COVID-19

A message from Ballad Heath Corporate Emergency Operations Center (CEOC)

>> PLEASE READ AND CASCADE TO ALL MEDICAL STAFF<<

TO: Ballad Health Medical Staff, Physician Liaisons, Facility Leadership, Regional Community Physicians
FROM: Ballad Health Corporate Emergency Operations Center
DATE: December 23, 2021
TITLE: URGENT updated information regarding Monoclonal Antibody availability and Infusion options
ACTION: Please cascade

Ballad Health has a very limited supply of monoclonal antibodies (MABs) on hand and has been notified that shipments of additional doses of bamlanivimab plus etesevimab (the Lilly product) and casirivimab plus imdevimab (REGEN-COV®) are being halted since these MABs are not considered effective against the Omicron variant of COVID-19.

Just this morning, the U.S. Depart of Health and Human Services announced that, *"circulating SARS-CoV-2 viral variants, including Omicron, may be associated with resistance to monoclonal antibodies. Health care providers should review the Antiviral Resistance information in the Healthcare Provider Fact Sheet for each authorized therapeutic for details regarding specific variants and resistance. The Centers for Disease Control and Prevention (CDC) publishes information about circulating variants in the United States by region. The frequency of the Omicron variant is increasing throughout the U.S. and health care providers should refer to these frequency data as they choose a therapeutic option for their patients."* Furthermore, *"data show that it is unlikely that bamlanivimab and etesevimab administered together or REGEN-COV will retain activity against this variant."*

Please note that the MAB effective against Omicron (sotrovimab) has not been made available to Ballad Health at this time.

Updated EUA information is included in the Ballad Health MAB request packet which is to be used for patients of all ages who are experiencing moderate to severe symptoms of COVID-19 and are deemed to be at high risk for progression of the disease. Please be judicious in the prescribing of MABs considering the limited supply and the increasing incidence of Omicron across our region. If Epic access is not available for order entry, then completed paperwork must still be faxed to (423) 952-2122.

The latest MAB document package is available in its entirety on the external Ballad Health internet. The documents can be accessed from the Ballad Health home page by clicking on "Doctors & Team Members" (https://www.balladhealth.org/doctors-team-members).

The best way to combat COVID-19 in general, and the omicron mutation specifically, is by getting your patients vaccinated. Ballad Health strongly encourages all eligible people to receive their vaccination and to stay fully vaccinated.

###

Monoclonal Antibody (MAB) Provider Verification and Patient Request for Treatment

BalladHealth

Paper Only

Patient Identification

*** All highlighted sections must be completed and executed including the consent (page 2) for the patient to be scheduled.**

Clinical Staff Section

Practice Location: _____ Practice contact #: _____

Patient Name: _____ DOB: _____

Address: _____ SSN: _____

Patient Contact #: _____

Allergies: _____

COVID Test: ❑ PCR: ❑ positive ❑ negative Date: _____ **OR** ❑ Antigen: ❑ positive ❑ negative Date: _____

COVID Vaccination Status: ❑ Unvaccinated ❑ Partially Vaccinated ❑ Fully Vaccinated

Physician Section

Provider Attestation:

❑ I have evaluated the patient identified herein and reviewed the lab results provided. This patient has at least one Risk factor and a documented Positive PCR or Antigen test for Covid-19 and one or more risk factors as checked below:

Risk Factors – Please check all that apply. (These are straight from the FDA EUA)

	Older age (for example, age ≥ 65 years)
	Obesity or being overweight
	Pregnancy
	Chronic kidney disease
	Diabetes
	Immunosuppressive disease or immunosuppressive treatment
	Cardiovascular disease (including congenital heart disease) or hypertension
	Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)
	Sickle cell disease
	Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)
	Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID 19))
	Other medical conditions or factors (for example, race or ethnicity) which place the patient at high risk for progression to severe COVID-19

❑ Based on these findings, my patient **IS** at high risk for progression to severe COVID-19 and **IS** a candidate for Monoclonal Antibody Therapy. I have discussed the risks and benefits of Monoclonal Antibody Therapy with the patient and supplied the patient with FDA Emergency Use Authorization documents.

Provider Name: _____

_____ _____ _____

Signature of Provider Date Time

Patient Section

Patient Attestation

I have been educated on the indications, potential risks and benefits of Monoclonal Antibody therapy for COVID-19.
I have had the opportunity to ask questions related to this therapy and I consent to treatment with Monoclonal Antibody.

_____ _____ _____

Printed name of patient or legal guardian if minor Date Time

_____ _____ _____

Patient signature or signature of legal guardian if minor Date Time

*** All highlighted sections must be completed and executed including the consent (page 2) for the patient to be scheduled.**

Informed Consent for Monoclonal Antibody (MAB) Treatment - Adult

Patient Identification

BalladHealth

Your physician has recommended that you consider receiving monoclonal antibody administration for the treatment or prevention of COVID-19. ***YOU HAVE THE RIGHT TO ACCEPT OR DECLINE THE RECOMMENDED TREATMENT.*** We have provided you fact sheets and recommend that you read those fact sheets and that you ask questions of your healthcare provider if additional clarification is needed.

By signing the consent form below, you acknowledge and agree that you understand the following:

1. You have been provided the "Fact Sheet for Patients, Parents and Caregivers" and been given an opportunity to read it.
2. Monoclonal antibody administration for COVID-19 is voluntary and made available via Emergency Use Authorizations issued by the United States Food and Drug Administration (FDA).
3. The FDA has made MABs available for treatment or prevention of COVID-19 despite the fact that MABs are *not* FDA-approved drugs.
4. The decision to accept MAB treatment is *voluntary*, and you have the right to refuse or decline this therapy. If you decline, you will still be provided all standard treatments, but your condition may deteriorate. Even with the recommended proposed administration, your condition may deteriorate.
5. You have been informed of alternatives to receiving MAB treatment.
6. While there are studies which suggest a potential for benefit, there is no scientifically proven results that this therapy is beneficial.
7. The FDA has granted Emergency Authorization Use for these medications in certain situations.
8. There are risks associated with MAB administration. Adverse events have been reported in some patients who have received these therapies. All potential risks are not known at this time.
9. After review of available information, the FDA believed that the overall potential benefits appear to outweigh the potential risks, and with relatively few alternative available therapies, it has made MAB products available through the Emergency Use Authorization program.
10. Your healthcare provider can offer additional information and answer questions at your request, to supplement the information available in the Fact Sheet provided to you.

By signing below, I acknowledge that I have reviewed this document, understand its contents, and agree to receive monoclonal antibody treatment under the Emergency Use Authorization program discussed above.

Patient printed name: _____

Patient/Representative signature: _____ Date: _____ Time: _____

Representative relationship to the Patient: _____

Informed Consent for Monoclonal Antibody (MAB) Treatment – Pediatric Patient

Patient Identification

BalladHealth

Your physician has recommended that you consider allowing your child under the age of 18 to receive monoclonal antibody (MAB) treatment for the treatment or prevention of COVID-19. ***YOU HAVE THE RIGHT TO ACCEPT OR DECLINE THE RECOMMENDED TREATMENT.*** We have provided you one or more fact sheets and recommend that you read those fact sheets and that you ask questions of your child's healthcare provider if additional clarification is needed.

By signing the consent form below, you acknowledge and agree that you understand the following:

1. You have been provided the "Fact Sheet for Patients, Parents and Caregivers" and been given an opportunity to read it.
2. Monoclonal antibody administration for COVID-19 is *voluntary* and made available via Emergency Use Authorizations issued by the United States Food and Drug Administration (FDA).
3. The FDA has made MABs available for treatment or prevention of COVID-19 despite the fact that MABs are *not* FDA-approved drugs.
4. The decision to accept MAB treatment for your child is *voluntary*, and you have the right to refuse or decline this therapy for your child. If you decline, your child will still be provided all standard treatments, but your child's condition may deteriorate. Even with the recommended proposed administration, your child's condition may deteriorate.
5. You have been informed of alternatives to receiving MAB administration.
6. While there are studies in adults which suggest a potential for benefit from MAB administration, there are no scientifically proven results that this therapy is beneficial.
7. The FDA has granted Emergency Authorization Use for these medications in certain situations.
8. There are risks associated with MAB administration. Adverse events have been reported in some patients who have received these therapies. All potential risks are not known at this time.
9. After review of available information, the FDA believed that the overall potential benefits appear to outweigh the potential risks, and with relatively few alternative available therapies, it has made MAB products available through the Emergency Use Authorization program.
10. Your healthcare provider can offer additional information and answer questions at your request to supplement the information available in the Fact Sheet provided to you.

By signing below, I acknowledge that I have reviewed this document, understand its contents, and agree to allow my child to receive monoclonal antibody treatment under the Emergency Use Authorization program discussed above.

Patient printed name: _____

Parent or Guardian printed name: _____

Parent or Guardian relationship to the Patient: _____

Parent or Guardian signature: _____ Date: _____ Time: _____

BalladHealth Epic

Form No. 3040007057
CEOC Approved: 12/23/2021
OSSC Approved: 09/06/2021

Patient Information

GEN COVID-19 Monoclonal Antibody Orders [3040007057]

THIS ORDER SET IS ONLY FOR USE WITH PATIENTS WHO ARE POSITIVE FOR COVID-19 AND NOT HOSPITALIZED.
THIS SHOULD ONLY BE USED FOR PATIENTS 12 YEARS OF AGE OR OLDER AND AT A CURRENT COVID-19 MONOCLONAL ANTIBODIES INFUSION SITE.

Patient must **MEET CRITERIA** below:

- Mild to moderate symptoms
- Weighing at least 40 kg
- At high risk for progressing to severe COVID-19 and/or hospitalization

Post-Exposure Prophylaxis Use:

- ***In Adult and Pediatric individuals*** (12 years of age and older weighing at least 40 kg) for post-exposure prophylaxis of COVID-19 in individuals who are at ***high risk for progression to severe COVID-19***, including hospitalization or death, ***and*** are:
- ***Not fully vaccinated or who are not expected to mount an adequate immune response*** to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications) ***and***
    - Have been ***exposed to an individual infected with SARS-CoV-2*** consistent with close contact criteria per CDC ***or***
    - Who are at **high risk of exposure to an individual infected with SARS-CoV-2** because of occurrence of COVID-19 infection in other individuals in the same institutional setting (for example, nursing homes, or prisons)

Monoclonal Antibody Criteria Review:

EXCLUSION CRITERIA:

- Patient hospitalized due to COVID-19
- Patients who require oxygen therapy due to COVID-19
- Patients on chronic oxygen therapy that requires an increase in baseline oxygen flow rate due to COVID-19
- **NOTE:** Extreme Limited Availability

INCLUSION CRITERIA:

- Order must be received within 8 days of symptom onset to ensure administration of monoclonal antibody within 10 days of symptom onset
- Weighing at least 40 kg
- Patient age greater than or equal to 12 years
- At high risk for progressing to severe COVID-19 and / or hospitalization

Casirivimab and imdevimab EUA Approval	URL: "https://www.fda.gov/media/145610/download""
Casirivimab and imdevimab Health Providers EUA Fact Sheet:	URL: "https://www.regeneron.com/sites/default/files/treatment-covid19-eua-fact-sheet-for-hcp.pdf"
Casirivimab and imdevimab Patient and Caregivers EUA Fact Sheet:	URL: "https://www.regeneron.com/sites/default/files/treatment-covid19-eua-fact-sheet-for-patient.pdf"
CDC growth charts	URL: "https://www.cdc.gov/growthcharts/clinical_charts.htm"

Informed Consent for Monoclonal Antibody Treatment	URL: "MS-7742s.pdf (balladhealth.org)"
Informed Consent for Monoclonal Antibody (MAB) Treatment – Pediatric Patient	URL: "http://insideballadhealth.balladhealth.org/2/forms/MS-7745s.pdf"
Bamlanivimab / etesevimab Health Care Providers EUA Fact Sheet	URL: "https://www.fda.gov/media/145802/download"
Bamlanivimab / etesevimab Patients, Parents, and Caregivers EUA Fact Sheet	URL: "http://pi.lilly.com/eua/bam-and-ete-eua-factsheet-patient.pdf"
Sotrovimab Health Care Providers EUA Fact Sheet	URL:https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Sotrovimab/pdf/SOTROVIMAB-EUA.PDF#nameddest=HCPFS
Sotrovimab Patients, Parents, and Caregivers EUA Fact Sheet	URL:https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Sotrovimab/pdf/SOTROVIMAB-PATIENT-FACT-SHEET.PDF

Scheduling Referral

COVID-19 OP INFUSION - Virtual Health Enrollment

[X]	Covid-19 OP INFUSION-Virtual Health Enrollment	Referral Dept - UCH EMERGENCY, Referral Dept Specialty - Emergency Medicine, Referral reason - Specialty Services Required
[X]	Nursing Communication	Routine, Once, Starting S For 1 Occurrences May discharge to home after transfusion complete and vital signs stable

General

[X]	Verify Informed Consent for Infusion	Routine, Once, Starting S Procedure: monoclonal antibody infusion Proceduralist Obtained Informed Consent:

Code Status (Single Response) (Selection Required)

❍	Full Code / Attempt Resuscitation	Details
❍	DNAR / DNI - Allow Natural Death (Do Not Attempt Resuscitation / Do Not Intubate	Details
❍	Do Not Intubate (DNI) (May administer CPR and ACLS protocols but do not intubate.)	Details

❍	DNAR but May Intubate (No CPR / ACLS, but intubation due to respiratory failure is acceptable.)	Details
❍	DNAR / Cardiac Medications Only (May administer emergency medications only without CPR or intubation.)	Details
❍	DNAR / DNI - Comfort Measures Only (Measures include interventions to alleviate the patient's misery short of heroic measures.)	Details

Nursing / Isolation Orders

[X]	**COMMUNICATION:** Immediately place patient in Enhanced Droplet Plus Eye Protection Isolation Status	Routine, Until discontinued, Starting S
[X]	**NOTIFY:** Facility Nursing Supervisor for Enhanced Droplet Plus Eye Protection Isolation Status	Routine, Until discontinued, Starting S
[X]	Place patient into COVID-19 designated bed / room	Routine, Until discontinued, Starting S
[X]	Enhanced Droplet Plus Eye Protection Isolation Status	Routine, Continuous

IV Fluids

Insert and Maintain IV

❑	Insert and Maintain IV	**"And" Linked Panel**
❑	Insert Peripheral IV	STAT, Once, Starting S For 1 Occurrences
❑	Maintain IV Access	Routine, Until discontinued, Starting S
❑	Saline Lock IV	Routine, Once, Starting S For 1 Occurrences
❑	sodium chloride 0.9 % flush	3 mL As needed, Intravenous, line care, For 90 Days

Insert and Maintain IV

[X]	Insert and Maintain IV	**"And" Linked Panel**
[X]	Insert peripheral IV	STAT, Once, Starting S For 1 Occurrences
[X]	Maintain IV access	Routine, Until discontinued, Starting S
[X]	Saline lock IV	Routine, Once, Starting S For 1 Occurrences
[X]	sodium chloride 0.9 % flush	3 mL As needed, Intravenous, line care, For 90 Days

Medications

COVID-19 Confirmed Treatment (Selection Required)

Best Practice References Advise:

- Clinically monitor patients during administration and observe for at least 1 hour after administration is completed

[X]	COVID-19 virus infection	Diagnosis

[X] Monoclonal Antibody Criteria Review **(Pharmacist may interchange route below therapeutics)** (Single Response)

Notes: Extreme limited availability
****MUST SELECT ONE OPTION BELOW****

❍	casirivimab and imdevimab infusion	**"Followed by" Linked Panel**
❑	casirivimab 600 mg and imdevimab 600 mg in sodium chloride 0.9 % 100 mL infusion	110 mL Once, Intravenous, For 1 Doses Total volume 110 mL, infusion over 20 minutes Has the "Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of casirivimab and imdevimab" been reviewed? if (answer = No) Please provide additional information why requirement is not met. Has the information in the "Casirivimab and Imdevimab Fact Sheet for Patients and Patients/Caregivers" been provided to the patient/caregiver? if (answer = No) Please provide additional information why requirement is not met. Patient must meet at least one of the criteria below:
❍	casirivimab and imdevimab injection	**"Followed by" Linked Panel**
❑	casirivimab 600 mg and imdevimab 600 mg 10 mL subcutaneous injection	10 mL Once, Subcutaneous, For 1 Doses Has the "Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of casirivimab and imdevimab" been reviewed? Patient must meet at least one of the criteria below: **Administration Instructions:** Administer the subcutaneous injections consecutively, each at a different injection site, into the thigh, back of the upper arm, or abdomen, except for 2 inches (5 cm) around the navel. The waistline should be avoided. **DO NOT** inject into skin that is tender, damaged, bruised, or scarred. Clinically monitor patients after injections and observe patients for at least 1 hour.
❍	bamlanivimab and etesevimab infusion	**"Followed by" Linked Panel**
❑	bamlanivimab 700 mg and etesevimab 1400 mg in sodium chloride 0.9 % IVPB	Once, Intravenous, For 1 Doses, **Maximum infusion rate 310 mL / hour** Has the "Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of bamlanivimab and etesevimab" been reviewed?
❍	sotrovimab 500 mg in 50 mL sodium chloride 0.9 % IVPB	500 mg Once, Intravenous, Administer over 30 minutes, For 1 Doses Has the "Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of sotrovimab" been reviewed?

[X]	acetaminophen (Tylenol) PO / PR	**"Or" Linked Panel**
[X]	acetaminophen (Tylenol) tablet	650 mg Every 4 hours PRN, Oral, mild pain (1 to 3), or fever greater than 101, For 90 Days. Oral route preferred over rectal route.
[X]	acetaminophen (Tylenol) suppository	650 mg Every 4 hours PRN, Rectal, mild pain (1 to 3), or fever greater than 101, For 90 Days Give if unable to tolerate PO.
[X]	diphenhydrAMINE (Benadryl) oral	25 mg Every 4 hours PRN, Oral, allergies, for infusion related reactions and / or nausea, For 90 Days, Oncology

[X]	albuterol (Proventil / Accuneb) 0.083 % nebulizer solution	2.5 mg Every 20 min PRN, Nebulization, wheezing, bronchospasm, For 2 Doses, Oncology A second dose may be repeated in 20 minutes, if needed.
[X]	ondansetron (Zofran-ODT) disintegrating tablet	4 mg Every 1 hour PRN, Oral, nausea, vomiting, For 2 Doses, Oncology A second dose may be repeated in one hour, if nausea persists.

Time: _____ Date: _____ Physician's Signature: _____

BalladHealth Epic

Patient Identification

Form No. 3040017064
Date: 12/23/2021 CEOC Approved

PED COVID-19 Monoclonal Antibody Orders (Age less than 12 and Weight less than 40 kg) (3040017064)

- **THIS ORDER SET IS ONLY FOR USE WITH PATIENTS WHO ARE POSITIVE FOR COVID-19 AND NOT HOSPITALIZED.**
- **THIS SHOULD ONLY BE USED FOR PEDIATRIC PATIENTS AGE LESS THAN 12 YEARS OLD AND / OR WEIGHT LESS THAN 40 kg.**

Patient must **MEET CRITERIA** below:
- Mild to moderate symptoms
- At high risk for progressing to severe COVID-19 and / or hospitalization

Post-Exposure Prophylaxis Use:
For post-exposure prophylaxis of COVID-19 in individuals who are at high risk for progression to severe COVID-19, including hospitalization or death, and are:
- Not fully vaccinated or who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications)

AND
- Have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per CDC

OR
- Who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of COVID-19 infection in other individuals in the same institutional setting (for example, nursing homes, or prisons)

Monoclonal Antibody Criteria Review:
EXCLUSION CRITERIA:
- Patient hospitalized due to COVID-19
- Patients who require oxygen therapy due to COVID-19
- Patients on chronic oxygen therapy that requires an increase in baseline oxygen flow rate due to COVID-19
- **NOTE:** Extreme Limited Availability

INCLUSION CRITERIA:
- Order must be received within 8 days of symptom onset to ensure administration of monoclonal antibody within 10 days of symptom onset
- At high risk for progressing to severe COVID-19 and / or hospitalization

Yale / New Haven Health System Link	URL: "https://files-profile.medicine.yale.edu/documents/7801c631-3dcc-48fc-a438-3aa18f3b7130"
Bamlanivimab/estesevimab Health Care Providers EUA Fact Sheet	URL: "https://www.fda.gov/media/145802/download"
Bamlanivimab/etesevimab EAU Fact Sheet for Patients, Parents and Caregivers:	URL: "https://insideballadhealth.balladhealth.org/2/forms/BamlanivimabPatientCaregiverFactSheet.pdfv"
CDC growth charts	URL: "https://www.cdc.gov/growthcharts/clinical_charts.htm"
Informed Consent for Monoclonal Antibody Treatment - Pediatric	URL: "http://insideballadhealth.balladhealth.org/2/forms/MS-7745s.pdf"

Scheduling Referral

COVID-19 OP INFUSION - Virtual Health Enrollment

[X]	Covid-19 OP INFUSION-Virtual Health Enrollment	Referral reason - Specialty Services Required
[X]	Nursing Communication	Routine, Once, Starting S For 1 Occurrences May discharge to home after transfusion complete and vital signs stable

General

Verify Consent (Selection Required)

[X]	Verify Informed Consent for Infusion	Routine, Once, Starting S Procedure: monoclonal antibody infusion Proceduralist Obtained Informed Consent:

Code Status (Single Response) (Selection Required)

❍	Full Code / Attempt Resuscitation	Oncology
❍	DNAR / DNI - Allow Natural Death (Do Not Attempt Resuscitation / Do Not Intubate	Oncology
❍	Do Not Intubate (DNI) (May administer CPR and ACLS protocols but do not intubate.)	Oncology
❍	DNAR but May Intubate (No CPR / ACLS, but intubation due to respiratory failure is acceptable.)	Oncology
❍	DNAR / Cardiac Medications Only (May administer emergency medications only without CPR or intubation.)	Oncology
❍	DNAR / DNI - Comfort Measures Only (Aggressive treatment will be discontinued or not provided and only treatment to promote comfort will be delivered.)	Oncology
❍	Modified Code Status	May do: Modified Code Status - Use this order only if other code status orders do not meet the needs of the patient. Oncology

Nursing / Isolation Orders

[X]	**COMMUNICATION**: Immediately place patient in Enhanced Droplet Plus Eye Protection Isolation Status	Routine, Until discontinued, Starting S
[X]	**NOTIFY:** Facility Nursing Supervisor for Enhanced Droplet Plus Eye Protection Isolation Status	Routine, Until discontinued, Starting S
[X]	Place patient into COVID-19 designated bed / room	Routine, Until discontinued, Starting S
[X]	Enhanced Droplet Plus Eye Protection Isolation Status	Routine, Continuous

Pediatric Adverse Reaction Orders

FOR MILD ADVERSE SKIN AND RESPIRATORY SYMPTOMS / REACTION ORDERS (itching, hives, rash, and / or flushing, mild dyspnea, mild wheezing, or shortness of breath)
If stridor, utilize Severe Adverse Reaction Orders.

[X]	**STOP** the Infusion and Notify Ordering Provider **STAT**	STAT, Continuous, For infusion reaction
[X]	Notify Respiratory Therapy **STAT**	STAT, Once, Starting S For 1 Occurrences For infusion reaction Reason/s?
[X]	Vital Signs	Routine, Every 15 minutes Monitor Vital Signs every 5 minutes until within normal limits for mild adverse skin reaction (itching, hives, rash, and/or flushing) and respiratory symptoms (mild dyspnea, mild wheezing, or shortness of breath). Monitor Vital Signs every 2 to 5 minutes until within normal limits for severe adverse reaction (stridor, severe bronchospasm, hypoxemia, or hypotension)
[X]	Resume Infusion Only Upon Provider Approval	Routine, Until discontinued, Starting S Resume infusion only upon provider approval and 20 minutes after Vital Signs have returned to normal for mild adverse skin reaction (itching, hives, rash, and/or flushing) and respiratory symptoms (mild dyspnea, mild wheezing, or shortness of breath). **ABORT** infusion for severe adverse reaction (stridor, severe bronchospasm, hypoxemia, or hypotension)
[X]	Report Adverse Drug Reaction per Policy	Routine, Until discontinued, Starting S For infusion reaction. Complete after patient has been stabilized or transferred to higher level of care.

Pediatric Severe Adverse Reaction Orders

FOR SEVERE ADVERSE REACTION ORDERS: (stridor, severe bronchospasm, hypoxemia, or hypotension). Select Pediatric Adverse Reaction Orders in addition to these orders.

[X]	Perform ACLS or PALS Activities As Needed	STAT, Until discontinued, Starting S Perform ACLS or PALS activities as needed and activate emergency response for severe infusion reaction.
[X]	Maintain Airway	STAT, Until discontinued, Starting S For severe adverse infusion reaction.
[X]	Pediatric Oxygen Therapy	STAT, Continuous, Starting S Administering Device: Non Rebreather if (answer = Nasal Cannula) **Titration Instructions**: Initiate Oxygen via Nasal Cannula at 0.5 L/min and titrate at 0.5 L/min increments up to 2 L/min to reach target oxygen saturation range. Consult RT if patient is requiring 2 L/min or greater to reach target oxygen saturation.

	Weaning Instructions (DO NOT wean below current home oxygen settings): Once patient has achieved target saturation or greater, oxygen may be decreased by 0.5 LPM as tolerated to maintain target oxygen saturation until weaned to room air.
	if (answer = Venturi Mask)
	Venturi Mask Settings:
	Liters Per Minute:
	Fio2 %: 100
	Adjust FiO2 to keep O2 saturation:
	if (answer = Other)
	Keep Oxygen Saturation - Other (Specify):
	Adjust FiO2 to keep O2 saturation:
	Administer oxygen by non-rebreather mask (FiO2 100%) if bag mask or intubation is not required for severe adverse reaction orders.

[X] Abort Infusion	Routine, Continuous For Severe Adverse Reaction- Abort infusion.

IV Fluids

Insert and Maintain IV

❑ Insert and Maintain IV	**"And" Linked Panel**
❑ Insert Peripheral IV	STAT, Once, Starting S For 1 Occurrences
❑ Maintain IV Access	Routine, Until discontinued, Starting S
❑ Saline Lock IV	Routine, Once, Starting S For 1 Occurrences
❑ sodium chloride 0.9 % flush	3 mL As needed, Intravenous, line care, For 90 Days
❑ sodium chloride 0.9 % flush	3 mL 2 times daily, Intravenous, For 90 Days

Insert and Maintain IV

[X] Insert and Maintain IV	**"And" Linked Panel**
[X] Insert peripheral IV	STAT, Once, Starting S For 1 Occurrences
[X] Maintain IV access	Routine, Until discontinued, Starting S
[X] Saline lock IV	Routine, Once, Starting S For 1 Occurrences
[X] sodium chloride 0.9 % flush	3 mL As needed, Intravenous, line care, For 90 Days
[X] sodium chloride 0.9 % flush	3 mL 2 times daily, Intravenous, For 90 Days

Medications

Monoclonal Antibody Orders (Single Response) (Selection Required)

****MUST SELECT ONE OPTION BELOW BASED ON PATIENT'S ACTUAL WEIGHT****

❍ WEIGHT Greater than 40 kg - bamlanivimab 700 mg, etesevimab 1,400 mg in sodium chloride 0.9 % IVPB	Once, Intravenous, For 1 Doses Has the "Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of bamlanivimab and etesevimab" been reviewed? if (answer = No) Please provide additional information why requirement is not met. Has the information in the “Bamlanivimab and Etesevimab Fact Sheet for Patients and Patients/Caregivers” been provided to the patient/caregiver? if (answer = No) Please provide additional information why requirement is not met. Patient must meet at least one of the criteria below: [bamlanivimab]Ballad Health's allotment of this drug is to be used exclusively on patients that are residents of Tennessee or Virginia, please select which state this patient is a resident of:
❍ WEIGHT Greater than 20 kg to Less than 40 kg - bamlanivimab 350 mg, etesevimab 700 mg in sodium chloride 0.9 % IVPB	Once, Intravenous, For 1 Doses Has the "Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of bamlanivimab and etesevimab" been reviewed? if (answer = No) Please provide additional information why requirement is not met. Has the information in the “Bamlanivimab and Etesevimab Fact Sheet for Patients and Patients/Caregivers” been provided to the patient/caregiver? if (answer = No) Please provide additional information why requirement is not met. Patient must meet at least one of the criteria below: [bamlanivimab]Ballad Health's allotment of this drug is to be used exclusively on patients that are residents of Tennessee or Virginia, please select which state this patient is a resident of:

❍ WEIGHT Greater than 12 kg to 20 kg - bamlanivimab 175 mg, etesevimab 350 mg in sodium chloride 0.9 % IVPB	Once, Intravenous, For 1 Doses Has the "Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of bamlanivimab and etesevimab" been reviewed? if (answer = No) Please provide additional information why requirement is not met. Has the information in the “Bamlanivimab and Etesevimab Fact Sheet for Patients and Patients/Caregivers” been provided to the patient/caregiver? if (answer = No) Please provide additional information why requirement is not met. Patient must meet at least one of the criteria below: [bamlanivimab]Ballad Health's allotment of this drug is to be used exclusively on patients that are residents of Tennessee or Virginia, please select which state this patient is a resident of:
❍ WEIGHT Greater than 11 kg to 12 kg - bamlanivimab 138 mg, etesevimab 276 mg in sodium chloride 0.9 % IVPB	Once, Intravenous, For 1 Doses Has the "Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of bamlanivimab and etesevimab" been reviewed? if (answer = No) Please provide additional information why requirement is not met. Has the information in the “Bamlanivimab and Etesevimab Fact Sheet for Patients and Patients/Caregivers” been provided to the patient/caregiver? if (answer = No) Please provide additional information why requirement is not met. Patient must meet at least one of the criteria below: [bamlanivimab]Ballad Health's allotment of this drug is to be used exclusively on patients that are residents of Tennessee or Virginia, please select which state this patient is a resident of:

❍ WEIGHT Greater than 10 kg to 11 kg - bamlanivimab 126 mg, etesevimab 252 mg in sodium chloride 0.9 % IVPB	Once, Intravenous, For 1 Doses Has the "Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of bamlanivimab and etesevimab" been reviewed? if (answer = No) Please provide additional information why requirement is not met. Has the information in the “Bamlanivimab and Etesevimab Fact Sheet for Patients and Patients/Caregivers” been provided to the patient/caregiver? if (answer = No) Please provide additional information why requirement is not met. Patient must meet at least one of the criteria below: [bamlanivimab]Ballad Health's allotment of this drug is to be used exclusively on patients that are residents of Tennessee or Virginia, please select which state this patient is a resident of:
❍ WEIGHT Greater than 9 kg to 10 kg - bamlanivimab 114 mg, etesevimab 228 mg in sodium chloride 0.9 % IVPB	Once, Intravenous, For 1 Doses Has the "Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of bamlanivimab and etesevimab" been reviewed? if (answer = No) Please provide additional information why requirement is not met. Has the information in the “Bamlanivimab and Etesevimab Fact Sheet for Patients and Patients/Caregivers” been provided to the patient/caregiver? if (answer = No) Please provide additional information why requirement is not met. Patient must meet at least one of the criteria below: [bamlanivimab]Ballad Health's allotment of this drug is to be used exclusively on patients that are residents of Tennessee or Virginia, please select which state this patient is a resident of:

❍ WEIGHT Greater than 8 kg to 9 kg - bamlanivimab 102 mg, etesevimab 204 mg in sodium chloride 0.9 % IVPB	Once, Intravenous, For 1 Doses Has the "Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of bamlanivimab and etesevimab" been reviewed? if (answer = No) Please provide additional information why requirement is not met. Has the information in the “Bamlanivimab and Etesevimab Fact Sheet for Patients and Patients/Caregivers” been provided to the patient/caregiver? if (answer = No) Please provide additional information why requirement is not met. Patient must meet at least one of the criteria below: [bamlanivimab]Ballad Health's allotment of this drug is to be used exclusively on patients that are residents of Tennessee or Virginia, please select which state this patient is a resident of:
❍ WEIGHT Greater than 7 kg to 8 kg - bamlanivimab 90 mg, etesevimab 180 mg in sodium chloride 0.9 % IVPB	Once, Intravenous, For 1 Doses Has the "Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of bamlanivimab and etesevimab" been reviewed? if (answer = No) Please provide additional information why requirement is not met. Has the information in the “Bamlanivimab and Etesevimab Fact Sheet for Patients and Patients/Caregivers” been provided to the patient/caregiver? if (answer = No) Please provide additional information why requirement is not met. Patient must meet at least one of the criteria below: [bamlanivimab]Ballad Health's allotment of this drug is to be used exclusively on patients that are residents of Tennessee or Virginia, please select which state this patient is a resident of:

❍ WEIGHT Greater than 6 kg to 7 kg - bamlanivimab 78 mg, etesevimab 156 mg in sodium chloride 0.9 % IVPB	Once, Intravenous, For 1 Doses Has the "Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of bamlanivimab and etesevimab" been reviewed? if (answer = No) Please provide additional information why requirement is not met. Has the information in the “Bamlanivimab and Etesevimab Fact Sheet for Patients and Patients/Caregivers” been provided to the patient/caregiver? if (answer = No) Please provide additional information why requirement is not met. Patient must meet at least one of the criteria below: [bamlanivimab]Ballad Health's allotment of this drug is to be used exclusively on patients that are residents of Tennessee or Virginia, please select which state this patient is a resident of:
❍ WEIGHT Greater than 5 kg to 6 kg - bamlanivimab 66 mg, etesevimab 132 mg in sodium chloride 0.9 % IVPB	Once, Intravenous, For 1 Doses Has the "Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of bamlanivimab and etesevimab" been reviewed? if (answer = No) Please provide additional information why requirement is not met. Has the information in the “Bamlanivimab and Etesevimab Fact Sheet for Patients and Patients/Caregivers” been provided to the patient/caregiver? if (answer = No) Please provide additional information why requirement is not met. Patient must meet at least one of the criteria below: [bamlanivimab]Ballad Health's allotment of this drug is to be used exclusively on patients that are residents of Tennessee or Virginia, please select which state this patient is a resident of:

❍ WEIGHT Greater than 4 kg to 5 kg - bamlanivimab 54 mg, etesevimab 108 mg in sodium chloride 0.9 % IVPB	Once, Intravenous, For 1 Doses Has the "Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of bamlanivimab and etesevimab" been reviewed? if (answer = No) Please provide additional information why requirement is not met. Has the information in the “Bamlanivimab and Etesevimab Fact Sheet for Patients and Patients/Caregivers” been provided to the patient/caregiver? if (answer = No) Please provide additional information why requirement is not met. Patient must meet at least one of the criteria below: [bamlanivimab]Ballad Health's allotment of this drug is to be used exclusively on patients that are residents of Tennessee or Virginia, please select which state this patient is a resident of:
❍ WEIGHT Greater than 3 kg to 4 kg - bamlanivimab 42 mg, etesevimab 84 mg in sodium chloride 0.9 % IVPB	Once, Intravenous, For 1 Doses Has the "Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of bamlanivimab and etesevimab" been reviewed? if (answer = No) Please provide additional information why requirement is not met. Has the information in the “Bamlanivimab and Etesevimab Fact Sheet for Patients and Patients/Caregivers” been provided to the patient/caregiver? if (answer = No) Please provide additional information why requirement is not met. Patient must meet at least one of the criteria below: [bamlanivimab]Ballad Health's allotment of this drug is to be used exclusively on patients that are residents of Tennessee or Virginia, please select which state this patient is a resident of:

❍ WEIGHT Greater than 2 kg to 3 kg - bamlanivimab 30 mg, etesevimab 60 mg in sodium chloride 0.9 % IVPB	Once, Intravenous, For 1 Doses Has the "Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of bamlanivimab and etesevimab" been reviewed? if (answer = No) Please provide additional information why requirement is not met. Has the information in the “Bamlanivimab and Etesevimab Fact Sheet for Patients and Patients/Caregivers” been provided to the patient/caregiver? if (answer = No) Please provide additional information why requirement is not met. Patient must meet at least one of the criteria below: [bamlanivimab]Ballad Health's allotment of this drug is to be used exclusively on patients that are residents of Tennessee or Virginia, please select which state this patient is a resident of:
❍ WEIGHT Greater than 1.5 kg to 2 kg - bamlanivimab 21 mg, etesevimab 42 mg in sodium chloride 0.9 % IVPB	Once, Intravenous, For 1 Doses Has the "Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of bamlanivimab and etesevimab" been reviewed? if (answer = No) Please provide additional information why requirement is not met. Has the information in the “Bamlanivimab and Etesevimab Fact Sheet for Patients and Patients/Caregivers” been provided to the patient/caregiver? if (answer = No) Please provide additional information why requirement is not met. Patient must meet at least one of the criteria below: [bamlanivimab]Ballad Health's allotment of this drug is to be used exclusively on patients that are residents of Tennessee or Virginia, please select which state this patient is a resident of:

❍ WEIGHT 1 kg to 1.5 kg - bamlanivimab 15 mg, etesevimab 30 mg in sodium chloride 0.9 % IVPB	Once, Intravenous, For 1 Doses Has the "Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of bamlanivimab and etesevimab" been reviewed? if (answer = No) Please provide additional information why requirement is not met. Has the information in the “Bamlanivimab and Etesevimab Fact Sheet for Patients and Patients/Caregivers” been provided to the patient/caregiver? if (answer = No) Please provide additional information why requirement is not met. Patient must meet at least one of the criteria below: [bamlanivimab]Ballad Health's allotment of this drug is to be used exclusively on patients that are residents of Tennessee or Virginia, please select which state this patient is a resident of:

Medications - Supplemental (Selection Required)

[X] acetaminophen (Tylenol) oral / rectal

Reminder: Do not administer rectal suppositories if patient is neutropenic. Neutropenia is defined as an absolute neutrophil count less than 500 cells / uL.

❑ acetaminophen (Tylenol) 160 mg / 5 mL oral liquid	15 mg / kg Every 4 hours PRN, Oral, mild pain (1 to 3), fever greater than 100.4 F, For 90 Days Oral route is preferred over rectal route.
❑ acetaminophen (Tylenol) chewable tablet	15 mg / kg Every 4 hours PRN, Oral, mild pain (1 to 3), fever greater than 100.4 F, For 90 Days Oral route is preferred over rectal route.
❑ acetaminophen (Tylenol) tablet	15 mg / kg Every 4 hours PRN, Oral, mild pain (1 to 3), fever greater than 100.4 F, For 90 Days Oral route is preferred over rectal route.
❑ acetaminophen (Tylenol) tablet	325 mg Every 4 hours PRN, Oral, mild pain (1 to 3), fever greater than 100.4 F, For 90 Days Oral route is preferred over rectal route.
❑ acetaminophen (Tylenol) tablet	650 mg Every 4 hours PRN, Oral, mild pain (1 to 3), fever greater than 100.4 F, For 90 Days Oral route is preferred over rectal route.
❑ acetaminophen (Tylenol) suppository	15 mg / kg Every 4 hours PRN, Rectal, mild pain (1 to 3), fever greater than 100.4 F, For 90 Days Oral route is preferred over rectal route.

[X] ondansetron (Zofran-ODT) disintegrating tablet	0.15 mg / kg Every 1 hour PRN, Oral, nausea, vomiting, For 2 Doses A second dose may be repeated in one hour if nausea persists.

Medications for Adverse Reactions

[X]	diphenhydrAMINE (Benadryl) injection	1 mg / kg Once as needed, Intravenous, other, mild adverse skin reactions, mild adverse respiratory reactions, or severe adverse reactions (Maximum dose 50 mg), For 1 Doses
[X]	methylPREDNISolone sodium succinate (Solu-MEDROL)	1 mg / kg Once as needed, Intravenous, mild adverse respiratory reactions or severe adverse reactions (Maximum dose 125 mg), For 1 Doses
[X]	sodium chloride 0.9 % bolus	20 mL / kg Once as needed, Intravenous, for 30 Minutes, severe adverse reactions, For 1 Doses **(Maximum 1000 mL)**
[X]	EPINEPHrine (Adrenalin) injection	0.01 mg / kg Once as needed, Intramuscular, other, severe adverse reactions, For 1 Doses **(Maximum dose 0.3 mg)**

Time:_____ Date: _____ Physician's Signature:_____