

## Statement on Use of Monoclonal Antibody for Pre-Exposure Prophylaxis

Tixagevimab and cilgavimab (Evusheld, AZD7442) received [FDA emergency use authorization](#) for COVID-19 pre-exposure prophylaxis in adults and children age 12 and older and who weigh at least 40 kg and who have moderate to severe immunocompromise or a medical contraindication to vaccine. AZD7442 has a longer half-life compared to other currently used antibody preparations (e.g., sotrovimab, casirivimab/imdevimab). The PROVENT trial has shown a 77% reduction of infection in the AZD7442 group compared to placebo up to 183 days. Data are awaited for the need for repeat doses and effectiveness specifically in the transplant population. Due to reduced neutralization against the omicron variant with standard dosing, the FDA has recommended that the dose of AZD7442 be increased to 300mg each of tixagevimab and cilgavimab. AZD7442 is not currently indicated for post-exposure prophylaxis or early treatment. At this time, the supply of this agent continues to be limited with state governments determining allocation protocols.

The following provides a framework to help transplant centers plan for allocation of this monoclonal within their institutions:

- **Monoclonal antibody (mAb) therapy should NOT be used as a substitute for vaccination or for primary prevention strategies, including masking, social distancing, and avoidance of large indoor social gatherings.**
  - Vaccination of close contacts, including household members, continues to be an important measure to protect transplant recipients from COVID-19 infection
- Given the limited supply, centers should consider allocating AZD7442 based on stratification of individual patient risk. Risk assessments should incorporate both underlying patient risk factors for severe outcomes from COVID-19 infection as well as risk of exposure to COVID-19 infection.

### Risks Associated with Severe disease<sup>1</sup>

- Anti-RBD seronegativity after a complete series of vaccine<sup>2</sup>
- Age ≥ 60
- 2 or more comorbidities<sup>3</sup>
- Lung transplantation
- Immunosuppression (recent B-cell depletion e.g., rituximab; T-cell depletion e.g., ATG, alemtuzumab; Belatacept use)

### Risks Associated with Increased Exposure<sup>4</sup>

- High-risk occupations especially schools, day cares, health care
- Residence in a long-term care facility or other congregate setting (e.g., dormitory, prison)

1- Not a comprehensive list

2- Access to serologic testing may not be routinely available to all transplant recipients. Centers choosing to use serologic testing to risk stratify should ensure equity in access to serology. Healthcare funding bodies should ensure serology is available free of cost to patients in order to rationalize the use of pre-exposure mAb.

3- Includes BMI≥30, hypertension, diabetes, chronic kidney disease, chronic lung disease, congestive heart failure, neurodevelopmental disorders

4- Especially if masking and vaccination rates in these areas are low

### **Practical Considerations**

- Given the increase in dosing to 300mg of each antibody, the volume of each injection has also increased to 3mL. Intragluteal injection remains the most practical although larger volumes may be difficult to administer to individuals with low body mass index.
- In order to ensure equitable allocation of monoclonal antibody, we encourage institutions to develop plans to defray any administration fees which would be attributed to the patient.
- Vaccinated individuals should wait 2 weeks from the last dose of vaccine to receive AZD7442.
- Booster doses of vaccine can be given anytime after AZD7442.