Iowa Department of Public Health
COVID-19 Therapeutics - Guidance for Providers
Pre-Exposure Prophylaxis - Monoclonal Antibody Prioritization

Date: January 3, 2022

Purpose of this Guidance: In response to extremely limited allocations of monoclonal antibody products for pre-exposure prophylaxis of COVID-19 to the state from the United States Government, the Iowa Department of Public Health (IDPH) provides this guidance to assist providers in prioritizing patient populations for this treatment. This document is intended to serve as guidance as a supplement to, but not a replacement for, clinical judgment.

Products covered by this Guidance: The federal food and drug administration (FDA) has granted Emergency Use Authorization (EUA) for the following product for pre-exposure prophylaxis which is the subject of this guidance:

- EVUSHELD (AstraZeneca)

Entities covered by this Guidance: All Iowa licensed health care providers, hospitals, clinics, pharmacies, local boards of health, and public health agencies; and any person licensed, certified, or otherwise authorized or permitted by the laws of the state of Iowa or current Gubernatorial Proclamations of Disaster Emergency to prescribe, dispense or administer medications that are covered by this Guidance.

Prioritization of limited supplies: When supplies of mAb do not meet clinical demand, IDPH recommends the following prioritization:

Tier One[1]:

Congenital or acquired immunodeficiency	Hematologic Malignancies	Solid Organ Transplant
● Hypogammaglobulinemia requiring routine IVIG administration ● CVID ● X-linked agammaglobulinemia (XLA) ● Severe selective IgA deficiency ● Severe specific Ab deficiency ● Autosomal agammaglobulinemia ● Autosomal recessive hyper IgM syndrome ● Chronic Granulomatous Disease ● Severe Combined Immunodeficiency (SCID)	● CAR T-Cell Therapy (any time) ● Allo/Hapto HSCT ≤ 1 year ● ALL/AML/MDS, on therapy ● Auto HSCT ≤ 6 months ● CLL, on therapy ● Anti-CD20/52 antibody ≤ 1 year ● ATG within 1 year in heme malignancy ● cGVHD on IS ≤ 6 months or known/suspected lung GVHD	● All SOT patients following discharge from their index hospitalization ● All lung and small bowel transplant recipients ● SOT receiving T-cell (rATG, alemtuzumab), or B-cell (rituximab) depleting agents ≤ 1 year ● All SOT with all 3 COVID-19 vaccine doses and a negative SARS-CoV-2 antibody, if testing done/requested

[1] Ideally treat patients within the first month of product availability

• Wiskott-Aldrich • Dock 8 or Stat 3 deficiency • DiGeorge Syndrome • All patients receiving anti CD20/52 therapy ≤ 1 year		

Tier Two[2]:

Congenital or acquired immunodeficiency	Hematologic Malignancies	Solid Tumors	Solid Organ Transplant
• HIV+ with CD4<200, uncontrolled, or not on treatment	• Multiple myeloma • Lymphoma on therapy • Allo HSCT 1-3 years • Auto HSCT 6-12 months • Other chronic leukemias • Lymphoma (surveillance) • Castleman's, on therapy • Myeloproliferative neoplasms (MPN) • Aplastic anemia • Cutaneous T-cell lymphoma (CTCL) on topical treatment	• Curative intent + adjuvant cytotoxic chemotherapy ≤ 6 months • Lung cancer on treatment	• SOT and on antimetabolite (heart w/in 1 yr, renal w/in 9 months, liver w/in 6 months) • All SOT patients on belatacept, regardless of time from transplant • All heart transplant recipients

Tier Three[3]:

Congenital or acquired immunodeficiency	Solid Tumors	Solid Organ Transplant
HIV+ controlled on treatment, with comorbidities, and unvaccinated Patients receiving antimetabolite therapies (e.g., cyclophosphamide, azathioprine, mycophenolate, cyclosporine, tacrolimus, Janus kinase inhibitors, or moderate- to high-dose prednisone >20mg daily	Non-curative intent (i.e. metastatic disease) on cytotoxic chemotherapy	All abdominal transplant recipients within 5 yrs of transplant and on antimetabolite Any SOT patient and age > 65 yrs

[2] Ideally treat patients within the first 3 months of product availability

[3] Ideally treat patients within the first 6 months of product availability

Tier Four[4]:

Congenital or acquired immunodeficiency	Solid Organ Transplant
● Most specific Ab deficiency patients ● Most selective IgA deficiency patients ● Complement deficiencies ● HIV+ controlled on treatment with no comorbidities or vaccinated ● Patients on immunosuppressive therapy for other conditions ● Immunocompetent w/COVID-19 vaccine contraindication	● Any other SOT recipients

Evaluation and redistribution: Entities covered by this Guidance which are allocated COVID-19 mAbs are required to timely report administration of allocated products. Entities are strongly encouraged to redistribute underutilized mAb products in the manner directed by the Department in order to protect those at highest risk for hospitalization and death from COVID-19. Entities are strongly encouraged to provide this Guidance to appropriate personnel who may prescribe, dispense or administer COVID-19 mAbs subject to this Guidance.

[4] Patients are EUA eligible; however, initially deprioritized for treatment until higher risk categories complete