Monoclonal Antibody Therapeutics (mAb)

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(Enter) DEPARTMENT (ALL CAPS) (Enter) Division or Office (Mixed Case)

What are monoclonal antibodies (mAb)?

- Lab-created antibodies that target the spike protein of the SARS-CoV2 virus.
- Emergency Use Authorization (EUA):
 - treatment of mild to moderate infection for those who are confirmed COVID-19 positive
 - Reduces hospitalizations by up to 70% when used as treatment.
 - post-exposure prophylaxis (PEP) treatment for certain eligible individuals.
 - Reduces hospitalization by up to 81% when used as PEP.
- All products effective against Delta
- IV and subcutaneous (SQ) administration options



Eligibility

- People ages 12 and older who weigh more than 40kg/88lbs who:
 - Test positive for COVID-19
 - Are experiencing mild to moderate symptoms
 - Onset within 10 days
 - Are considered high risk for going into the hospital due to age (more than 65 years old), weight, pregnancy, immunosuppressive disease or treatment, or other chronic conditions

OR

- People ages 12 and older, weighing more than 40 kg/88lbs, who are exposed or at high risk for exposure (such as in congregate settings) and are:
 - Incompletely vaccinated i.e. unvaccinated or partially vaccinated
 - Fully vaccinated but expected not to have as strong an immune response because of immunocompromising illness or being on immunosuppressive medications.



Supply and distribution

- September 13, 2021 allocation transitioned to states
- National distributor: Amerisource Bergen
 - Supply constraints
 - Delays
- Every Monday, HHS releases state allocation numbers for mAb therapeutics.
- Sites have until Wednesday at 11:59 PM to place their orders with OHA



Centering Equity in Allocation

- Equitable mAb administration can help mitigate COVID-19's disproportionate impacts on certain populations.
- Priority: FQHCs & Tribal Clinics
- weighted average of % hospitalizations & % cases informs proportionate allocation to counties/regions
- CCVI by ordering site when there is a greater demand versus supply within a given county or region
- Future methodology considerations include:
 - Utilization data, LPHA selection of priority sites, & demographic data



Weekly cadence

Monday Tuesday	Wednesday Thursday	Friday
HHS notifies OHA of allocation amount for Oregon	Epi team reports on mAb team prior week's data calculates allocatic including COVID using methodolog	ý í
Ordering email goes out to providers	hospitalizations and cases Utilization	Email confirmation of order amount with sites
	reporting due 11:59 p.m. ET	Email or phone communication with sites denied orders;
	Orders from sites due by 11:59 p.m. PST	offer TA to assist with registration



Thank you!

- OHA mAb webpage
 - <u>https://www.oregon.gov/oha/covid19/Pages/monoclonal-antibody-therapy.aspx</u>



Distribution

- mAb planning team convenes on Thursdays to apply methodology to all requests.
- OHA submits final orders on Friday to Amerisource Bergen and sends an email to all ordering sites receiving mAbs with a confirmation.
- Future distribution is expected to decrease by 25% nationwide due to supply constraints.
- OHA will continue to monitor and modify our allocation methodology in partnership with the governor's office to ensure equitable distribution of product as much as can be accommodated by existing clinical capacity.
- In the upcoming week, OHA will publish the allocations to the ordering sites on the OHA mAbs webpage.

