COVID-19 Treatment Guidance Update
January 5, 2022

Situation
COVID-19 cases are increasing rapidly across the United States, including Missouri and Illinois. The Omicron variant has become the dominant variant in many parts of the United States.

- Sotrovimab is the only monoclonal antibody (mAb) expected to retain activity against Omicron.

The U.S. Food and Drug Administration (FDA) has recently issued Emergency Use Authorizations (EUAs) for several new outpatient therapies for COVID-19:

- Nirmatrelvir/ritonavir (Paxlovid™) – oral antiviral for treatment of mild to moderate COVID
- Sotrovimab – intravenous mAb for treatment of mild to moderate COVID
- Molnupiravir – oral antiviral for treatment of mild to moderate COVID
- Tixagevimab/cilgavimab (Evusheld™) – intramuscular mAb injection for pre-exposure prophylaxis

The BJC/WUSM COVID-19 Treatment Guidance Group and Incident Command have approved the use of these agents. Full clinical recommendations are in the attached document.

Background

- Allocations of the agents listed above are currently being determined by the U.S. Department of Health and Human Services (HHS) and distributed to each state.
- The Missouri Department of Health & Senior Services (DHSS) and the Missouri Hospital Association (MHA) are responsible for distribution within Missouri. The Illinois Department of Public Health (IDPH) is responsible for distribution within Illinois.
- Due to supply and capacity constraints, and increasing COVID-19 cases, it is not possible to provide outpatient therapeutics to all eligible patients.
- The NIH has provided a tiered prioritization system when there are logistical or supply constraints.
- The primary goal of prioritization of these agents is to prevent progression to severe disease and hospitalization, and protect our strained and overburdened healthcare system.

Assessment

- During this time of supply and capacity constraints, patients will be prioritized for these agents by highest risk of clinical progression according to the NIH tiered prioritization tiers.
- As supply and capacity increase, eligibility will be evaluated for expansion into additional tiers. Conversely, if supply and capacity decrease, eligibility will be narrowed if necessary.
- Since Missouri and Illinois have different allocations and processes, the recommendations and implementation timelines may differ between the states, as products may not be shared across state lines.
- Missouri BJC facilities have received limited amounts of Paxlovid, sotrovimab, Evusheld, and molnupiravir.
- Illinois BJC facilities have received a limited amount of sotrovimab but have not yet received any of the other agents above and the timeline for availability is unknown.
Recommendations
Nirmatrelvir/ritonavir (Paxlovid™) (See the Appendix for prescribing screenshots and tips)
- Barnes-Jewish Hospital Pharmacy has an extremely limited supply. Dispensing will be centralized to this BJC retail pharmacy location, as it is the only pharmacy open 7 days/week.
- Illinois supply and timeline are unknown at this time.
- Although dispensing will be centralized to Barnes-Jewish Hospital Pharmacy, any provider in Missouri may prescribe Paxlovid and route it to Barnes-Jewish Hospital Pharmacy.
- Barnes-Jewish Hospital Pharmacy will contact the patient to coordinate pick up or delivery to their home.
  - During this call, pharmacy will confirm no significant drug interactions with patient’s other drugs and provide medication counseling.
- Paxlovid is authorized for use in high-risk patients 12 years of age and older. It has many serious drug interactions and must be started within 5 days of symptom onset.
- While supply is extremely limited, Paxlovid will be restricted to the following patients due to being at the highest risk of hospitalization according to NIH Tier 1 recommendations:
  - Immune compromised, regardless of vaccination status
  - Unvaccinated and > 75 years old
  - Unvaccinated and ≥ 65 years old with additional risk factors
- Beginning Tuesday, January 4, 2022, providers may begin e-prescribing Paxlovid for eligible patients
- Once supply runs out, an Epic alert will notify the prescriber upon ordering.
- If a prescription cannot be filled for any reason, the pharmacy will notify the prescriber.

Monoclonal Antibody Therapy for COVID-19 Treatment
- Beginning Tuesday, January 4, 2022, Missouri BJC facilities will change from casirivimab/imdevimab to sotrovimab.
- Illinois BJC facilities will change to sotrovimab as soon as recommended by IDPH based on Omicron prevalence.
- While supply and capacity are limited, monoclonal antibody therapy will be restricted to the following patients due to being at the highest risk of hospitalization according to NIH Tier 1 and Tier 2 recommendations:
  - Immune compromised regardless of vaccination status
  - Pregnant
  - Unvaccinated and > 65 years old
  - Unvaccinated and < 65 with additional clinical risk factors
- Sotrovimab is not authorized for post-exposure prophylaxis or for patients < 12 years old.
- St. Louis Children’s will change from bamlanivimab/etesevimab to sotrovimab and will no longer offer mAb therapy to children < 12 years old.
- The NIH recommends outpatient IV remdesivir (3-day course) as an alternative to sotrovimab. BJC is working to make this available as soon as possible for both adult and pediatric patients.
Molnupiravir (See the Appendix for prescribing screenshots and tips)

- Missouri BJC facilities have recently received molnupiravir with sufficient supply that criteria for use do not need to be narrowed beyond the EUA criteria.
- Illinois BJC facilities have not received supply yet and the timeline is unknown at this time.
- Molnupiravir is authorized for high-risk patients > 18 years old when no other FDA-authorized treatments are clinically appropriate or accessible. Treatment must start within 5 days of symptom onset.
- Dispensing will initially be limited to the following BJC retail pharmacies.
  - Family Care Pharmacy CH, Monday through Friday
  - Family Care Pharmacy – MBMC, Monday through Friday
  - Barnes Jewish Hospital Pharmacy, 7 days a week
- Although dispensing will be limited to the pharmacies above, any provider in Missouri may prescribe molnupiravir and route it to one of these pharmacies.
- The pharmacy will contact the patient to coordinate pick up or delivery to their home and provide medication counseling.
- Beginning Friday, January 7, 2022, providers may e-prescribe Molnupiravir for eligible patients
- If a prescription cannot be filled for any reason, the pharmacy will notify the prescriber.
- A plan for dispensing from Emergency Departments is in progress.

Tixagevimab/cilgavimab (Evusheld™)

- Missouri BJC facilities have received a limited supply.
- Illinois supply and timeline are unknown at this time.
- Due to limited supply, Evusheld will be administered to eligible patients in phases, with the most immunocompromised patients being offered the therapy initially. As supply allows, we will move through the tiered risk groups.
- An equitable allocation and distribution process is in progress and further provider communications will be forthcoming.

BJC will continue to monitor supply and update guidance as new information merits.
For questions or concerns, please contact Maya Jerath at mjerath@wustl.edu or Helen Newland at helen.newland@bjc.org or 913-526-5631.

See Appendix on next page
APPENDIX

Paxlovid Prescribing

1. Uncheck the box that limits the pharmacies to a geographical area or previous pharmacies listed
2. Type in “Barnes” and search
3. Choose the Barnes Jewish Hospital Pharmacy

Molnupiravir Prescribing

1. Uncheck the box that limits the pharmacies to a geographical area or previous pharmacies listed
2. Enter “MO” as the United States has many pharmacies that contain “Family Care” in them.
3. Type in “family care” and search
   a. or type in “Barnes” if routing to Barnes Jewish Hospital Pharmacy
4. Choose the Family Care Pharmacy at either CH or MBMC