Bird's Eye Medical COVID-19 Monoclonal Antibody (mAb) EUA Treatment Referral: EVUSHELD

Patient Information

Name: _____ **Sex: M / F** **Date of birth:** _____

Weight/BMI if high risk factor: _____ **Phone:** _____ **Alt phone:** _____

Home Address: _____

NOTE: For patients with moderate to severely compromised immune systems and not currently infected with COVID-19. This product is available for use by Emergency Use Authorization (EUA) as pre-exposure prevention of COVID-19 for up to six months in people 12 years of age and older weighing at least 40 kg who are not currently infected with COVID-19 and who have had no known recent exposure to COVID-19 **and** have moderate to severely compromised immune systems due to a medical condition or immunosuppressive medications or treatments **and** may not mount an adequate immune response to COVID-19 vaccination **or** a history of severe adverse reactions to a COVID-19 vaccine and/or component(s) of those vaccines. This product is NOT a substitute for vaccination, nor authorized for the treatment of COVID-19 or for post-exposure prevention of COVID-19.

NOTE on EVUSHELD dosing: The FDA updated dosing guidelines of EVUSHELD from 150 mg each of tixagevimab and cilgavimab to 300 mg of each medication on 2/24/22. Per the updated guidance on 4/1/22, all patients who previously received one 150 mg dose of each medication should receive a second dose. Patients who received who previously received 150 mg of each should return for a repeat dose of 150 mg of tixagevimab and cilgavimab **if the previous dose was ≤3 months prior**. Those who received a 150 mg dose of each medication **> 3 months prior** should receive 300 mg each of tixagevimab and cilgavimab.

Treatment Criteria for Use (all fields must be completed to be eligible for treatment)

Treatment-qualifying high-risk condition(s):

- ☐ Active treatment for solid tumor and hematologic malignancies
- ☐ Receipt of solid-organ transplant and taking immunosuppressive therapy
- ☐ Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- ☐ Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- ☐ Advanced or untreated HIV infection (people with HIV and CD4 cell count <200mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- ☐ Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent/day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell depleting agents)
- ☐ Other medical conditions or factors: _____ (see CDC website for considerations)

Monoclonal Antibody Order:

- ☐ **Repeat dosing; first dose ≤ 3 months prior (previously received 150 mg each of tixagevimab and cilgavimab):** Tixagevimab 150 mg IM and Cilgavimab 150 mg IM
- ☐ **Repeat dosing; first dose >3 months prior (previously received 150 mg each of tixagevimab and cilgavimab):** Tixagevimab 300 mg IM ad Cilgavimab 300 mg IM
- ☐ **First time dosing (all new EVUSHELD patients after 2/24/22):** Tixagevimab 300mg IM and Cilgavimab 300 mg IM

Prescriber Attestation

I affirm that my patient meets above criteria for use and has been:

1. Informed that this mAb is an unapproved drug authorized for use under an **Emergency Use Authorization.**
2. Informed of alternatives to receiving EVUSHELD.
3. I have discussed this treatment option with the patient and patient is agreeable to this treatment.

I am aware that:

1. EVUSHELD will be administered as a two separate, consecutive ventrogluteal IM injections. Patient will be monitored in the clinic for 1 hour post infusion. Standard hypersensitivity reaction therapy will be provided as needed.

Signature signifies agreement of the above orders / attestation.

Provider Name (print): _____ Office Number: _____ After hours phone: _____

Provider Signature: _____ Date/Time: _____ NPI: _____

The prescribing health care provider and/or provider's designee should complete and submit a MedWatch form to FDA within 7 calendar days from the onset of a serious and unexpected adverse event that appears to be associated with the use of a monoclonal antibody.

PLEASE FAX this form to **360.878.8330**. *If possible, attach copy of problem list, allergies, and medications.*

Bird's Eye Medical will reach out to schedule your patient ASAP. For questions, please call 360-688-7044.

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