Update: Allocation and Distribution of COVID-19 Therapeutics Products EVUSHELD and sotrovimab

DECEMBER 20, 2021
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

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Ordering of EVUSHELD

- Ordering for EVUSHELD now open to jurisdictions (based on distribution determinations)
  - Ordering through HPOP only
  - 50,000 doses allocated by USG
  - Distribution determinations made on pro rata basis

- Preliminary data listed in FDA fact sheet regarding neutralizing activities of EVUSHELD against the Omicron variant of concern:
  - Testing of EVUSHELD for neutralization of a pseudovirus expressing the spike protein representative of the predominant lineage of the SARS-CoV-2 Omicron variant demonstrated a 132 to 183-fold reduction of potency (IC50) compared with its activity against the D614G variant.
  - A 12 to 30-fold reduction in potency was demonstrated using authentic Omicron virus.
  - Data collection is ongoing to better understand how the reductions in activity seen in pseudovirus assays or authentic SARS-CoV-2 assays may correlate with clinical outcomes.

50,000 doses being prepared for distribution
Sotrovimab Distribution Resumed

- USG paused shipment of sotrovimab late November to:
  - Help ensure a more balanced portfolio of monoclonal antibody products and
  - Allow more time to assess data regarding the drug’s effectiveness against the Omicron variant

- Early in vitro data suggests sotrovimab retains activity against the Omicron variant

- Ordering portal now re-open (through AmerisourceBergen C19 Portal)
  - 55,000 doses being prepared for immediate distribution
  - More product available in January
  - Allocated doses will remain available to jurisdictions and will not be reallocated into the federal pool.
  - Jurisdictions will see product arrive as early as tomorrow - Tuesday, December 21
  - Weekly reporting requirements remain the same

55,000 doses being prepared for distribution
Sotrovimab Distribution Resumed

- Allocation of sotrovimab to state and territorial health departments determined using same methodology as before, taking into account COVID-19 incidence rates and hospitalizations.

- USG current supply extremely limited – additional doses available week of January 3rd.

- Recommend jurisdictions continue use of the bam/ete and REGEN-COV while reserving sotrovimab for treatment of eligible outpatients at highest risk who are either:
  - diagnosed with a test that may identify a potential case of the Omicron variant in a clinically relevant timeframe
  - are present in local settings where reported prevalence of Omicron is high.

Reserve for treatment of eligible outpatients at highest risk.
New! Recording of ASPR TRACIE webinar “Monoclonals and More – Allocation and Distribution of Outpatient COVID-19 Therapeutics”

Updated! Side-by-Side Overview of Outpatient mAb Therapies

Updated! HHS Clinical Implementation Guide

HHS Protect Therapeutics Dashboard https://protect.hhs.gov/workspace/module/view/latest/ri.workshop.main.module.084a09b4-bcd0-4a6b-817a-90af7a3cd1d

HHS Monoclonal Antibody Therapeutics Homepage https://www.phe.gov/mabs

COVID-19 Monoclonal Antibody Therapeutics Communications Toolkit https://www.phe.gov/mabs-toolkit

Updated information sheets and resources for providers in English and Spanish https://combatcovid.hhs.gov/hcp/resources
Helpful Information and Resources (II/II)

➢ REGEN-COV: Subcutaneous Injection Instructions for Healthcare Providers

➢ ASPR Regional Teams
   - Consult the ASPR Regional Team in your area for questions regarding COVID-19 medical countermeasures

➢ HRSA Uninsured Program fact sheet

Thank you!