Central Maine Healthcare

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# EVUSHELD (tixagevimab and cilgavimab) for the pre-exposure prophylaxis of COVID-19

## Inclusion/Exclusion Criteria Checklist

Deliver Completed form to Med Onc Pharmacist Fax # 207-795-8319

| Patient Name/DOB/FIN (if no sticker):<br><br>Date: | Provider: |
|---|---|

**Inclusion criteria (Check all that Apply) Must meet all Criteria:**

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| ☐ | Not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 | ☐ | Age greater than or equal to 12 |
| | In individuals who have received a COVID-19 vaccine, EVUSHELD should be administered at least two weeks after vaccination | ☐ | Pediatric patients (12 to 17 years old) must weigh at least 40 kg |
| ☐ | Considered the risks and benefits prior to initiating EVUSHELD in individuals at high risk for cardiovascular events (A higher proportion of subjects who received EVUSHELD versus placebo reported myocardial infarction and cardiac failure serious adverse events. All of the subjects with events had cardiac risk factors and/or a prior history of cardiovascular disease, and there was no clear temporal pattern) | | |
| ☐ | Considered bleeding risk: Evusheld is 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<br>Contraindications for administration:<br>• Clinically significant heritable bleeding disorder or bleeding diathesis despite a normal platelet count.<br>• Platelet count <20,000/uL.<br>• On anticoagulation with warfarin, direct acting oral anticoagulation (DOACs) drug(s), or heparin agents, unless they can be safely held in advance.<br>Dual antiplatelet therapy for stent or other considerations. | | |

If all the above Inclusion Criteria are met, patients **MUST** have at least one of the listed Medical conditions or treatments in the **ACTIVE Categories**. A tiered approach to eligibility is being utilized by the Maine CDC to ensure supply is available for the most vulnerable populations. Criteria was established based on the requirements of the EUA and by a consensus from a state collaborative of clinicians.

**ACTIVE CATEGORIES ARE CATEGORY 1, 2, 3 and 4 (All)**

**Prioritizing those in Categories 1 and 2 over those in Categories 3 and 4.**

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| ☐ | **Category 1 (Active)** | • Lung Transplant Recipient (any time frame)<br>• Small Bowel Recipient (any time frame)<br>• Receipt of the following immunosuppressive medication within the past 12 months (for any condition, oncology and non-oncology):<br>  ◦ Anti-thymocyte globulin (ATG)<br>  ◦ Alemtuzumab<br>  ◦ Anti-B-Cell Therapy: Rituximab, Ocrelizumab, Ofatumumab<br>• B-Cell Malignancies, on active treatment (e.g., B-cell lymphomas, chronic lymphocytic leukemia, acute B-cell lymphoblastic leukemia, etc.)<br>• Multiple Myeloma, on active treatment with two or more agents<br>• Allogeneic Stem Cell Transplant, within 12 months of Transplant<br>• Autologous Stem Cell Transplant, within 6 months of Transplant<br>• Recipient of more than one active Transplant, different Organs (any time frame)<br>• Acute Myeloid Leukemia under Active Treatment<br>• Receipt of anti-CD19 or anti-BCMA (CAR)-T-Cell Immunotherapy, within six months of treatment |

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| ☐ | **Category 1 Continued (Active)** | • Primary or Secondary T-Cell Immunodeficiency, including Severe Combined Immunodeficiency:<br>  • Agammaglobulinemia (XLA/ARAG)<br>  • Common Variable Immunodeficiency (CVID) and similar phenotype with T-cell dysfunction<br>  • Defects of Innate Immunity with predominant susceptibility to Viral Infections (e.g., WHIM Syndrome)<br>• Additional pediatric conditions (age 12–17 years):<br>  • Combined immune deficiencies with or without immune dysregulation (e.g., APDS, STAT3 GOF, ALPS)<br>  • Primary immune regulatory disorders with or without immune deficiency (e.g., APECED, XIAP)<br>  • High-risk or relapsed acute lymphoblastic leukemia/lymphoblastic lymphoma on intensive therapy (not maintenance therapy) |
| ☐ | **Category 2 (Active)** | • Allogeneic stem cell transplant, more than 12 months since transplant<br>• Autologous stem cell transplant, more than 6 months since transplant<br>• Multiple myeloma, on maintenance therapy<br>• Any solid tumor, on active myelosuppressive chemotherapy<br>• Any solid organ transplant recipient not otherwise eligible in Category 1<br>• Other chronic leukemias, on treatment<br>• *Patients in lower categories with more than one qualifying condition* |
| ☐ | **Category 3 (Active)** | • Active treatment with high-dose corticosteroids (i.e., more than 20 mg prednisone or equivalent per day when administered for two weeks or longer)<br>• Active treatment with other biologic agents that are immunosuppressive or immunomodulatory, not otherwise listed in Categories 1–2<br>• Advanced or untreated HIV infection:<br>  • HIV with CD4 less than 200/mm$^3$ (if aged less than 14 years, CD4% less than 15%)<br>  • AIDS-defining illness |
| ☐ | **Category 4 (Active)** | • 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).<br>• 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). |

**I attest to the following:**

☐ I have provided and reviewed the information consistent with the FDA "Fact Sheet for Patients, Parents and Caregivers" with the patient/caregiver

☐ Obtained drug specific written consent and delivered to Med Onc Pharmacist; Fax # 207-795-8319

☐ Informed individuals that they may need to receive additional doses of EVUSHELD for ongoing protection but that the optimal timing of redosing is unknown at this time

☐ Informed individuals that a higher proportion of subjects who received EVUSHELD versus placebo reported cardiovascular serious adverse events and advised individuals to seek immediate medical attention if they experience any signs or symptoms suggestive of a cardiovascular event

☐ I understand I am responsible for reporting all potentially medication error or adverse event to the FDA within 7days

☐ Patient will be clinically monitored after injections and observed for at least 1 hour

Provider Name: _____ Provider Signature: _____ Date:_____