Pediatric COVID-19 Monoclonal Antibody Outpatient Therapy Workflow for Outside Referrals

Patients, regardless of where they test positive, may have the therapy offered for they speak with their provider, assuming they qualify. The product is currently provided at no cost from the manufacturer, so the only charge is for the chair time in the infusion suite.

Four products have received emergency use authorization (EUA) from the Food and Drug Administration (FDA): bamlanivimab/etesevimab (authorization letter), casirivimab/imdevimab (authorization letter), sotrovimab (authorization letter) and bebtelovimab (authorization letter). Based on available information, including data on the SARS-CoV-2/COVID-19 variants, bebtelovimab retains neutralizing antibody activity against the Omicron subvariant BA.2. As bebtelovimab is not FDA approved for this defined patient population, the following fact sheet containing drug information should be carefully reviewed when considering use: Bebtelovimab EUA - Fact Sheet for Healthcare Providers.

Indication and Dosing:

Treatment of mild to moderate COVID-19 infection in pediatric patients 12 to < 18 years **AND** weighing at least 40 kg: *see additional inclusion criteria below*

- Bebtelovimab 175 mg as an intravenous infusion, given over at least 30 seconds
- Clinically monitor patients during treatment administration and for at least **1 hour** after dosing is complete

Screening and Selection of Appropriate Candidates:

It is important to note that COVID-19 does not affect all population groups equally.

- The risk of severe COVID-19 increases as the number of underlying medical conditions increases in an individual.
- Long-standing systemic health and social inequities have put various groups of people at increased risk of getting sick and dying from COVID-19, including many **racial and ethnic minority groups** and **people with disabilities**

Inclusion Criteria:

- Pediatric patients 12 to < 18 years of age **AND** weighing at least 40 kg meeting at least one of the high risk criteria (below) for developing a severe COVID-19 infection and are currently outpatient and **not** hospitalized for COVID-19 (as listed per exclusion criteria below) with:
    - Mild-to-moderate COVID-19 infection with positive results of direct SARS-CoV-2 viral testing (PCR or antigen) with the following:
        - Symptomatic (at least 2 of the following: fever, cough, sore throat, malaise, headache, myalgias, gastrointestinal symptoms, shortness of breath) **AND** within **7 days** of symptom onset

High risk criteria outlined in the EUA include the following:

- Obesity or being overweight (BMI ≥ 85% for their age and gender on CDC growth charts)
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease)
- Sickle cell disease
- Pregnant
- Chronic lung disease (moderate to severe asthma, interstitial lung disease, cystic fibrosis and pulmonary hypertension)
- Neurodevelopmental disorders or other conditions that confer medical complexity (i.e., cerebral palsy, genetic/metabolic syndromes, severe congenital anomalies)
- Medical-related technological dependent (i.e., tracheostomy, gastrostomy, positive pressure ventilation not related to COVID-19)
- Other medical conditions/factors associated with increased risk for progression to severe COVID, per CDC website

Exclusion Criteria:

- Hospitalization due to COVID-19
- Requiring oxygen therapy due to COVID-19, including patients on chronic oxygen therapy who require an increase in baseline oxygen flow rate due to COVID-19
- Hypersensitivity to product or ingredients

COVID-19 Monoclonal Antibody Infusion Referral Process: *Patients will be scheduled as referrals are received*

Process	Responsible Party
Patient is deemed candidate for COVID-19 monoclonal antibody therapy upon review of patient specific criteria outlined above per the EUA. The preferred product will be bebtelovimab	Referring Provider
↓	
Legal Guardian is informed of alternatives to receiving the COVID-19 monoclonal antibody therapy and that this therapy is an unapproved drug authorized for use under FDA EUA. Legal Guardian is counseled and provided with Fact Sheet for Parents and Caregivers (English; Spanish) and expressly agrees to treatment.	Referring Provider
↓	
Complete and sign the COVID-19 monoclonal antibody therapy EUA criteria referral **AND** order forms and submit to **859-218-7670.** [Tip Sheet Found on Website and **Appendix A**]	Referring Provider
↓	
Upon receipt of referral and order forms, scheduling staff will register the patient in to EPIC. The scheduler will call patient/legal guardian and schedule infusion appointment at next available infusion date and time. During this call, the scheduler will provide guidance to the patient/legal guardian on parking, registration, and arrival.	Designated Scheduler
↓	
Scheduler will upload the completed referral and order forms to the patient's medical record through EPIC "Media Manager"	Designated Scheduler
↓	
Within 48 to 72 hours of the COVID-19 monoclonal antibody infusion, the patient must have a documented telehealth visit in order to evaluate clinical status and ensure no disease progression or escalation of care is warranted.	Referring Provider

Within 7 to 10 days of COVID-19 monoclonal antibody infusion, the referring provider or designee (i.e., RN) completes a telephone call with patient or caregiver to evaluate clinical status and ensure no disease progression or escalation of care is warranted.	Referring Provider or Designee (i.e., Nurse)

Report all medication errors and adverse events occurring during COVID-19 monoclonal antibody therapy use and consider potentially attributable to therapy within 7 calendar days from onset of event • UKHC SI Report (reported through this system only if reaction occurs at UKHC) • FDA MedWatch: www.fda.gov/medwatch/report.htm ○ Bebtelovimab: Follow all instructions for reporting within the EUA Prescribing Information Listed in the Healthcare Provider Fact Sheet	Any Patient Care Provider (i.e., Referring Provider, Pharmacist, Nurse, etc.)

HealthCare
KENTUCKY CHILDREN'S HOSPITAL

Patient Information:
Name: _____
DOB: _____

Pediatric COVID-19 Monoclonal Antibody Referral Form

This form must be completed by the referring provider. Complete the required fields and submit this referral form along with the order form (page 2) via fax to: ***859-218-7670***

Indication: *patient must meet both of the below criteria in addition to at least one of the listed high risk criteria*

This patient is:

☐ 12 years of age or older

☐ At least 40 kg (documented weight: ____ kg (date obtained: _____ (MM/DD/YYYY))

Select the Patient's High Risk Criteria outlined in the EUA include the following: *select all that apply*

☐ Obesity or being overweight (BMI ≥ 85% for their age and gender on CDC growth charts)

☐ Chronic kidney disease

☐ Diabetes

☐ Immunosuppressive disease or immunosuppressive treatment

☐ Cardiovascular disease (including congenital heart disease)

☐ Sickle cell disease

☐ Pregnant

☐ Chronic lung disease (moderate to severe asthma, interstitial lung disease, cystic fibrosis and pulmonary hypertension)

☐ Neurodevelopmental disorders or other conditions that confer medical complexity (i.e., cerebral palsy, genetic/metabolic syndromes, severe congenital anomalies)

☐ Medical-related technological dependent (i.e., tracheostomy, gastrostomy, positive pressure ventilation not related to COVID-19)

☐ Other medical conditions/factors associated with increased risk for progression to severe COVID, per CDC website
If other, please specify: _____

☐ **Treatment**

1. ☐ Mild to moderate COVID-19 infection with **positive** results of direct SARS-CoV-2 viral testing (PCR or antigen):
   - Date of SARS-CoV-2 Test: _____ (MM/DD/YYYY)
   - Date of Symptom Onset:_____ (MM/DD/YYYY) [patient must be within **7 days** of symptom onset]

   AND

2. ☐ At least **two** of the following symptoms: *select all that apply*

   ☐ Fever ☐ Cough ☐ Sore Throat ☐ Shortness of Breath
   ☐ Malaise ☐ Headache ☐ Myalgias ☐ Gastrointestinal Symptoms
   ☐ Other: _____

☐ **I have provided the patient's legal guardian with a copy of the Fact Sheet for Parents and Caregivers** (English; Spanish)

Legal Attestation:

_____(First Name, Last Name) is a _____ (age) year old _____ (gender) under my care for COVID-19. I have assessed my patient as eligible to receive bebtelovimab under the FDA Emergency Use Authorization (EUA). I have reviewed the mandatory requirements for drug use within the Fact Sheet for Health Care Providers and obtained approval for use according to institutional policy. I have provided information consistent with the Fact Sheet for Patients and Parents/Caregivers EUA of bebtelovimab and given the patient/legal representative a copy. The patient/legal representative was informed of the potential risks and benefits of bebtelovimab, alternatives to bebtelovimab, and that bebtelovimab is an unapproved drug that is authorized for use under EUA. The patient or patient's legal representative has expressly agreed to this treatment.

_____	_____	_____
Signature, Referring Provider	Date (MM/DD/YYYY)	Contact Information

HealthCare
KENTUCKY CHILDREN'S HOSPITAL

Patient Information:
Name: _____
DOB: _____

Pediatric COVID-19 Monoclonal Antibody Order Form

*Complete the required fields (annotated by *) and submit this order form along with the referral form (page 1) via fax to:* ***859-218-7670***

Patient Name*: _____ **Date of Birth*:** _____

Legal Guardian Name*: _____ **Phone Number*:** _____

Allergies*: _____

☐ No Known Drug Allergies

Indication:

☒ Treatment

Bebtelovimab Order:

☒ bebtelovimab 175 mg (2 mL) administered over 30 seconds

Additional Drug Therapy Orders:

☒ lidocaine (Anecream) 1 application topically as needed for line insertion

Nursing Orders:

☒ Insert peripheral IV

☒ Clinically monitor patient during administration and observe patient for at least 1 hour after administration is complete; monitor vital signs at baseline, at end of the administration and 1 hour after administration is completed

Hypersensitivity Orders: *medication dose must be completed by referring provider, if left blank, it will be returned*

☒ Hypersensitivity Management per University of Kentucky HealthCare Protocol

☒ hydrocortisone ____ *mg (2 mg/kg (max: 100 mg)) intravenous **or** prednisolone ____ *mg (2 mg/kg (max: 60 mg)) oral as needed for Grade 2, 3 or 4 infusion reactions

☒ diphenhydramine ____ *mg (1 mg/kg (max: 50 mg)) intravenous/oral as needed for Grade 2, 3 or 4 infusion reactions

☒ famotidine ____ *mg (0.5 mg/kg (max: 20 mg)) intravenous/oral as needed for Grade 2, 3 or 4 infusion reactions

☒ albuterol 108 (90 base) mcg/act inhaler 4 puffs as needed for Grade 3 or 4 infusion reactions

☒ epinephrine ____ *mg (0.01 mg/kg (max: 0.3 mg)) intramuscular as needed for Grade 4 infusion reactions

_____	_____	_____
Signature, Referring Provider	Date (MM/DD/YYYY)	Telephone Number
_____	_____	_____ /_____
Printed Name, Referring Provider	Credentials	License Number/DEA Number

_____	_____	_____	_____
Address	City	State	Zip Code

Tip Sheet

COMPLETING THE REQUIRED PEDIATRIC COVID-19 MONOCLONAL ANTIBODY REFERRAL FORM

This form can be printed and the information completed by hand or the referral form can be digitally completed and signed.

Step 1: Complete the Patient Specific Information

HealthCare
KENTUCKY CHILDREN'S HOSPITAL

Patient Information:
Name: _____
DOB: _____

Pediatric COVID-19 Monoclonal Antibody Referral Form

*This form must be completed by the referring provider and will be uploaded as a PDF to the patient's chart in EPIC via Media Manager function. Complete the required fields (annotated by *) and submit this referral form along with the order form (page 2) via fax to:* ***859-218-7670***

Step 2: Review patient specific information to confirm that patient meets the Emergency Use Authorization (EUA) criteria as outlined in the *Interim Guidance for the Outpatient Management of SARS-CoV-2 (COVID-19) with Monoclonal Antibody Therapy in Pediatric Patients*

- **Step 2a:** Indicate that the patient is 12 years of age or older **AND** weights at least 40 kg (list the patient's weight and date in which that weight was obtained)

These boxes can be selected within the PDF or simply annotate with a check mark (√) or X

Indication: *patient must meet both of the below criteria in addition to at least one of the listed high risk criteria*
This patient is:
☐ 12 years of age or older
☐ At least 40 kg (documented weight: ____ kg (date obtained: _____ (MM/DD/YYYY))

- **Step 2b** Select the high risk criteria that align with the being referred for monoclonal antibody administration

Select the Patient's High Risk Criteria outlined in the EUA include the following:

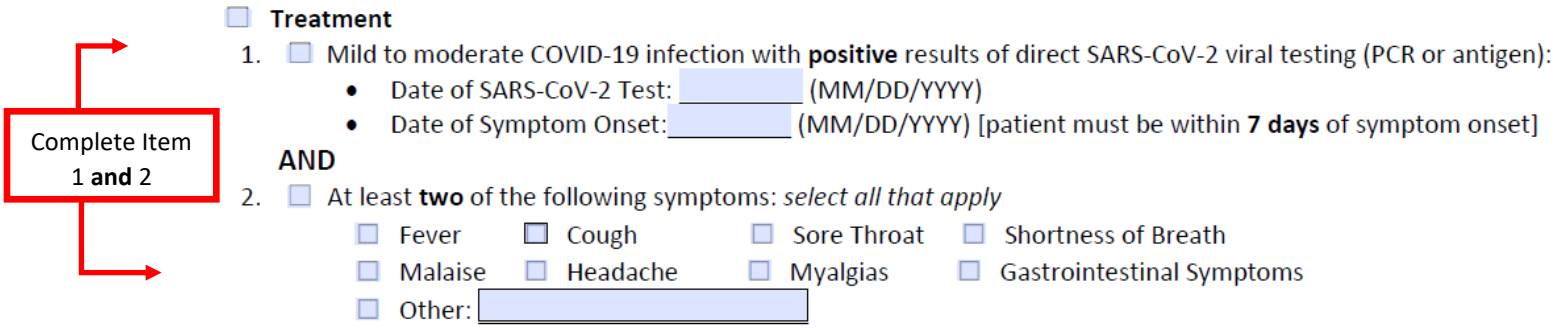
☐ Obesity or being overweight (BMI ≥ 85% for their age and gender on CDC growth charts)
☐ Chronic kidney disease
☐ Diabetes
☐ Immunosuppressive disease or immunosuppressive treatment
☐ Cardiovascular disease (including congenital heart disease)
☐ Sickle cell disease
☐ Pregnant
☐ Chronic lung disease (moderate to severe asthma, interstitial lung disease, cystic fibrosis and pulmonary hypertension)
☐ Neurodevelopmental disorders or other conditions that confer medical complexity (i.e., cerebral palsy, genetic/metabolic syndromes, severe congenital anomalies)
☐ Medical-related technological dependent (i.e., tracheostomy, gastrostomy, positive pressure ventilation not related to COVID-19)
☐ Other medical conditions/factors associated with increased risk for progression to severe COVID, per CDC website
If other, please specify: _____

These boxes can be selected within the PDF or simply annotate with a check mark (√) or X

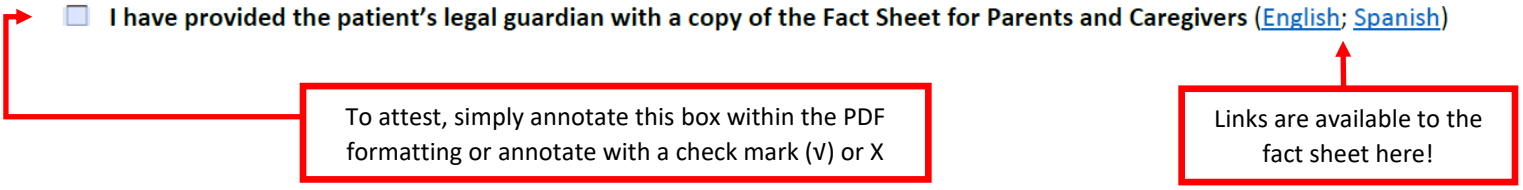
Patient only needs to meet one of the listed high risk criteria

Tip Sheet

- **Step 2c:** Indicate the specific indication for use: **treatment**. Based on the indication selected, complete the required fields



- **Step 2d:** Attest that you have provided the patient's legal guardian with the Fact Sheet. This is a requirement per EUA criteria!



Step 3: Complete the legal attestation that has been previously reviewed and approved for EUA therapies offered at UK HealthCare – this includes COVID-19 monoclonal antibody therapy!

Legal Attestation:

_____(First Name, Last Name) is a _____ (age) year old _____ (gender) under my care for COVID-19. I have assessed my patient as eligible to receive bebtelovimab under the FDA Emergency Use Authorization (EUA). I have reviewed the mandatory requirements for drug use within the Fact Sheet for Health Care Providers and obtained approval for use according to institutional policy. I have provided information consistent with the Fact Sheet for Patients and Parents/Caregivers EUA of bebtelovimab and given the patient/legal representative a copy. The patient/legal representative was informed of the potential risks and benefits of bebtelovimab, alternatives to bebtelovimab, and that bebtelovimab is an unapproved drug that is authorized for use under EUA. The patient or patient's legal representative has expressly agreed to this treatment.

Step 4: Sign, date, and list contact information as the referring provider. This signature can be completed through a digital signature **OR** alternative means of legal signature (i.e., ink or stamp)

Tip Sheet

COMPLETING THE REQUIRED PEDIATRIC COVID-19 MONOCLONAL ANTIBODY ORDER FORM

Step 1: Complete the Patient Specific Information, including the name and contact information of the patient's legal guardian [this information will be needed for scheduling purposes!]

HealthCare
KENTUCKY CHILDREN'S HOSPITAL

Pediatric COVID-19 Monoclonal Antibody Order Form

Complete the required fields (annotated by *) and submit this order form along with the referral form (page 1) via fax to: **859-218-7670**

Patient Name*: _____ **Date of Birth*:** _____

Legal Guardian Name*: _____ **Phone Number*:** _____

Allergies*: _____

☐ No Known Drug Allergies

Step 2: Other orders have been selected on the order form based on indication, sotrovimab dosing and administration requirements, nursing needs, including topical lidocaine for line insertion, inserting a peripheral IV and vital sign monitoring orders

Indication:

☒ Treatment

Bebtelovimab Order:

☒ bebtelovimab 175 mg (2 mL) administered over 30 seconds

Additional Drug Therapy Orders:

☒ lidocaine (Anecream) 1 application topically as needed for line insertion

Nursing Orders:

☒ Insert peripheral IV

☒ Clinically monitor patient during administration and observe patient for at least 1 hour after administration is complete; monitor vital signs at baseline, at end of the administration and 1 hour after administration is completed

Tip Sheet

Step 3: Be sure to complete the patient specific dosing for the hypersensitivity kit medications – **hydrocortisone, prednisolone, diphenhydramine, famotidine** and **epinephrine**. These fields must be completed by the referring provider based on the patient specific weight provider. If left blank, the form will be returned.

Hypersensitivity Orders: *medication dose must be completed by referring provider, if left blank, it will be returned*

- ☒ Hypersensitivity Management per University of Kentucky HealthCare Protocol
- ☒ hydrocortisone ____ *mg (2 mg/kg (max: 100 mg)) intravenous **or** prednisolone ____ *mg (2 mg/kg (max: 60 mg)) oral as needed for Grade 2, 3 or 4 infusion reactions
- ☒ diphenhydramine ____ *mg (1 mg/kg (max: 50 mg)) intravenous/oral as needed for Grade 2, 3 or 4 infusion reactions
- ☒ famotidine ____ *mg (0.5 mg/kg (max: 20 mg)) intravenous/oral as needed for Grade 2, 3 or 4 infusion reactions
- ☒ albuterol 108 (90 base) mcg/act inhaler 4 puffs as needed for Grade 3 or 4 infusion reactions
- ☒ epinephrine ____ *mg (0.01 mg/kg (max: 0.3 mg)) intramuscular as needed for Grade 4 infusion reactions

Step 4: Sign, date, and list contact information (including address) along with credentials, license number and DEA number as the referring provider. This signature can be completed through a digital signature **OR** alternative means of legal signature (i.e., ink or stamp)

Signature, Referring Provider | Date (MM/DD/YYYY) | Telephone Number

Printed Name, Referring Provider | Credentials | License Number/DEA Number

Address | City | State | Zip Code

Once Page 1 (Referral Form) and Page 2 (Order Form) are completed, fax to 859-218-7670. A team member will contact your patient (or patient's legal guardian) to schedule their infusion.

Completed referral documents are provided below as an example

Tip Sheet

HealthCare
KENTUCKY CHILDREN'S HOSPITAL

Patient Information:
Name: Mickey Mouse
DOB: 01/01/2008

Pediatric COVID-19 Monoclonal Antibody Referral Form

This form must be completed by the referring provider. Complete the required fields and submit this referral form along with the order form (page 2) via fax to: 859-218-7670

Indication: *patient must meet both of the below criteria in addition to at least one of the listed high risk criteria*
This patient is:

- ☑ 12 years of age or older
- ☑ At least 40 kg (documented weight: 85 kg (date obtained: 05/16/2022 (MM/DD/YYYY))

Select the Patient's High Risk Criteria outlined in the EUA include the following: *select all that apply*

- ☑ Obesity or being overweight (BMI ≥ 85% for their age and gender on CDC growth charts)
- ☐ Chronic kidney disease
- ☐ Diabetes
- ☐ Immunosuppressive disease or immunosuppressive treatment
- ☐ Cardiovascular disease (including congenital heart disease)
- ☐ Sickle cell disease
- ☐ Pregnant
- ☐ Chronic lung disease (moderate to severe asthma, interstitial lung disease, cystic fibrosis and pulmonary hypertension)
- ☐ Neurodevelopmental disorders or other conditions that confer medical complexity (i.e., cerebral palsy, genetic/metabolic syndromes, severe congenital anomalies)
- ☐ Medical-related technological dependent (i.e., tracheostomy, gastrostomy, positive pressure ventilation not related to COVID-19)
- ☐ Other medical conditions/factors associated with increased risk for progression to severe COVID, per CDC website
  If other, please specify: _____

☑ **Treatment**

1. ☑ Mild to moderate COVID-19 infection with **positive** results of direct SARS-CoV-2 viral testing (PCR or antigen):
   - Date of SARS-CoV-2 Test: 05/16/2022 (MM/DD/YYYY)
   - Date of Symptom Onset: 05/14/2022 (MM/DD/YYYY) [patient must be within **7 days** of symptom onset]

   AND
2. ☑ At least **two** of the following symptoms: *select all that apply*
   - ☑ Fever ☑ Cough ☐ Sore Throat ☐ Shortness of Breath
   - ☐ Malaise ☐ Headache ☐ Myalgias ☐ Gastrointestinal Symptoms
   - ☐ Other: _____

☑ **I have provided the patient's legal guardian with a copy of the Fact Sheet for Parents and Caregivers** (English; Spanish)

Legal Attestation:

Mickey Mouse (First Name, Last Name) is a 14 (age) year old male (gender) under my care for COVID-19. I have assessed my patient as eligible to receive bebtelovimab under the FDA Emergency Use Authorization (EUA). I have reviewed the mandatory requirements for drug use within the Fact Sheet for Health Care Providers and obtained approval for use according to institutional policy. I have provided information consistent with the Fact Sheet for Patients and Parents/Caregivers EUA of bebtelovimab and given the patient/legal representative a copy. The patient/legal representative was informed of the potential risks and benefits of bebtelovimab, alternatives to bebtelovimab, and that bebtelovimab is an unapproved drug that is authorized for use under EUA. The patient or patient's legal representative has expressly agreed to this treatment.

Test Provider (Digitally signed by Test Provider Date: 2022.05.16 17:50:33 -04'00')	05/16/2022	859-000-1234
Signature, Referring Provider	Date (MM/DD/YYYY)	Contact Information

Updated: 04182022

Tip Sheet

HealthCare
KENTUCKY CHILDREN'S HOSPITAL

Patient Information:
Name: Mickey Mouse
DOB: 01/01/2008

Pediatric COVID-19 Monoclonal Antibody Order Form

*Complete the required fields (annotated by *) and submit this order form along with the referral form (page 1) via fax to:* ***859-218-7670***

Patient Name*: Mickey Mouse **Date of Birth*:** 01/01/2008

Legal Guardian Name*: Minnie Mouse **Phone Number*:** 859-123-4567

Allergies*:

☐ No Known Drug Allergies

Indication:

☒ Treatment

Bebtelovimab Order:

☒ bebtelovimab 175 mg (2 mL) administered over 30 seconds

Additional Drug Therapy Orders:

☒ lidocaine (Anecream) 1 application topically as needed for line insertion

Nursing Orders:

☒ Insert peripheral IV

☒ Clinically monitor patient during administration and observe patient for at least 1 hour after administration is complete; monitor vital signs at baseline, at end of the administration and 1 hour after administration is completed

Hypersensitivity Orders: *medication dose must be completed by referring provider, if left blank, it will be returned*

☒ Hypersensitivity Management per University of Kentucky HealthCare Protocol

☒ hydrocortisone 100 *mg (2 mg/kg (max: 100 mg)) intravenous or prednisolone 60 *mg (2 mg/kg (max: 60 mg)) oral as needed for Grade 2, 3 or 4 infusion reactions

☒ diphenhydramine 50 *mg (1 mg/kg (max: 50 mg)) intravenous/oral as needed for Grade 2, 3 or 4 infusion reactions

☒ famotidine 20 *mg (0.5 mg/kg (max: 20 mg)) intravenous/oral as needed for Grade 2, 3 or 4 infusion reactions

☒ albuterol 108 (90 base) mcg/act inhaler 4 puffs as needed for Grade 3 or 4 infusion reactions

☒ epinephrine 0.3 *mg (0.01 mg/kg (max: 0.3 mg)) intramuscular as needed for Grade 4 infusion reactions

Test Provider — Digitally signed by Test Provider Date: 2022.05.16 17:58:06 -04'00' — Signature, Referring Provider

05/16/2022 — Date (MM/DD/YYYY)

859-000-1234 — Telephone Number

Test Provider — Printed Name, Referring Provider

MD — Credentials

KY1234 / DEA123456 — License Number/DEA Number

123 COVID mAb Way — Address

Lexington — City

KY — State

40536 — Zip Code

Updated: 04182022