Dear Partner,

The U.S. Department of Health and Human Services has led the fair and equitable distribution of COVID-19 therapeutics over the course of the pandemic. This has included distribution of the Eli Lilly and Company monoclonal antibody product bebtelovimab.

Bebtelovimab is transitioning to the commercial marketplace. To ensure there is no break in availability of bebtelovimab to states/territories and providers, HHS has coordinated with Lilly to enable the transition from US government distributed supply to commercially available supply. Lilly will make the product commercially available for purchase through a sole distributor, AmerisourceBergen, beginning the week of August 15th, prior to the end of distribution of the government's supply.

Please carefully review the important information below to assist you with this transition:

Ordering

The US government supply will support a full threshold, 30,000 doses, the week of August 15 and a partial threshold, to be determined based on unordered inventory, the week of August 22. US government orders will be processed through HPOP. On Monday, August 29, all HPOP ordering activity for bebtelovimab only will be temporarily suspended to allow for final accounting of all remaining supply. On September 6, all remaining supply will be used to establish a final allocation of bebtelovimab to jurisdictions to use for the under- and uninsured population. This allocated amount will remain available for ordering for an extended period of time or until 100% of a jurisdiction's allocated supply has been ordered. No replenishment of the final allocation will occur, and there will be at least two weeks notification before ordering against the final allocation closes. We encourage all receiving sites to use the final weeks of supply of US government-procured product for those patients who do not have health insurance or cannot afford their cost share.

Lilly has established an ordering process for purchase of bebtelovimab with their distributor, AmerisourceBergen, that opens the week of August 15. Additional information on the ordering process for commercial bebtelovimab is included below and will be distributed to all sites of care that have previously ordered the product. A maximum order limit of 270 doses per week per provider site will be imposed. There will be no minimum order quantity. Exceptions for weekly dose quantities beyond 270 will be evaluated on a case-by-case basis. Please note that to limit the potential for overstocking, **no returns will be accepted for bebtelovimab**.

To ensure your site has immediate access to purchase bebtelovimab, please see the ordering guidance below:

Existing AmerisourceBergen Accounts:

AmerisourceBergen will sell bebtelovimab to licensed and approved customers such as hospitals, infusion centers, long term care facilities, clinics, etc. However, retail pharmacies will be excluded.
For any questions regarding product access, please contact c19therapies@amerisourcebergen.com

Sites Without an AmerisourceBergen Account:

To purchase bebtelovimab, your site must have a fully-vetted commercial account with AmerisourceBergen. To initiate the account creation process, please contact AmerisourceBergen at the following email address: asdaccountsetup@amerisourcebergen.com.
If you have any questions regarding the commercial purchase of bebtelovimab, please contact AmerisourceBergen at c19therapies@amerisourcebergen.com.

HPOP Reporting

Reporting inventory and administration of all US government-procured and distributed supply of bebtelovimab remains a requirement until all US government-procured bebtelovimab is consumed (a provider site's inventory is depleted). Please continue to log into your HPOP account to report twice each week, at minimum. To maintain visibility on access to bebtelovimab and to keep the therapeutic locator up to date for the US population, reporting of ordering and utilization of commercially purchased product is desired. Details about how to report commercially purchased product inventory and administrations are still in development and will be shared when available.

Payment and Cost Sharing

US Government-Procured Supply

When the US government provides monoclonal antibody products for free to treat COVID-19, providers should only bill for the administration of the drug and should not include the monoclonal antibody product codes on these claims. If a site received the product for free, and internal systems require a product code to bill for the administration, sites should enter $0.01 for the billed amount.

Commercially-Procured Supply

For bebtelovimab product purchased commercially, sites should continue to use HCPCS codes:

- Q0222: Injection, 175 mg for the product
- M0222: Intravenous injection, includes injection and post administration monitoring
- M0223: Intravenous injection, 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

HCPCS Code	HCPCS Short Descriptor	Labeler Name	National Payment Allowance Effective for Claims with DOS on or after 05/6/2021	National Payment Allowance Effective for Claims with DOS through 05/5/2021	Effective Dates
Q0222	Bebtelovimab 175 mg	Eli Lilly	$2394 [1] [1a]	Code not active during this time period	02/11/2022 - TBD
M0222	Bebtelovimab injection	Eli Lilly	$350.50[3]	Code not active during this time period	02/11/2022 - TBD
M0223	Bebtelovimab injection (home)	Eli Lilly	$550.50[3]	Code not active during this time period	02/11/2022 - TBD

[1] Providers shouldn't bill for the product if they received it for free through the USG-purchased inventory.
[1a] Payment rate effective for dates of service on or after August 15, 2022. Providers should only bill Medicare for commercially-purchased products.
[3] These rates will be geographically adjusted for many providers. For providers and suppliers with payments that are geographically adjusted by the methodology used by the Medicare Physician Fee Schedule (MPFS), files with the geographically adjusted payment rates for monoclonal antibody administration are included in the "Additional Resources" section below. Certain settings utilize other payment methodologies, such as payment based on reasonable costs

No cost sharing (no copayment/coinsurance or deductible) for monoclonal antibody therapies to treat COVID-19 for people with Medicare fee-for-service and Medicare Advantage beneficiaries will be required for the duration of the calendar year in which the COVID-19 public health emergency ends.

For more information, please visit the following CMS sites:

- COVID-19 Monoclonal Antibodies
- COVID-19 Vaccine and Monoclonal Antibodies ASP webpage

Medicaid will pay for the cost of the bebtelovimab and its administration without the requirement for cost sharing through the last day of the first calendar quarter that begins one year after the last day of the Public Health Emergency. Under the American Rescue Plan Act of 2021 (ARP), state Medicaid programs cannot charge cost sharing on drugs to treat COVID-19 through the last day of the first calendar quarter that begins one year after the day that the PHE ends.

Regulatory

The US Food and Drug Administration FDA updated the letter of authorization for bebtelovimab on August 5, 2022, allowing for commercial distribution of the product.

Under- and Uninsured Drug Coverage

Lilly and the US government are actively engaging to develop a path forward for ensuring access of bebtelovimab for the under- and uninsured populations during the transition to commercialization. Clinical sites with an excess of bebtelovimab starting the week of August 15, 2022, should prioritize the US government-supplied drug for the under- and uninsured patients at their sites and use the commercially available supply for those with Medicare, Medicaid and private insurance.

While a full plan for under- and uninsured drug coverage is under development, a final allocation of USG-supplied bebtelovimab will be made available on September 6 to jurisdictions on a pro rata population basis. This supply can be shipped to state and territorial health departments for further distribution or direct shipment to clinical sites in their jurisdictions administering drug to under- and uninsured patients.

Thank you for your continued partnership in helping to ensure critical COVID-19 therapeutics reach communities across the country. We will keep you informed as additional details develop regarding the commercialization of bebtelovimab.

Regards,
HHS Coordination Operations and Response Element
Administration for Strategic Preparedness and Response
U.S. Department of Health and Human Services