonal antibody therapy available under an EUA for details regarding specific variants and resistance.

Sincerely,

Howard Haft, MD, MMM, CPE, FACPE
Executive Director
Maryland Primary Care Program

Aliya Jones, M.D., MBA
Deputy Secretary
Behavioral Health

Attachment and links

Please reference the following FDA materials and review with patients prior to referral. Infusion site clinicians will also review the information with the patient, based on the selected therapeutic.

- Referral form standard for monoclonal antibody treatment across all sites
- FDA Fact Sheet for Healthcare Providers-Regeneron MAbs (Casirivimab and imdevimab)
- FDA Fact Sheet for Healthcare Providers: Sotrovimab
- FDA Fact Sheet for Health Care Providers: Bamlanivimab and etesivimab