



January 14, 2022

Monoclonal Antibody or Paxlovid Treatment from Cincinnati Children's

Omicron is now the dominant COVID-19 variant in the region (97% in Region 5 based on most recent CDC report). Based on studies, our currently available monoclonals Bamlanivimab/Etesevimab and Casirivimab/Imdevimab (REGEN-COV) do NOT have activity against Omicron and will no longer be offered for treatment or post-exposure prophylaxis.

The only currently monoclonal option is Sotrovimab (ages 12 and older and >40kg only). The FDA also recently provided Emergency Use Authorization (EUA) for an oral antiviral treatment for mild/moderate COVID-19 in patients over 12 years and 40 kg at high-risk for disease progression. Both treatments can be provided through Cincinnati Children's COVID treatment team, but there is very limited supply.

The **Sotrovimab monoclonal antibody** infusion is provided via IV and **takes about 3 hours**. Treatment is ideally provided within 4-5 days of symptom onset but could be considered up to 10 days. It must be scheduled by the PCP at an infusion center after approval is granted. Most or all of the cost of the medication will be covered by the federal government, but the infusion center charge will be billed to insurance.

Paxlovid (nirmatrelvir/ritonavir) is authorized for patients 12 years and older AND 40kg that who are within 5 days of symptom onset. Paxlovid (3 tablets) is taken twice a day for five days and cannot be chewed, broken or crushed. Paxlovid has known drug-drug interactions as well as dose considerations in those with renal or liver impairment. If considering Paxlovid, please review the [Provider Fact Sheet](#). Review contraindications (page 6) and significant drug-drug interactions (pages 9-15) and **confirm** that your patient is not taking any of the listed medications.

The COVID Treatment Team will prioritize COVID positive patients that are COVID Positive with risk factors for progression to severe disease who are identified within 4 days of symptom onset. Use of oral Paxlovid will be prioritized depending on availability and presence of drug interactions.

Please **share details with families to ensure their interest *before* requesting treatment from Children's**. FDA Fact Sheets for [Sotrovimab](#) and [Paxlovid](#) should be shared with

families. We have children that have been approved but end up not being interested. The following steps should be used as a guide:

- Positive COVID-19 test
- Chart review for age/weight/underlying diagnosis/medications – assess risk for progression (since most don't progress, we recommend that the pediatrician who knows the patient best assess this potential risk)
- Review of underlying renal or hepatic disease
- Notify family that the patient may be a candidate for monoclonal antibody infusion or Paxlovid, discuss risk/benefits, share FDA patient Fact Sheets, and **determine if family is interested** in PCP asking for approval.
- OPTION - If the patient has a CCHMC subspecialty provider for their underlying risk factor, the physician can reach out to that service to get their input/ask them to request
- Email treatment team (see details below)

If you are seeking approval for Monoclonal or oral therapy for a patient:

The team typically responds to an email within hours. Infusions can usually be scheduled within 24-48 hours of the request (including weekends). The PCP will need to contact the infusion center to schedule after approval.

1. Send email to COVIDmonoclonalrequest@cchmc.org and include the following key pieces of information.

- a. Name
- b. MRN
- c. Age
- d. Weight
- e. Date of positive test
- f. Date of symptom onset
- g. Symptoms
- h. Oxygen therapy
- i. Drug interactions (see FDA.GOV)
- j. COVID-19 Vaccination status, including date of most recent vaccine
- k. Underlying diagnosis that increases risk for progression

The patient is **high risk** of progressing to severe disease and/or hospitalization, as defined in the EUA criteria listed below.

- i. BMI \geq 85th percentile for their age/gender based on CDC growth charts
- ii. Chronic kidney disease (CKD)

- iii. Diabetes mellitus (T1DM or T2DM)
- iv. Immunosuppressed due to a disease
- v. Immunosuppressed due to medication
- vi. Sickle Cell Disease
- vii. Hemodynamically significant congenital or acquired heart disease (cyanotic heart disease, severe pulmonary hypertension, acyanotic heart disease receiving medications to control heart failure)
- viii. Asthma, reactive airway or other chronic respiratory disease that requires daily medication for control
- ix. Chronic tracheostomy patients
- x. Severe neurodevelopmental disorders

The process map and guidelines are included [HERE](#).