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PUBLIC HEALTH ADVISORY

To:	All Health Care
From:	Dr. Isaac Benowitz, Maine CDC State Epidemiologist
Subject:	**Expanded Eligibility for COVID-19 Pre-exposure Prophylaxis for Patients with Moderate/Severe Immunocompromise**
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Expanded Eligibility for COVID-19 Pre-exposure Prophylaxis for Patients with Moderate/Severe Immunocompromise

I. Summary

This health alert provides updates on patient eligibility for EVUSHELD, a long-acting monoclonal antibody that is available under U.S. Food and Drug Administration Emergency Use Authorization for pre-exposure prophylaxis to prevent COVID-19 infection in persons with moderate to severe immunocompromise. *Additional groups of people in Maine are now eligible to get pre-exposure prophylaxis.* For the latest information regarding the patient conditions that determine eligibility for EVUSHELD and the locations in Maine where this medication is available, visit the Maine CDC *COVID-19: Healthcare Providers* page at https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/airborne/coronavirus/providers.shtml#prophylaxis.

Vaccination for COVID-19 remains the best protection against infection, hospitalization, and death. However, individuals with immunocompromising conditions, or taking certain immunocompromising medications, may be less likely to mount an appropriate immune response to COVID-19 vaccination, leaving them at elevated risk for COVID-19 infection, hospitalization, and death. Many such persons are already at elevated risk for severe disease from COVID-19 due to their existing health conditions. Pre-exposure prophylaxis is now available for certain individuals who have been vaccinated against COVID-19 but remain highly susceptible to this infection and subsequent severe disease.

For additional information on EVUSHELD™ (tixagevimab co-packaged with cilgavimab) for the pre-exposure prophylaxis of COVID-19 in certain adults and pediatric individuals (12+ years and weighing 40+ kg), please refer to the Health Advisory "COVID-19 Pre-exposure Prophylaxis for Patients with Moderate/Severe Immunocompromise" distributed on February 7, 2022.

II. Current Eligibility for EVUSHELD in Maine

Providers should provide EVUSHELD to individuals in the following categories, prioritizing those in Categories 1 and 2 over those in Categories 3 and 4. Supplies in the State are intended for residents of the State and other patients who receive their primary or specialist medical care in the State. Patients living in other states or other countries should be directed to receive this treatment in their home area.

Category 1

- Lung Transplant Recipient (any time frame)
- Small Bowel Recipient (any time frame)
- Receipt of the following immunosuppressive medication within the past 12 months (for any condition, oncology and non-oncology):
    - Anti-thymocyte globulin (ATG)
    - Alemtuzumab
    - Anti-B-Cell Therapy: Rituximab, Ocrelizumab, Ofatumumab
- B-Cell Malignancies, on active treatment (e.g., B-cell lymphomas, chronic lymphocytic leukemia, acute B-cell lymphoblastic leukemia, etc.)
- Multiple Myeloma, on active treatment with two or more agents
- Allogeneic Stem Cell Transplant, within 12 months of Transplant
- Autologous Stem Cell Transplant, within 6 months of Transplant
- Recipient of more than one active Transplant, different Organs (any time frame)
- Acute Myeloid Leukemia under Active Treatment
- Receipt of anti-CD19 or anti-BCMA (CAR)-T-Cell Immunotherapy, within six months of treatment
- Primary or Secondary T-Cell Immunodeficiency, including Severe Combined Immunodeficiency:
    - Agammaglobulinemia (XLA/ARAG)
    - Common Variable Immunodeficiency (CVID) and similar phenotype with T-cell dysfunction
    - Defects of Innate Immunity with predominant susceptibility to Viral Infections (e.g., WHIM Syndrome)
- Additional pediatric conditions (age 12–17 years):
    - Combined immune deficiencies with or without immune dysregulation (e.g., APDS, STAT3 GOF, ALPS)
    - Primary immune regulatory disorders with or without immune deficiency (e.g., APECED, XIAP)
    - High-risk or relapsed acute lymphoblastic leukemia/lymphoblastic lymphoma on intensive therapy (not maintenance therapy)

Category 2

- Allogeneic stem cell transplant, more than 12 months since transplant
- Autologous stem cell transplant, more than 6 months since transplant
- Multiple myeloma, on maintenance therapy
- Any solid tumor, on active myelosuppressive chemotherapy
- Any solid organ transplant recipient not otherwise eligible in Category 1
- Other chronic leukemias, on treatment
- *Patients in lower categories with more than one qualifying condition*

Category 3

- Active treatment with high-dose corticosteroids (i.e., more than 20 mg prednisone or equivalent per day when administered for two weeks or longer)
- Active treatment with other biologic agents that are immunosuppressive or immunomodulatory, not otherwise listed in Categories 1–2
- Advanced or untreated HIV infection:
    - HIV with CD4 less than 200/mm^3 (if aged less than 14 years, CD4% less than 15%)
    - AIDS-defining illness

Category 4

- Persons 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) and/or COVID-19 vaccine component(s).
    - Patients with severe allergic reactions to a COVID-19 vaccine include those with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of a COVID-19 vaccine or known (diagnosed) allergy to a component of a COVID 19 vaccine, any angioedema affecting the airway (tongue, uvula, or larynx), or diffuse rash which also involves mucosal surfaces (e.g., Stevens-Johnson Syndrome).
        - *Phone consultation with and/or referral to an allergist is strongly recommended for this group as defined by the U.S. CDC since history and/or skin testing may allow these patients to receive a vaccine.*
        - NOTE: Severe allergic reactions include anaphylaxis, a progressive life-threatening reaction that can include urticaria (hives) with other symptoms such as wheezing, difficulty breathing, or low blood pressure. Angioedema of the tongue, uvula, or larynx is considered a severe allergic reaction. Severe allergic reactions do NOT include urticaria beyond the injection site or angioedema (visible swelling) of the lips, facial skin, or skin in other locations.
    - Patients with other non-allergic severe adverse vaccine reactions to a COVID-19 vaccine should undergo review/consultation by an appropriate specialist who is well-informed regarding state and federal guidelines to review possible contraindications. Myocarditis or pericarditis following a dose of mRNA vaccine are considered a contraindication.

III. Hemostatic considerations

EVUSHELD is a new combination monoclonal antibody administered as two concomitant IM injections in the gluteal muscle. Maine is experiencing extreme scarcity of blood products to support patients should they have a bleed or hematoma from a deep muscle injection. Thus, strong considerations and judicious clinical discretion is advised for those patients who may be at risk for bleeding from a deep muscle injection.

Contraindications for administration in patients who otherwise meet EUA eligibility criteria include:

- **Clinically significant** heritable bleeding disorder or bleeding diathesis despite a normal platelet count.
- Platelet count **<30,000/uL**.
- On anticoagulation with warfarin, direct acting oral anticoagulation (DOACs) drug(s), or heparin agents, unless they can be safely held in advance.
- Dual antiplatelet therapy for stent or other considerations.

IV. Obtaining EVUSHELD For Eligible Patients

Healthcare providers with patients who fit into any of the categories listed above can contact one of the several healthcare systems/facilities in Maine to refer their patient(s) for EVUSHELD treatment.

The current list of healthcare systems/facilities currently offering EVUSHELD therapy is available at Maine CDC's *COVID-19: Healthcare Providers* page at https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/airborne/coronavirus/providers.shtml#prophylaxis.

Information is also available at that web location for healthcare systems/healthcare facilities that would like to obtain their own supplies of EVUSHELD instead of referring patients to existing locations.

V. Recommendations for Healthcare Providers

- Identify all patients who are eligible for treatment with EVUSHELD and contact those patients to encourage them to receive this treatment.
- Obtain further information on clinical use of products through NIH's COVID-19 Treatment Guidelines, the Assistant Secretary for Preparedness and Response Public Health Emergency COVID-19 Therapeutics site, and through professional societies such as IDSA's Guidelines on the Management of Patients with COVID-19.
- Continue to encourage COVID-19 vaccination, including booster vaccination.

For More Information

- Fact Sheet for Healthcare Providers: Emergency Use Authorization for EVUSHELD™ (tixagevimab co-packaged with cilgavimab)
- Fact Sheet for Patients, Parents And Caregivers Emergency Use Authorization (EUA) of EVUSHELD™ (tixagevimab co-packaged with cilgavimab) for Coronavirus Disease 2019 (COVID-19)
- Frequently Asked Questions on the Emergency Use Authorization for Evusheld (tixagevimab co-packaged with cilgavimab) for Pre-exposure Prophylaxis (PrEP) of COVID-19
- Omicron Variant: What You Need to Know | CDC
- COVID-19 Treatment Guidelines: What's New
- COVID-19 Treatment Guidelines: Antiviral Therapy
- NIH Statement on Therapies for High-Risk, Nonhospitalized Patients
- Maine CDC: COVID-19: Healthcare Providers