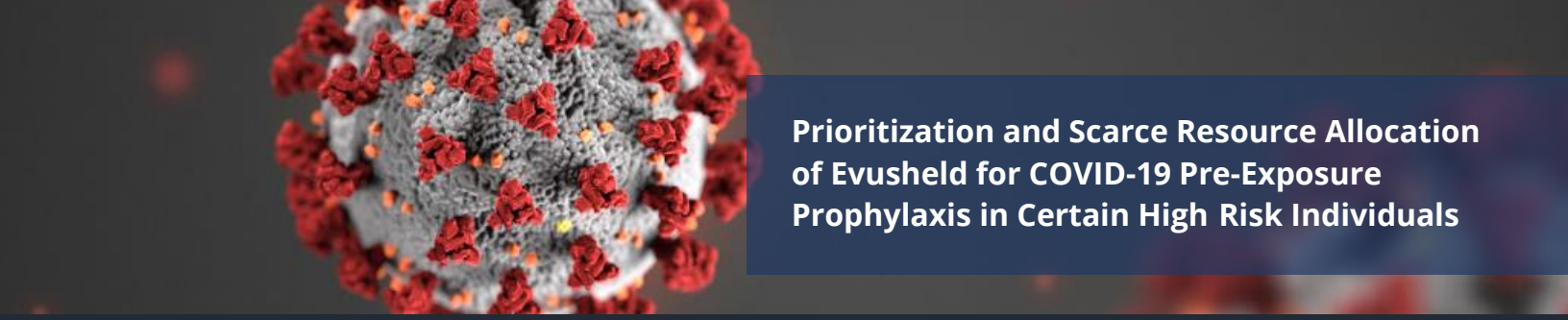

Prioritization and Scarce Resource Allocation of Evusheld for COVID-19 Pre-Exposure Prophylaxis in Certain High Risk Individuals

Michigan.gov/Coronavirus

December 29, 2021

Summary

Evusheld (tixagevimab/cilgavimab) is a long-acting monoclonal antibody that was recently issued an emergency use authorization (EUA) by the Food and Drug Administration (FDA) for COVID-19 pre-exposure prophylaxis (PrEP) in certain high-risk, immunocompromised individuals. It is administered through two intramuscular injections, repeated every six months. PrEP is not a substitute for vaccination.

The federal government has allocated this medication to states who must reallocate to healthcare providers. The Michigan Department of Health and Human Services (MDHHS) has developed a strategic framework for allocating Evusheld in which the medication will be primarily distributed to 17 healthcare systems. It is believed that over 95% of eligible patients receive care through one of these healthcare systems. As the anticipated demand for this medication is expected to exceed the available supply, it is essential that healthcare systems provide this medication in a manner that assures equal and fair access, that patients at higher risk are prioritized, and that fundamental principles of scarce resource allocation are followed. Therefore, MDHHS is providing this guidance to assist healthcare systems in operationalizing the timely administration of this medication to appropriate patients.

The core components in this scarce resource allocation process for healthcare systems include:

- Establish prioritization criteria to stratify risk based on MDHHS tiers (see below)
- Identify potentially eligible patients based on prioritization tiers
- Select patients for treatment using a fair and ethical allocation process
    - This results in the order in which patients will receive the medication based on initial and subsequent supplies
- Provide counseling on potential risks and benefits to patients selected for therapy
    - Provide patients with the FDA's Fact Sheet for Patients and Caregivers
- Order/distribute Evusheld to sites (including providers' offices) and schedule appointments
- Administer the medication as directed by the FDA's Fact Sheet for Healthcare Providers
- Complete required state and federal reporting in the timeframe indicated by MDHHS and U.S. Department of Health and Human Services (HHS)
- Readminister medication every six months, as indicated
- Monitor safety and effectiveness

To assure timely access of this medication and to assure Michigan's allocations are not reduced by the federal government if we do not use our supply, healthcare systems will need to quickly put in place processes for the selection of and administration to qualifying patients based on prioritization criteria. These criteria have been developed by MDHHS and align with the NIH Treatment Panel Guidelines.[1] Patient selection should involve a process in which higher risk Tier 1 patients receive the medication prior to those in the Tier 2 category. As 80% or more of eligible Tier 1 patients receive Evusheld expansion to Tier 2 may occur. Healthcare systems may further stratify risk within Tier 2, as appropriate. Subsequent allocations to healthcare systems will be adjusted based on priority need.

Allocation to Healthcare Systems

MDHHS has previously developed a process for the initial allocation of Evusheld to 17 Michigan healthcare systems. This was determined based on data received from the Michigan Health and Hospital Association (MHA) on the number of unique patients receiving inpatient or outpatient care with an associated diagnosis consistent with an immunocompromising condition. These data were used to proportionately allocate the medication between healthcare systems. Subsequent (anticipated) biweekly allocations will be adjusted based on the ability of the healthcare systems to use the medication based on priority tiers and available supply. Inability to use the medication may result in decreased future allocations.

Access to Independent Hospitals and Special Populations

Independent hospitals not affiliated with one of the 17 healthcare systems directly receiving shipments of medication will be able to request medication from a small cache maintained by MDHHS for this purpose. This cache will also be used to serve other special populations (e.g., Michigan Department of Corrections) who have eligible patients meeting current priority tiers. Like the healthcare systems, those requesting medication from the MDHHS cache will be required to have in place scarce resource allocation processes that will allow fair and equitable access. Healthcare systems should make additional efforts to reach eligible patients who may be more difficult to contact and who may have barriers to communications.

Tiered Prioritization

As demand for this medication is likely to exceed supply, a two-tiered prioritization system has been developed to help assure those who are at higher risk receive priority access. The following tiered prioritization categories has been adapted from the NIH Treatment Panel Guidelines. To assure fair and equitable access, this stratification will be used in allocating this medication in Michigan. Healthcare system scarce resource allocation (or similar) committees may further stratify within the second tier, as appropriate for their system.

[1] National Institutes of Health. (2021, December 23). *Statement on patient prioritization for outpatient therapies*. NIH COVID-19 Patient Treatment Guidelines. Retrieved December 27, 2021, from https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-patient-prioritization-for-outpatient-therapies/

Priority Criteria to Receive Evusheld (tixagevimab/cilgavimab) for Pre-Exposure Prophylaxis for COVID-19 in High-Risk Individuals
Tier 1 Criteria1
a. Patients within 1 year of receiving B-cell depleting therapies (e.g., rituximab, ocrelizumab, ofatumumab, alemtuzumab) b. Patients receiving Bruton tyrosine kinase inhibitors c. Chimeric antigen receptor T cell recipients d. Post-hematopoietic cell transplant recipients who have chronic graft versus host disease or who are taking immunosuppressive medications for another indication e. Patients with hematologic malignancies who are on active therapy f. Solid-organ transplant recipients who: 1) are lung transplant recipients, or 2) are within 1 year of receiving a solid-organ transplant (other than lung transplant), or 3) solid-organ transplant recipients with recent treatment for acute rejection with T or B cell depleting agents g. Patients with severe combined immunodeficiencies h. Patients with untreated HIV who have a CD4 T lymphocyte cell count <50 cells/mm^3 i. Other patients with severe immunodeficiency to be reviewed on an individual basis by designated senior clinicians, with no established physician obligation to the patient
Tier 2 Criteria[2]
a. Patients with active treatment for solid tumor malignancies b. Patients with moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome) c. Advanced or untreated HIV infection (people with HIV and CD4 cell counts of 50-200/mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV) d. Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive that are immunosuppressive or immunomodulatory (e.g., B-cell depleting agents), tumor-necrosis (TNF) blockers, and other biologic agents e. For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s)

[2] US Food and Drug Administration. (2021, December 20). *FACT SHEET FOR HEALTHCARE PROVIDERS: EMERGENCY USE AUTHORIZATION FOR EVUSHELD™ (*. Retrieved December 27, 2021, from https://www.fda.gov/media/154701/download

Operationalizing Tiered Prioritization within Healthcare Systems

Recognizing the uniqueness of healthcare systems, it is understood that operationalizing access to Evusheld will be done in different ways within healthcare systems. It is also understood that this is a formative process that will need to be adapted and revised over time to best serve high-risk patients. Healthcare systems should consider the following, in consultation with their scarce resource allocation committees, in establishing policies for Evusheld administration to qualifying patients.

Establish Prioritization Criteria

To assure statewide equity and fairness in providing access to Evusheld in higher risk patients, healthcare systems should adopt the MDHHS Prioritization Criteria. Tier 1 Criteria are based on the NIH Treatment Panel Guidelines for prioritization of outpatient therapies. Patients meeting Tier 1 Criteria should receive Evusheld prior to those meeting Tier 2 Criteria. Healthcare systems may elect to further stratify Tier 1 and Tier 2 criteria to better address system needs and patient types. Given demand exceeding supply, systems may wish to further prioritize severely immunocompromised individuals over moderately immunocompromised individuals. It should be noted that this medication is not FDA-approved and therefore off-label ordering is not permitted under the EUA.

Identify and Screen Potentially Eligible Patients

Beginning with Tier 1, patients should be identified and screened who potentially meet the criteria. This can be accomplished through one or more processes including through an electronic medical record search for appropriate conditions or through direct referral from the patient's healthcare provider.

Patient Selection and Order of Administration

Using a list of identified and screened patients identified above, those meeting the criteria should be placed in the order to receive Evusheld.

Patient Contact and Counseling

Once patients are selected, they should be contacted by a qualified healthcare provider and counseled on the potential risks and benefits of Evusheld, in accordance with the Fact Sheet for Patients and Caregivers. Special attention should be provided to **those at high-risk for cardiovascular events** as described in the Fact Sheet. Patients wishing to receive Evusheld are required to receive the FDA's Fact Sheet for Patients and Caregivers prior to receiving the medication.

Order and Provide the Medication to the Site of Distribution and Schedule Appointment
Once patients have been selected and agree to receive Evusheld, an order should be provided by an authorized healthcare provider. The medication should be provided to the site of administration and an appointment should be scheduled.

Administer the Medication
The medication should be administered as directed by the FDA's Fact Sheet for Healthcare Providers and patients must be observed for at least 60 minutes after administration.

Complete Required State and Federal Reporting
All healthcare systems must complete, in a timely manner, all required federal and state reporting requirements. Failure to comply with this may jeopardize future allocations to healthcare systems and to the state.

Readminister Medication Every 6 Months
The current EUA calls for the re-administration of Evusheld every 6 months to sustain pre-exposure prophylaxis.

Monitor Safety and Effectiveness
Healthcare systems should monitor patients receiving Evusheld for safety and effectiveness in preventing COVID-19 infections, and especially hospitalizations or deaths.

Centralized or Decentralized Distribution
MDHHS will initially allocate Evusheld to one central receiving pharmacy for each healthcare system. Based on a variety of factors, healthcare systems may adopt a centralized, decentralized, or hybrid process for selection of patients and administration of medication. The selection process could occur centrally, but the medication should be administered at multiple sites. Alternatively, healthcare systems could adopt a more decentralized approach in which multiple sites serving specific geographic areas (e.g., norther region) or populations (e.g., the oncology clinic). Medication may be redistributed to various sites, clinics, etc. as needed to best serve patients.

Redistribution Between Healthcare Systems
In the event a healthcare system is underusing Evusheld, inventory assigned to that healthcare system may be redistributed to other healthcare systems who are in need.