Monoclonal Antibody Treatment for Adults with COVID-19

SARS COV-2 monoclonal antibody therapy is available at Kaleida as an outpatient treatment intended for COVID-19 positive patients at high risk of deterioration 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):

Key points:
1. This is authorized for outpatient therapy only.
2. Authorized for patient at high risk of deterioration (see provider fact sheet) who do not require new or increasing oxygen requirements.
3. Patient must have a positive SARS COV2 result at the time of referral.
4. 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.
5. Patient must be receive the treatment within 10 days of symptom onset.
6. This is not an FDA approved therapy rather offered under emergency use authorization (EUA), as such it’s important to engage patients or caregivers in shared decision making. This includes providing patient/caregiver fact sheet and explaining the meaning of EUA status, potential risks (chiefly anaphylaxis) and benefits (study demonstrated decreased hospitalizations) and discuss alternative treatment options. While consent is not formally required under the EUA, we request you ensure your patients or their caregivers are aware of the aforementioned information and complete Kaleida Health’s Administration Consent for Chemotherapy/Biologic Agent provided.

If considering treatment for your patient, 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.

*Please note, referral will be restricted to providers with admitting or referring privileges at Kaleida who are able to independently order the medication. There will be no onsite provider available to place the order.
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   e. Consent (KH00049-035)..........................................................................................8

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Adult Monoclonal Antibody Referral Packet

Five Pages + additional documents requested
This packet includes form numbers KH24918, KH24919, KH24920, KH24917 + requested documents

Patient Name ___________________________ DOB _______________________

Patient emergency contact and phone number _______________________________________

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

Referring/Ordering Physician _____________________________________________________

Facility/Location ___________________________ Phone # ___________________________

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

___ Completed checklist (KH24919)

___ Completed provider note (KH24920) or equivalent

___ Order for infusion, premedication or any other requirements (KH24917)

___ Administration Consent for Chemotherapy/Biologic Agent (KH00049-035)

___ Demographic form including insurance information (KH01181)

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.

Outpatient SARS CoV Monoclonal Antibody Orders
Version 4 Updated 7/20/2021
**CHECKLIST FOR EMERGENCY USE AUTHORIZATION OF MONOCLONAL ANTIBODY THERAPY IN COVID**

**Criteria met under EUA (Emergency Use Authorization) for monoclonal antibody administration as defined below**

<table>
<thead>
<tr>
<th>Check all that apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Older age (for example age ≥65 years of age)</td>
</tr>
<tr>
<td>☐ Obesity or being overweight</td>
</tr>
<tr>
<td>☐ Adults with BMI &gt;25 kg/m²</td>
</tr>
<tr>
<td>☐ Age 12-17, have BMI ≥85th percentile for their age and gender based on CDC growth charts</td>
</tr>
<tr>
<td><a href="https://www.cdc.gov/growthcharts/clinical_charts.htm">https://www.cdc.gov/growthcharts/clinical_charts.htm</a></td>
</tr>
<tr>
<td>☐ Pregnancy</td>
</tr>
<tr>
<td>☐ Chronic kidney disease</td>
</tr>
<tr>
<td>☐ Diabetes</td>
</tr>
<tr>
<td>☐ Immunosuppressive disease or immunosuppressive treatment</td>
</tr>
<tr>
<td>☐ Cardiovascular disease (including congenital heart disease) or hypertension</td>
</tr>
<tr>
<td>☐ Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)</td>
</tr>
<tr>
<td>☐ Sickle cell disease</td>
</tr>
<tr>
<td>☐ Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)</td>
</tr>
<tr>
<td>☐ Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19))</td>
</tr>
</tbody>
</table>

**Documentation of shared decision making regarding EUA status and consent**

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

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**Outpatient SARS CoV Monoclonal Antibody Orders**

**Version 4 Updated 7/20/2021**

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**Provider Name**

**Signature**

**Date**

**Time**
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
   - Nausea and vomiting
   - Death
   - Increased risk of bleeding
   - Organ damage
   - Other
   - Altered blood cell count/anemia
   - Increased risk of infection
   - Secondary cancers
   - Diarrhea
   - Infertility
   - Tiredness/Fatigue
   - Hair loss
   - Mouth sores
   - Secondary cancers
   - Other

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 outweigh 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/CREDENTIALLED 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/Credentialled Provider Signature ______________________

Date ___________ Time ___________ Physician/Credentialled Provider Name Print Name ______________________
Labs
For Female patients except those with a hysterectomy or post menopausal

- POC Pregnancy Screen/Urine
- HCG Pregnancy Test Qualitative Urine, Stat, Once, Urine Random

Vital Signs
- Vital Signs including pulse oximetry
  - Upon initiation of infusion: Pre-infusion, every 15 min x 1 hour, then every 30 min x 2 after infusion has completed.
- Notify Provider Vital Signs
  - Changes in vital signs (+/- 10%) during and immediately following infusion, T > 100.5°F (38°C)
- Notify Provider and stop infusion
  - Observe for infusion reaction: fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, dizziness during and immediately following infusion.

Medications
Premedications
If ordered, must be administered at least 30 minutes prior to starting the infusion.

- diphenhydrAMINE (Benadryl) 25 mg, cap, oral, Once, Indication: allergy prophylaxis
- diphenhydrAMINE (Benadryl) 50 mg, cap, oral, Once, Indication: allergy prophylaxis
- acetaminophen (Tylenol) 650 mg, tab, oral, Once, Indication: allergy prophylaxis
- ondansetron (Zofran CDT) 4 mg, tab DIS, oral, Once, Indication: nausea prophylaxis
- ondansetron (Zofran) 4 mg, injection, IV push, Once, Indication: nausea prophylaxis

Emergency Allergic Reaction Medications
If patient develops any signs of hypersensitivity reaction, stop infusion, contact provider and administer:

- methylPREDNISolone (SOLU-Medrol) 40 mg, injection, IV push, Once, PRN, Indication: allergic reaction
- diphenhydrAMINE (Benadryl) 50 mg, injection, IV push, Once, PRN, Indication: allergic reaction
- EPINEPHrine 1 mg/mL injectable solution 0.3 mg, injection, IM, Once, PRN, Indication: allergic reaction

Infusion
- casirivimab 600 mg and imdevimab 600 mg, injection, IV piggyback, Once, infuse over 30 minutes
  - casirivimab and imdevimab must be administered together after dilution by IV infusion. Use a 0.2 micron filter.
- sodium chloride 0.9% 50 mL, injection, IV piggyback, Once, Indication: line flush
  - Flush at same rate as monoclonal antibody therapy following infusion, do not administer for subcutaneous dose

Subcutaneous – only if IV route is unavailable
- casirivimab 600 mg and imdevimab 600 mg, injection, subcutaneous, Once
  - Dispense and administer as four separate 2.5 mL syringes.

Discharge instructions for patients to maintain quarantine

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Khe4917 Rev. 06/15/21
Link to Fact Sheet for Patients, Parents and Caregivers

Emergency Use Authorization (EUA) of Casirivimab with Imdevimab for COVID-19

Link to Fact Sheet for Healthcare Provider