Adult Outpatient Anti-SARS CoV 2 Monoclonal Antibody Administration

SARS COV-2 monoclonal antibody therapy is available at Kaleida as an outpatient treatment for patients who are EITHER COVID-19 positive patients at high risk of deterioration or post-exposure prophylaxis consistent with the Emergency Use Authorization (EUA).

Before referring a patient for treatment please familiarize yourself with the Fact Sheet for Health Care Providers for REGEN-COV (Casirivimab + Imdevimab):

This is not an FDA approved therapy but rather is offered under an emergency use authorization (EUA). As such it’s important to engage patients/caregivers in shared decision making by providing them with the necessary information to make an informed decision. The EUA specifically requires the “Fact Sheet for Patients, Parents and Caregivers” be provided to the patient/caregiver and documentation of the following made in the medical record.

- Given the “Fact Sheet for Patients, Parents and Caregivers”,
- Informed of alternatives to receiving REGEN-COV, and
- Informed that REGEN-COV is an unapproved drug that is authorized for use under this EUA

Key points

<table>
<thead>
<tr>
<th>Indication</th>
<th>COVID Positive</th>
<th>Post-Exposure Prophylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criteria</td>
<td>High risk of progression to severe disease who do not require new or increasing oxygen requirements (see checklist)</td>
<td>Not fully vaccinated OR Not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination</td>
</tr>
<tr>
<td>COVID Test</td>
<td>Positive Test at the time of referral</td>
<td>N/A</td>
</tr>
<tr>
<td>Treatment Window</td>
<td>Within 10 days of symptom onset</td>
<td>As soon as possible after exposed to a COVID positive individual consistent with close contact criteria OR at high risk for exposure to infected individuals</td>
</tr>
<tr>
<td>Referral Process</td>
<td>Patient must be seen (may be telehealth) by the provider on the day of referral to ensure referral is appropriate. If done via telehealth the consent may be done as a phone consent with a witness – write phone consent on patient signature line, patient to co-sign when they arrive for their infusion.</td>
<td>Kaleida Health’s Consent for Chemotherapy/Biologic Agent</td>
</tr>
</tbody>
</table>

Kaleida Health’s Consent for Chemotherapy/Biologic Agent
Ordering Process

**KALEIDA PROVIDERS:** Direct referral will be restricted to providers with admitting or referring privileges at Kaleida who are able to independently order the medication.

Please complete the attached Referral Packet *in its entirety* and fax to DeGraff Admissions (see packet for more instructions).

If there are any questions or discrepancies, we will reach out the contacting provider for clarification.

If approved, we will reach out to the patient directly and schedule their appointment. Due to very limited resource, many eligible may not receive this investigational drug. If it is unavailable the referring provider will be notified at the time of referral.

**NON-KALEIDA PROVIDERS:** Please refer patients through Emergency Medicine telemedicine services


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1. Adult Monoclonal Antibody Referral Packet.................................................................3

   All of the following are required:

   a. Adult Monoclonal Antibody Referral Packet (KH24918).................................3
   b. Checklist for Emergency Use Authorization Criteria (KH24919)..................4
   c. Orders (KH24917).................................................................................................5
   d. Consent (KH00049-035)....................................................................................6

2. Links to patient and provider information.....................................................................7
Kaleida Health

ADULT MONOCLONAL ANTIBODY REFERRAL PACKET

Patient Name ________________________ DOB __________________

Address

STREET __________ CITY ______ STATE __ ZIP __________

Patient emergency contact and phone # ______________________

Date of symptom onset __________________ Date of SARS CoV2 PCR __________________

Any patient mobility limitations ______________________________

Allergies/any history of anaphylaxis __________________________

Diagnosis Code:

☐ Covid Positive – ICD 10 Code U07-1
☐ Contact with and (suspected) exposure to COVID-19 – Z20.682

Referring/Ordering Physician ________________________________

Facility/Location ______________________________ Phone # __________________

Items to be sent with this intake form to DeGraff admissions prior to registration:

☐ Completed checklist (KH24919)
☐ Order for infusion, premedication or any other requirements (KH24917)
☐ Administration Consent for Chemotherapy/Biologic Agent (KH00049-035)

Please review and fax all paperwork to the DeGraff admission M-Th 7-3:30

Fax # 716-690-2263

Phone # 716-690-2266

Adult patients to report directly to DeGraff infusion location at scheduled appointment time.

Pediatric patients to report directly to OCH Emergency department at scheduled appointment time.
Criteria met under EUA (Emergency Use Authorization) for monoclonal antibody administration as defined below

The following medical conditions or other factors may place adults and pediatric patients (age 12-17 years and weighing at least 40 kg) at higher risk for progressing to severe COVID-19:

- Older age (for example age ≥65 years of age)
- Obesity or being overweight
  - adults with BMI >25 kg/m²
  - age 12-17, have BMI ≥85th percentile for their age and gender based on CDC growth charts [https://www.cdc.gov/growthcharts/clinical_charts.htm](https://www.cdc.gov/growthcharts/clinical_charts.htm)
- 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))

Documentation of shared decision making regarding EUA status and consent

The following have been discussed and understood by the patient or caregiver:

- Informed that monoclonal antibody therapy is an unapproved drug that is authorized for use under Emergency Use Authorization
- Informed of alternatives to receiving authorized monoclonal antibody therapy
- Patient or caregiver have been provided the “Fact Sheet for Patients, Parents and Caregivers” (attached) and all questions answered to their satisfaction
- Pregnancy test offered to women who may be pregnant (available to order on the attached Monoclonal Antibody Infusion Orders KH24917)
- Signed Administration Consent for Chemotherapy/Biologic Agent (KH00049-035)

Provider Name

Signature

Date

Time

KH24919 Rev. 05/19/21
Kaleida Health

SARS CoV2 MONOCLONAL ANTIBODY INFUSION ORDERS

Labs
For Female patients except those with a hysterectomy or post menopausal
☑ POC Pregnancy Screen/Urine
☐ HCG Pregnancy Test Qualitative Urine, Stat, Onco, Urine Random

Vital Signs
☑ Obtain vital signs immediately prior to administration and then q 15 minutes x 2 and q 30 minutes x 2
(i.e. at 15, 20, 60 and 90 minutes from initiation of administration).
☑ Notify Provider vital signs. Changes in vital signs (+/-10%) during and immediately following medication,
T > 100.5 F (38°C)
☑ Notify Provider and stop the intravenous infusion. Observe for medication reaction: fever, chills, nausea, headache,
bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, dizziness during
and immediately following medication.

Medications

Premedications
If ordered, must be administered at least 30 minutes prior to starting the medication:
☐ diphenhydRAMINE (Benadryl) 25 mg -OR- 50 mg, cap, oral, Onco, Indication: allergy prophylaxis
☐ acetaminophen (Tylenol) 650 mg, tab, oral, Onco, Indication: allergy prophylaxis
☐ ondansetron (Zofran ODT) 4 mg, tab DIS, oral, Onco, Indication: nausea prophylaxis
☐ ondansetron (Zofran) 4 mg, injection, IV push, Onco, Indication: nausea prophylaxis

Emergency Allergic Reaction Medications
If patient develops any signs of hypersensitivity reaction, stop the intravenous infusion, contact provider and administer:
☑ methylPREDNISolone (SOLU-Medrol) 40 mg, injection, IV push, Onco, PRN, Indication: allergic reaction
☑ diphenhydRAMINE (Benadryl) 50 mg, injection, IV push, Onco, PRN, Indication: allergic reaction
☑ EPINEPHrine 1 mg/mL injectable solution 0.3 mg, injection, IM, Onco, PRN, Indication: allergic reaction

Choose ONE of the following indications for the SARS CoV2 monoclonal antibody: (Pharmacy to dose per EUA)
☐ Treatment of a known COVID positive patient (Administer intravenously unless unable to establish access)
☐ Post exposure prophylaxis (Initial)
   ☐ Check here if subcutaneous route is preferred
☐ Post exposure prophylaxis (Subsequent – repeat close)
   ☐ Check here if subcutaneous route is preferred

Discharge instructions for patients to maintain quarantine

☐ TORB From_________ Date_________ Time_________
Signature_________

Date_________ Time_________
Print Name/Stamp_________
Signature_________

Orders
NOTED BY RNI Date_________ Time_________
Signature_________

ORDERS

K0D4917 Rev 00/16/21

Place STAT barcode sticker within this box only on form copy being scanned
ADMINISTRATION CONSENT FOR
CHEMOTHERAPY/BIOLOGIC AGENT

Patient's Room:

1. I have been informed by ______________________, that I have been diagnosed with ______________________ and that treatment with chemotherapy or other medications to treat my condition is recommended. I give permission to Kaleida Health under the direction of my physician, to provide me with the following therapy:

2. I have received information about my condition, the nature and purpose of the treatment noted above, expected benefits, related risks and the possibility of complications from the treatment. I understand that this treatment may have significant side effects and that some of the side effects can be life threatening. The risks associated with the chemotherapy may be included, but not limited to, those listed below:
   - Allergic or infusion reaction
   - Increased risk of bleeding
   - Nausea and vomiting
   - Death
   - Other
   - Increased risk of infection
   - Organ damage
   - Infertility
   - Tiredness/Fatigue
   - Mouth sores
   - Secondary cancers

3. I understand that my condition may change, requiring modification to the planned chemotherapy regimen. I authorize my physician and his/her associates to modify my chemotherapy regimen as they deem necessary and advisable in their professional judgement, provided that the reason for such change is discussed with me prior to the change. I also understand that my physician may stop chemotherapy treatment if he or she determines that it is not benefiting me or that the risk of continued treatment outweighs the benefits.

4. If the prescribed medication is to be given by peripheral intravenous infusion, I understand that I may experience discomfort in the region of the intravenous medication injection, ulcer formation, burns and/or tissue damage from extravasation or infiltration of the medication into surrounding tissue.

5. Other treatments or options for my condition and the benefits and risks of these treatments have been discussed with me. I am choosing not to pursue these options at this time. I understand that my physician cannot guarantee that the treatment I have chosen will be successful. I understand that although the treatment is anticipated to help me, it may not be effective for this purpose and may not help me.

6. I am aware that my treatment involves risk to an unborn child. I understand that my treatment may involve risk to my partner because some medications may be present in bodily fluids. I have been advised to use appropriate birth control and to use a barrier method, such as a condom, to prevent pregnancy and chemotherapy exposure to my partner. I understand that the treatment may affect my ability to reproduce in the future and I have discussed this issue with my physician.

7. I have had enough time to discuss my condition and treatment options with my physician and his/her associates and all my questions have been answered to my satisfaction.

By signing this consent, I confirm that I have been given enough information to make an informed decision about the treatment described above.

Date ____________________  Time ____________________  Patient/Parent/Legal Guardian/Surrogate Agent Signature ____________________

Date ____________________  Time ____________________  Witness Signature ____________________

PHYSICIAN/CREDENTIALED PROVIDER ATTESTATION

I hereby attest that I have reviewed the proposed operation, procedure and/or treatment with the patient or patient’s parent, guardian, surrogate or agent along with the indications for same, as well as the reasonably foreseeable risks, benefits, limitations and potential complications of said operation, procedure and/or treatment. I have further reviewed treatment alternatives with the patient or patient’s parent, guardian, surrogate or agent, including the option of no treatment. The patient and/or the patient’s parent, guardian, surrogate or agent have also been afforded the opportunity to ask questions regarding the above and have those questions answered prior to the procedure taking place.

Date ____________________  Time ____________________  Physician/Credentialed Provider Signature ____________________  Physician/Credentialed Provider Name ____________________

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**Link to Fact Sheet for Patients/Caregivers**

https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-patient.pdf (English)


**Link to Fact Sheet for Healthcare Provider**