COVID Outpatient Treatment
Referral Process and Order Form
July 6, 2022

Objective: 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™ (nirmatrelvir-ritonavir) (oral)
- Bebtelovimab (intravenous, single dose)
- 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 **or** there is no increase in baseline oxygen needs

AND

One (1) of the following:

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

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Prescribing and Referral Review Process:

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

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

2. Indicate patient is eligible for treatment per P&T approved criteria.

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

- ☐ Pregnancy ☐ Active Cancer ☐ Hematologic malignancy
- ☐ Immunocompromised (On biologic agents, high dose chronic steroids, B-cell depleting therapy, TK inhibitors, primary immunoc
- ☐ HIV Patients ☐ Solid organ transplant recipients ☐ Hematopoietic cell transplant recipients ☐ Graft-versus-host disease
- ☐ Chimeric antigen receptor T-cell recipients (CAR T-Cell Therapy) (Idecabtagene Vicleucel, Brexucabtagene Autoleucel, Axicabtag
- ☐ Age 65 or older ☐ Not fully vaccinated per CDC definition (See reference link 3 for definition) ☐ BMI of 35 or greater
- ☐ Cardiovascular Disease: HTN, CAD, or CHF ☐ Diabetes Mellitus (on insulin or oral hypoglycemics)
- ☐ Chronic Lung Disease: COPD, Asthma, Interstitial Lung Disease, Cystic Fibrosis, or Pulmonary Fibrosis
- ☐ CKD (Stage 4 and above, ESRD) ☐ End stage liver disease ☐ Neurodevelopmental disorders (eg. Cerebral palsy)
- ☐ Medical-related technological dependence (eg. Tracheostomy, gastrostomy, etc.) ☐ Sickle Cell disease

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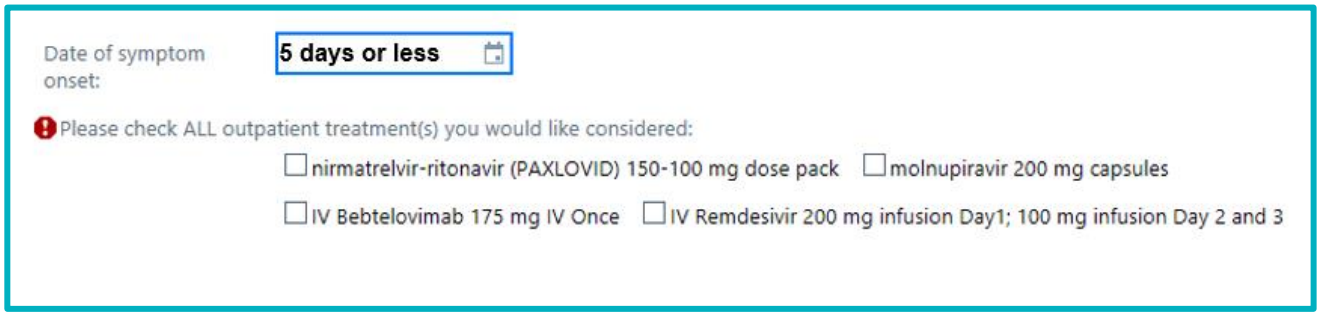
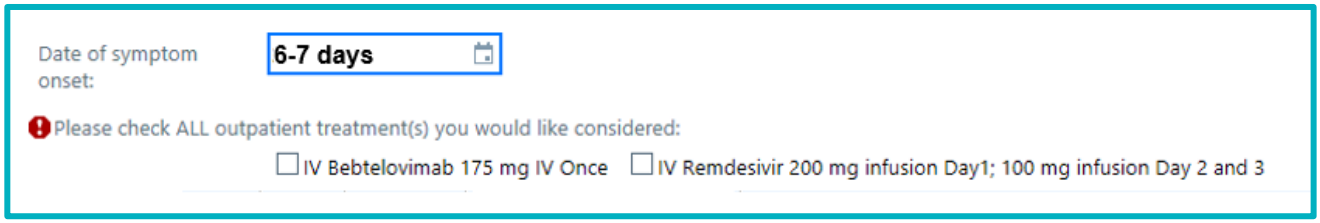
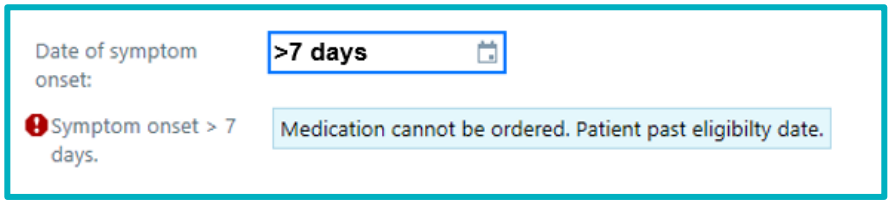
3. Enter date of symptom onset

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







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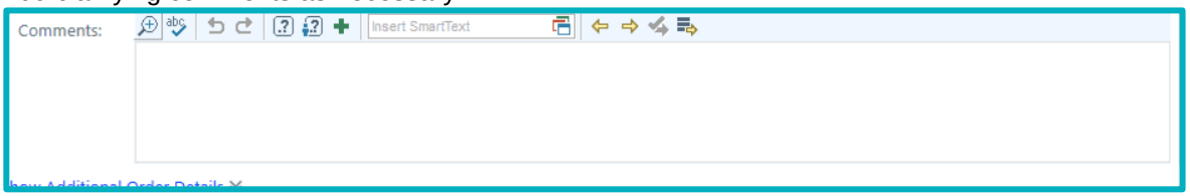
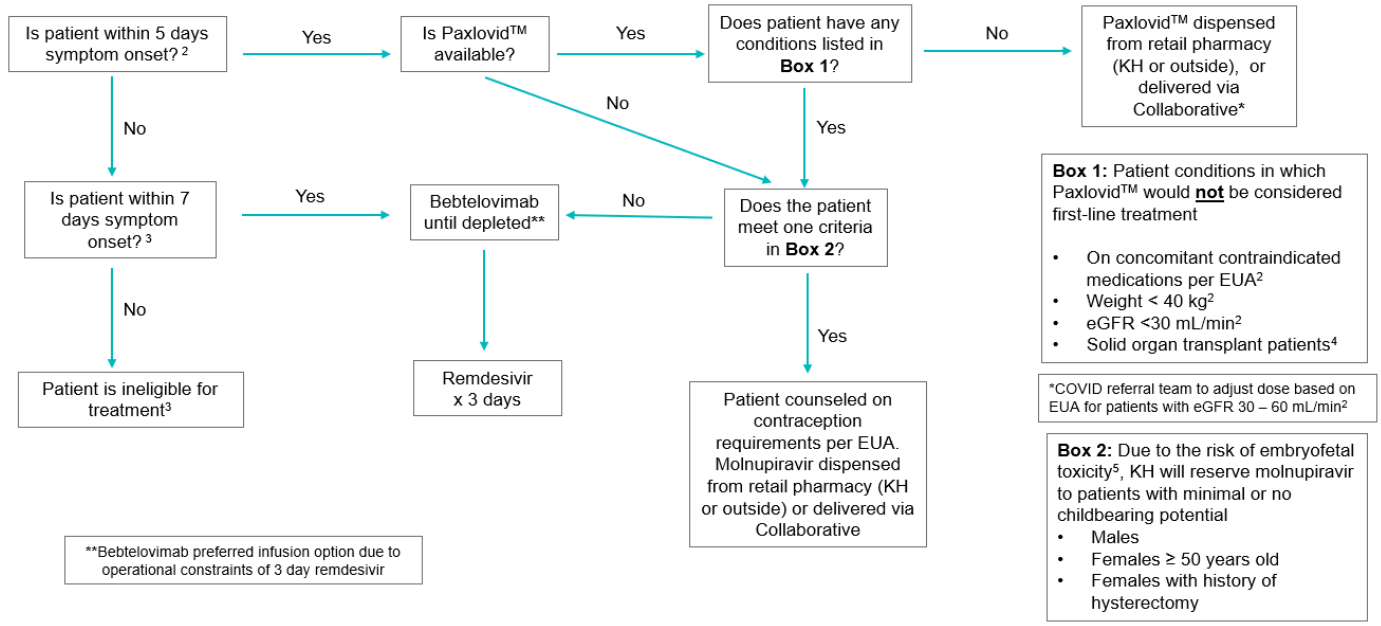
5. Add clarifying comments as necessary:



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 <u>24 hours</u> of their treatment option**

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

Figure 1: KH P&T Outpatient COVID Treatment Algorithm[1]



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Considerations for pregnant patients:

Molnupiravir is the only treatment option with a warning against use in pregnant patients.[5]
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."[5]
	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."[6]
Bebtelovimab	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)."[7]
Remdesivir	National Institute of Health (NIH)	**"**Remdesivir should not be withheld from pregnant patients if it is otherwise indicated."[8]

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: Patient Review - COVID Outpatient Treatment Referral

Please include the following information:

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

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References:

1. COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. Available at https://www.covid19treatmentguidelines.nih.gov/. Accessed January 17, 2022.
2. Food and Drug Administration. Fact sheet for healthcare providers: emergency use authorization for paxlovid. 2021. Available at: https://www.fda.gov/media/155050/download. Accessed January 17, 2022.
3. Food and Drug Administration. Fact sheet for healthcare providers: emergency use authorization for bebtelovimab. 2022. Available at: Bebtelovimab Health Care Provider Fact Sheet 03302022 (fda.gov). Accessed March 31, 2022.
4. American Society of Transplantation. AST Statement on Oral Antiviral Therapy for COVID-19 for Organ Transplant Recipients. 2022. Available at: AST Statement on Oral Antiviral Therapy for COVID Jan 4 (2).pdf (myast.org). Accessed January 17, 2022.
5. Food and Drug Administration. Fact sheet for healthcare providers: emergency use authorization for molnupiravir. 2021. Available at: molnupiravir-hcp-fact-sheet.pdf (merck.com)
6. 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: Treatment_1.10.pdf
7. American College of Obstetricians and Gynecologists. COVID-19 FAQs for obstetricians-gynecologists, obstetrics. Washington, DC: ACOG; 2020. Available at: COVID-19 FAQs for Obstetrician-Gynecologists, Obstetrics | ACOG. Accessed January 17, 2022.
8. COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. Available at Remdesivir | COVID-19 Treatment Guidelines (nih.gov) Accessed January 17, 2022

Originated: 01/24/2022

Approved via Emergency Pharmacy and Therapeutics Committee: 01/2022

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Revision History

Date	Update
6/30/2022	Amended algorithm to include molnupiravir per NIH Guidelines
4/1/2022	Sotrovimab removed from treatment algorithm and order form. Sotrovimab no longer authorized for Ohio. FDA updates Sotrovimab emergency use authorization | FDA Added bebtelovimab to treatment algorithm and order form
2/8/2022	Criteria for use expanded Updated prescribing process
1/31/2022	Criteria for use expanded Updated prescribing process

Kettering COVID Infusion Center
3535 Southern Blvd
Dayton, OH 45429
Phone: 937-395-6011
Fax: 937-401-6628

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****

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 **or** there is no increase in baseline oxygen needs

AND

One (1) of the following:

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

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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

☐ Bebtelovimab 175 mg/2mL x 1 dose

1. Administer via IV push over 30 seconds
2. After the entire contents of the syringe have been administered, flush the injection line with 0.9% Sodium Chloride to ensure delivery of the required dose
3. Observe patient for at least 1 hour following administration

OR

☐ Remdesivir

For IV Therapies Only

Consider premeds for patients with allergic tendencies or who have had allergic reactions to an immunoglobulin product.

Pre-meds (optional):

☐Tylenol 650 mg po or ☐ Tylenol 1000 mg po

☐Benadryl 25 mg po or ☐ Benadryl 25 mg IV

☐ Methylprednisolone 40 mg IV

KH infusion reaction protocol will be utilized if a patient has an infusion-related or hypersensitivity reaction.

Day 1:

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: _____ **Phone** _____ **Fax:** _____