

Penn Medicine SARS-CoV-2 Monoclonal Antibodies Use Criteria and Tip Sheet

Updated 6-21-2021

See www.uphs.upenn.edu/antibiotics/SMAtipsheet.pdf for most updated version



Background

- SARS-CoV-2 monoclonal antibodies (SCMA) have been approved by the FDA for Emergency Use Authorization (EUA) for **high-risk outpatients** with **symptomatic COVID-19 infection**
- **Casirivimab-imdevimab** is the only SCMA that is being infused at Penn Medicine based on efficacy data and *in vitro* activity against new strains
- SCMAs are administered via a single intravenous infusion
- The main clinical benefit appears to be reducing **risk of hospitalization or ER visit in high-risk patients** and achieving a modest reduction in duration of symptoms.
- The main risk is **allergic/transfusion reaction** in <1% of patients



Referral Process

- Eligible Penn Medicine outpatients can be referred using the order “**CONSULT TO SARS-COV-2 MONOCLONAL ANTIBODY.**”
- Inpatient or ER use requires **infectious diseases consultation**
- Patients should be **informed of their positive test result** prior to referral
- Patients may need to be allocated SCMA via weighted lottery based on patient eligibility and availability of SCMA and infusion resources
- Patients and referring providers of eligible patients selected to receive SCMA will be contacted within 2 business days of referral
- Treatment guidelines and information on SCMA process can be found at: www.uphs.upenn.edu/antibiotics/COVID19.html



Use Criteria

- ✓ Positive SARS-CoV-2 PCR or antigen test **AND**
- ✓ Symptoms attributable to COVID-19 **AND**
- ✓ Symptoms for ≤9 days at time of referral (≤10 days at time of infusion) **AND**

✓ At least one inclusion criterion

- Age ≥65 years
- Body mass index ≥25
- Pregnancy
- Diabetes mellitus
- Hypertension
- Chronic kidney disease
- Cardiovascular disease (including congenital heart disease, coronary artery disease, and cardiomyopathy)
- Chronic lung diseases (including chronic obstructive pulmonary disease, moderate-severe asthma, interstitial lung disease, cystic fibrosis and pulmonary hypertension)
- Immunosuppression*
- Sickle cell disease
- Neurodevelopmental, genetic, severe congenital, or metabolic disorders
- Technological dependence (including tracheostomy and enteric feeding tube)

✗ No exclusion criteria

- Age <18 years
 - Admitted to hospital due to COVID-19
 - Requiring new or increased supplemental oxygen for COVID-19 or SpO2 ≤93%
 - Previously received SCMA
 - Enrolled in SCMA clinical trial
 - Currently enrolled in hospice
- * Immunosuppressive condition (hematologic malignancy, metastatic cancer, asplenia or functional asplenia, HIV w/ CD4 <200, or other congenital or acquired deficits of humoral or cell-mediated immunity) **OR** medication (steroid equivalent of prednisone ≥20 mg/day for >14 days, chemotherapy within past 3 months, calcineurin inhibitor, anti-proliferative agent, mTor inhibitor, tumor necrosis factor alpha inhibitor, or anti-B-cell antibody)



Frequently Asked Questions

- **What does the treatment entail?** If the patient is eligible and selected, the patient will be scheduled at an outpatient infusion site and will complete a verbal consent. The infusion process takes approximately 3 hours.
- **Is there a cost to the treatment?** At this time, SCMA itself is free, but there is a charge for the administration of the infusion. Penn Medicine will process claims through insurance and bill patients as appropriate. For uninsured patients or those with concerns regarding out of pocket expenses, contact patientfinancialadvocacy@uphs.upenn.edu to see what programs are available
- **What are the most common side effects of SCMA?** There are no significant differences in side effects between SCMA and placebo. The main risk is allergic/transfusion reactions in <1% of cases.
- **Does the patient still need to quarantine after receiving SCMA?** Yes. Patients should continue to follow CDC guidelines for quarantine.
- **How does receiving SCMA affect timing of the COVID-19 vaccine?** CDC recommends that patients wait for 90 days after receiving SCMA before receiving the COVID-19 vaccine because of theoretical concern of decreased vaccine efficacy. If a patient has received one vaccine dose already, ideally the patient should wait 90 days before receiving the second dose.
- **If a patient does not fit EUA criteria, can they get it anywhere else?** There are occasionally clinical trials that involve the use of SCMAs, which may have less stringent eligibility criteria. Contact Pablo.tebas@penmedicine.upenn.edu and Miranda.Mastellone@penmedicine.upenn.edu to inquire for eligibility.