

**<u>Objective</u>**: The objective of this process is to ensure high-risk COVID outpatients receive the best available treatment based on National Institute of Health recommendations, inventory, and patient-specific factors.

## Kettering Health available outpatient COVID treatments:

- Paxlovid<sup>™</sup> (nirmatrelvir-ritonavir) (oral)
- Sotrovimab (intravenous)
- Remdesivir (intravenous, three-day course)
- Molnupiravir (oral)

## KH Pharmacy and Therapeutics (P&T) Criteria for Use:

#### Patient must meet ALL of the following criteria:

□ Positive test for SARS-CoV-2

□ Onset of symptoms within the past 7 days

□ Patient is 18 years of age or older

□ Patient does not require supplemental oxygen <u>or</u> there is no increase in baseline oxygen needs

### AND

One (1) of the following:	<u>OR</u>	Two (2) of the following:
Pregnancy		□ Age ≥ 65 years
Active Cancer		□ Not fully vaccinated per <u>CDC definition</u>
Hematologic malignancy		□ BMI ≥ 35
□ Immunocompromised (On biologic agents, high dose chronic steroids, B-cell depleting therapy*, TK inhibitors**,		□ Cardiovascular Disease: Hypertension, Coronary Artery Disease or Congestive Heart Failure
primary immunodeficiency, etc) □ HIV Patients		<ul> <li>Diabetes Mellitus (on insulin therapy or oral hypoglycemics)</li> </ul>
Solid organ transplant recipients		Chronic Lung Disease: COPD, Asthma, Interstitial
Hematopoietic cell transplant recipients		Lung Disease, Cystic Fibrosis, or Pulmonary Fibrosis
Graft-versus-host disease		Chronic Kidney Disease (stage 4 and above, ESRD)
Chimeric antigen receptor T-cell recipients		End stage liver disease
(CAR T-Cell Therapy) (Idecabtagene Vicleucel, Brexucabtagene Autoleucel, Axicabtagene Ciloleucel, Axicabtagene Ciloleucel)		<ul> <li>Neurodevelopmental disorders (Ex. Cerebral palsy)</li> </ul>
		Medical-related technological dependence (Ex. Tracheostomy, gastrostomy, etc.)
		□ Sickle Cell disease

\*B-cell depleting therapy: riTUXimab, ocrelizumab, ofatumumab, ibritumomab tiuxetan, obinutuzumab, belimumab

\*\*TK inhibitors:, ibrutinib, acalabrutinib, or zanubrutinib therapy



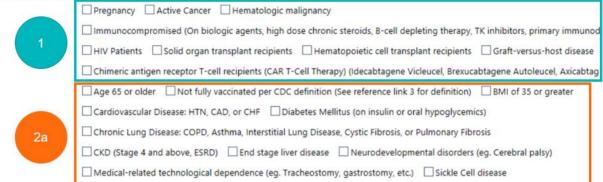
## Prescribing and Referral Review Process:

1. Order "Outpatient COVID-19 Treatment Referral" via EPIC or paper order form

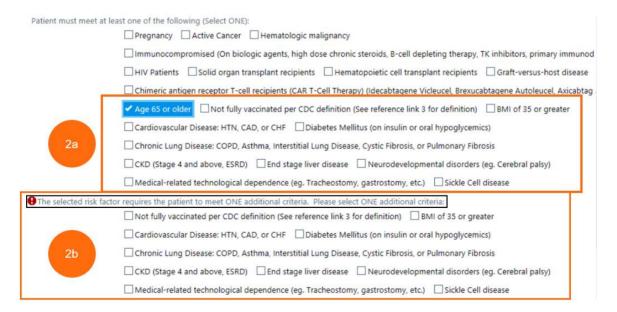
	Code
REF408001 Outpatient COVID-19 treatment (OUTPATIENT REFERRAL)	REF408001

2. Indicate patient is eligible for treatment per P&T approved criteria. Choose only one risk factor.

Patient must meet at least one of the following (Select ONE):



- Patients with criteria in Box #1 will only require one selection
- Patients with criteria in Box #2a will require a second risk factor selection (Box #2b)





3. Enter date of symptom onset

Date of symptom	Ċ.
onset:	

- 4. Indicate all treatments to be considered for patient
  - a. **Recommendation:** Consider choosing <u>all available</u> options if no obvious contraindications exist to maximize access to available treatment. **Patient will only receive one therapy.**

Date of symptom onset:	5 days or less 📋
Please check ALL outp	atient treatment(s) you would like considered:
	nirmatrelvir-ritonavir (PAXLOVID) 150-100 mg dose pack molnupiravir 200 mg capsules
	IV Sotrovimab 500 mg infusion - Once IV Remdesivir 200 mg infusion Day1; 100 mg infusion Day 2 and 3

Date of symptom onset:	6-7 days 📋
Please check ALL outpa	atient treatment(s) you would like considered:
	🗌 IV Sotrovimab 500 mg infusion - Once 🛛 IV Remdesivir 200 mg infusion Day1; 100 mg infusion Day 2 and 3

Date of symptom onset:	>7 days 📋
Symptom onset > 7	Medication cannot be ordered. Patient past eligibilty date.
days.	



5. Add clarifying comments as necessary:

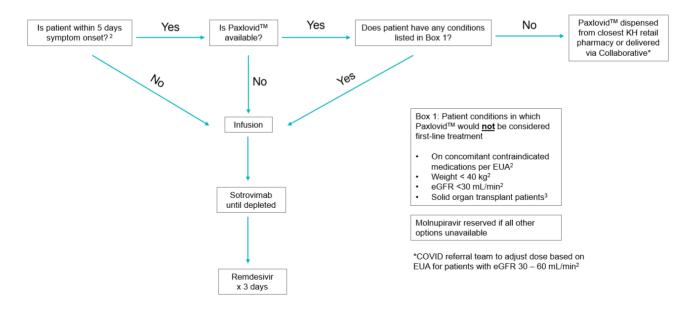


- 6. Referral Team will review and identify best treatment per KH P&T algorithm (Figure 1)
- 7. Referral Team will:
  - a. Send prescription to appropriate entity (KH Retail Pharmacy or Infusion Center)
    - i. Prescription will require co-signature from ordering provider if ordering via EPIC
    - ii. Retail Pharmacy or Infusion Center will contact patient about treatment
  - b. Communicate final treatment plan with provider via in-basket message
  - c. Contact patient if they are not eligible or no treatment available

## 8. Patient will be notified within 24 hours of their treatment option

Please contact the referral team with questions or concerns by following this link: <u>Provider Questions - COVID</u> <u>Outpatient Treatment Referral</u>

## Figure 1: KH P&T Outpatient COVID Treatment Algorithm<sup>1</sup>





### **Considerations for pregnant patients:**

Molnupiravir is the only treatment option with a warning against use in pregnant patients.<sup>4</sup> Initiation of COVID treatment should be a shared-decision making process following adequate counseling from patient's obstetric provider as able.

Drug	Organization	Statement/Recommendations
Paxlovid™	Society for Maternal Fetal Medicine (SMFM)	"SMFM supports the use of Paxlovid (nirmatrelvir [PF-07321332] tablets and ritonavir tablets) for treatment of pregnant patients with COVID-19 who meet clinical qualifications. Any therapy that would otherwise be given should not be withheld specifically due to pregnancy or lactation." <sup>5</sup>
	American College of Obstetricians and Gynecologists (ACOG)	"Obstetric care clinicians may consider the use of the oral SARS-CoV-2 protease inhibitor for the treatment of non-hospitalized COVID-19 positive pregnant individuals with mild to moderate symptoms, particularly if one or more additional risk factors are present (eg body mass index >25, chronic kidney disease, diabetes mellitus, cardiovascular disease). Clinicians should weigh the available data against the individual risks of COVID-19 in pregnancy in each situation." <sup>6</sup>
Sotrovimab	American College of Obstetricians and Gynecologists (ACOG)	"Obstetric care clinicians may consider the use of monoclonal antibodies for the treatment of non- hospitalized COVID-19 positive pregnant individuals with mild to moderate symptoms, particularly if one or more additional risk factors are present (eg BMI >25, chronic kidney disease, diabetes mellitus, cardiovascular disease)." <sup>6</sup>
Remdesivir	National Institute of Health (NIH)	"Remdesivir should not be withheld from pregnant patients if it is otherwise indicated." <sup>7</sup>

## Considerations for Pediatric Patients (12-17 years of age)

Therapy may be considered on a case-by-case basis for pediatric patients with risk factors for progression to severe COVID. Please contact the referral team by following this link: <u>Patient Review - COVID Outpatient</u> <u>Treatment Referral</u>

Please include the following information:

- 1. Patient MRN
- 2. Patient name
- 3. Patient-specific risk factors



## **References:**

- COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. Available at <u>https://www.covid19treatmentguidelines.nih.gov/</u>. Accessed January 17, 2022.
- 2. Food and Drug Administration. Fact sheet for healthcare providers: emergency use authorization for paxlovid. 2021. Available at: <u>https://www.fda.gov/media/155050/download</u>. Accessed January 17, 2022.
- American Society of Transplantation. AST Statement on Oral Antiviral Therapy for COVID-19 for Organ Transplant Recipients. 2022. Available at: <u>AST Statement on Oral Antiviral Therapy for COVID Jan 4</u> (2).pdf (myast.org). Accessed January 17, 2022.
- 4. Food and Drug Administration. Fact sheet for healthcare providers: emergency use authorization for molnupiravir. 2021. Available at: molnupiravir-hcp-fact-sheet.pdf (merck.com)
- Society for Maternal and Fetal Medicine. FDA Issues EUA for the Treatment of Mild-to-Moderate COVID-19: Maternal-Fetal Medicine Subspecialists Support Use in Pregnant Patients. Washington, DC: SMFM; 2021. Available at: <u>Treatment\_1.10.pdf</u>
- American College of Obstetricians and Gynecologists. COVID-19 FAQs for obstetricians-gynecologists, obstetrics. Washington, DC: ACOG; 2020. Available at: <u>COVID-19 FAQs for Obstetrician-Gynecologists</u>, <u>Obstetrics | ACOG</u>. Accessed January 17, 2022.
- COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. Available at <u>https://www.covid19treatmentguidelines.nih.gov/</u>. Accessed January 17, 2022

#### Originated: 01/24/2022

Approved via Emergency Pharmacy and Therapeutics Committee: 01/2022

#### **Revision History**

Date	Update
1/31/2022	Criteria for use expanded
	Updated prescribing process



# Order Form for Outpatient Treatment of COVID (+) patients

Patient Name		DOB
Address		
Phone #		ICD-10 Diagnosis: U07.1 – COVID-19
**Symptom Onset Date: Symptoms	:	
**Date patient tested positive:	**	Please fax copy of test result with order if available**
<ul> <li>Patient must meet ALL of the following criteria</li> <li>Positive test for SARS-CoV-2</li> <li>Onset of symptoms within the past 7 days</li> <li>Patient is 18 years of age or older</li> <li>Patient does not require supplemental oxy needs</li> </ul>	6	<b>or</b> there is no increase in baseline oxygen
One (1) of the following:	<u>OR</u>	Two (2) of the following:
Pregnancy		□ Age ≥ 65 years
Active Cancer		□ Not fully vaccinated per <u>CDC definition</u>
Hematologic malignancy		□ BMI ≥ 35
Immunocompromised (On biologic agents, high dose chronic steroids, B-cell depleting therapy, TK inhibitors, primary immunodeficiency, etc)		<ul> <li>Diabetes Mellitus (on insulin therapy or oral hypoglycemics)</li> </ul>
□ HIV Patients		Cardiovascular Disease: Hypertension, Coronary Artery Disease or Congestive Heart Failure
Solid organ transplant recipients		
Hematopoietic cell transplant recipients		Lung Disease, Cystic Fibrosis, or Pulmonary Fibrosis
□ Graft-versus-host disease		□ Chronic Kidney Disease (stage 4 and above, ESRD)
Chimeric antigen receptor T-cell recipients (CAR T-Cell		End stage liver disease
Therapy) (Idecabtagene Vicleucel, Brexucabtagene Autoleucel, Axicabtagene Ciloleucel, Axicabtagene Ciloleucel)		Neurodevelopmental disorders (Eg. Cerebral palsy)
		<ul> <li>Medical-related technological dependence (Eg. Tracheostomy, gastrostomy, etc.)</li> </ul>
		□ Sickle Cell disease



## **Order Form for Outpatient Treatment of** COVID (+) patients

RX: Please check all outpatient treatment(s) you would like considered for your patient.

Consider choosing all options if no obvious contraindications exist to maximize access to available treatment. Patient will only receive one therapy per KH P&T approved algorithm. Algorithm is based on NIH-preferred treatment recommendations, available inventory, and patient-specific considerations.

□ nirmatrelvir-ritonavir (PAXLOVID) 150-100 mg dose pack

- Take 2 nirmatrelvir and 1 ritonavir tablet by mouth every 12 hours for 5 days.
- Dispense #30 (thirty) with 0 (zero) refills
- \*COVID referral team to adjust dose based on EUA for patients with eGFR 30 60 mL/min\*

## OR

□ Sotrovimab 500 mg added to 100 mL of 0.9% sodium chloride for total volume of 108 mL x 1 dose

- 1. Infuse over 30 minutes
- 2. Administer using a 0.2-micron filter
- 3. Observe patient for at least 1 hour following administration
- 4. Start primary line with 500mL 0.9% sodium chloride and give the remainder of the bag as a bolus after the monoclonal antibody infusion is completed

For IV Therapies Only Consider premeds for patients with allergic tendencies or who have had allergic reactions to an immunoglobulin product.		
KHN infusion reaction protocol will be utilized if a patient has an infusion-related or hypersensitivity reaction.		
s		

Remdesivir 200 mg added to 60 mL of 0.9% sodium chloride for a total volume of 100mL

- 1. Infuse IV over 30 minutes
- 2. Observe patient for at least 1 hour following administration
- 3. Start primary line with 500mL 0.9% sodium chloride and give the remainder of the bag as a bolus after the remdesivir infusion is completed

## Days 2 + 3:

Remdesivir 100 mg added to 80 mL of 0.9% sodium chloride for a total volume of 100mL

- 4. Infuse IV over 30 minutes
- 5. Observe patient for at least 1 hour following administration
- 6. Start primary line with 500mL 0.9% sodium chloride and give the remainder of the bag as a bolus after the remdesivir infusion is completed

## OR

□ molnupiravir 200 mg capsules

- Take 4 capsules (800 mg total) by mouth every 12 hours for 5 days.
- Dispense #40 (forty) with 0 (zero) refills

Prescriber

Date

Prescriber Signature

Address: