**Updates to Outpatient IV Remdesivir Workflow at SLU**

Effective February 27, 2023, the process for ordering and scheduling outpatient IV remdesivir will be modified to integrate into existing clinic workflows. Infectious Diseases should be contacted to review use of IV remdesivir and discuss duration of therapy, but orders and scheduling of IV remdesivir will be managed by the primary teams.

1. Primary team identifies Covid+ patient who is at high risk for progression to severe Covid and who has contraindications to use of Paxlovid and reviews eligibility criteria (page 2).
2. Primary team contacts the On-Call Infectious Disease provider (as per Bellboy) to discuss IV remdesivir and planned duration of therapy (page 3).
3. Primary team discusses the plan for outpatient IV remdesivir with patient and confirms that the patient can return for consecutive days of therapy. If this is not feasible, an alternative treatment plan should be discussed (e.g. molnupiravir and plan to seek care should symptoms progress).
4. Primary team places order for IV remdesivir using FHCC OP Remdesivir supportive care plan
   a. Name of consulting ID provider is required in the order
   b. For patients initiated on remdesivir in the **outpatient clinic**, remdesivir is dosed as a **200 mg IV loading dose followed by 100 mg IV daily maintenance dose**
   c. For patients initiated on remdesivir in the **hospital and discharged to the outpatient clinic for continuation of therapy**, remdesivir should be ordered as a **100 mg IV daily maintenance dose**.
5. Primary team schedules appointments for IV remdesivir infusion.
   a. (See page 12 for scheduling workflow)
Outpatient IV Remdesivir Eligibility Criteria

Outpatient IV remdesivir is prioritized for **newly symptomatic patients who are at high risk for progression to severe COVID-19 who have contraindications to nirmatrelvir/ritonavir (Paxlovid)**. Based on a clinical trial and several observational studies, the primary benefit of remdesivir when used in the outpatient setting is to reduce the risk of progression to more serious illness, including hospitalization and death. It is unknown whether remdesivir will improve time to symptom recovery or viral clearance among outpatients. Patients must be 18 years and older and able to return for consecutive days of therapy.

**Decisions regarding treatment should be discussed with the On Call Infectious Disease Provider (as per Bellboy) and may be contingent on available slots for infusion.**

<table>
<thead>
<tr>
<th>Mild-Moderate Acute COVID-19 Infection</th>
<th>Persistent Covid-19 Infection</th>
</tr>
</thead>
</table>
| • At high risk for severe COVID-19 infection (NIH Tier 1 and 2 criteria*)
• Within 7 days of symptom onset
• Ineligible to receive Paxlovid (e.g. contraindicating drug-drug interaction where medication cannot be held/ dose adjusted; unable to take PO)
• Must be able to return for multiple days of consecutive therapy** | • Characterized by prolonged viral shedding (PCR positivity > 30 days) and persistent/progressive respiratory symptoms but not requiring hospitalization (particularly those unable to receive paxlovid through eIND mechanism)
• Regardless of time from symptom onset or history of prior treatment
• Must be able to return for multiple days of consecutive therapy |

*Please see page 3 for NIH Tier 1 and 2 criteria

**For high-risk patients with mild-moderate acute COVID-19 infection are unable to return for multiple days of consecutive therapy and who cannot receive Paxlovid, molnupiravir should be recommended instead.
Duration of Therapy

The optimal duration of therapy for IV remdesivir when used as early treatment for immunocompromised outpatients is unclear. The PINETREE Study found that a 3-day course of remdesivir decreased hospitalization or death among high-risk, unvaccinated outpatients by 87% when compared to placebo when given within 7 days of symptom onset. However, patients with cancer or underlying immunocompromise represented only about 5% of the study population so it is difficult to know whether these findings can be extrapolated to these groups. There are 2 observational studies in solid organ transplant recipients indicating that a 3-day course of IV remdesivir administered within 7 days of symptom onset significantly reduced the rate of hospitalization; notably, in one study where vaccination status was reported, ≥ 90% of patients had received 3 doses of vaccine. There are no data to guide duration of therapy for patients with persistent symptomatic Covid infection being treated remdesivir. It is unknown whether remdesivir will improve symptom recovery or facilitate viral clearance. We suggest the following general approaches to duration of therapy.

<table>
<thead>
<tr>
<th>Duration of Therapy</th>
<th>Patient Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 days</td>
<td>Solid tumor, benign heme on immunosuppression (e.g. tacrolimus/cyclosporine)</td>
</tr>
<tr>
<td>5 days</td>
<td>Heme malignancy, BMT/ CAR T cell therapy, receipt of anti-CD20 therapy within past year</td>
</tr>
<tr>
<td>7-10 days</td>
<td>Review on case-by-case basis with infectious diseases (e.g. persistent symptomatic Covid infection)</td>
</tr>
</tbody>
</table>

References:
2. Solera JT et al. Short-course Early Outpatient Remdesivir Prevents Severe Disease due to COVID-19 in Organ Transplant Recipients During the Omicron BA.2 Wave. American Journal of Transplantation
3. Colaneri M et al. Early remdesivir to prevent severe COVID-19 in recipients of solid organ transplant: a real-life study from Northern Italy.
**Covid Therapeutics: NIH Prioritization Tiers**

As of March 8, 2022, FHCC uses the following NIH criteria to prioritize those patients for use of Covid therapeutics based on local supply and guidance developed by the NIH on [Covid therapeutics prioritization](#). We will continue to reassess prioritization criteria based on supply and epidemiology of local variants.

<table>
<thead>
<tr>
<th>Tier 1 (mAb or Paxlovid)</th>
<th>Immunocompromised individuals not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to their underlying conditions, regardless of vaccine status (see Immunocompromising Conditions below); or Unvaccinated individuals at the highest risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years with additional risk factors).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tier 2 (mAb or Paxlovid)</td>
<td>Unvaccinated individuals at risk of severe disease not included in Tier 1 (anyone aged ≥65 years or anyone aged &lt;65 years with clinical risk factors*)</td>
</tr>
</tbody>
</table>
| Tier 3 (Paxlovid)       | Vaccinated individuals at high risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years with clinical risk factors)  
**Note:** Vaccinated individuals who have not received a COVID-19 vaccine booster dose are likely at higher risk for severe disease; patients in this situation within this tier should be prioritized for treatment. |
| Tier 4 (Paxlovid)       | Vaccinated individuals at risk of severe disease (anyone aged ≥65 years or anyone aged <65 with clinical risk factors)  
**Note:** Vaccinated individuals who have not received a COVID-19 vaccine booster dose are likely at higher risk for severe disease; patients in this situation within this tier should be prioritized for treatment. |

*Molnupiravir* may be used for all tiers only if monoclonal antibodies and paxlovid cannot be used and patient meets molnupiravir eligibility criteria.
## Tier 1 immunocompromising conditions*

<table>
<thead>
<tr>
<th>Moderate to Severe Immunosuppression</th>
<th>Severe Immunosuppression</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Been receiving active cancer treatment for tumors or cancers of the blood</td>
<td>• Patients who are within 1 year of receiving B-cell depleting therapies (e.g., rituximab, ocrelizumab, ofatumumab, alemtuzumab)</td>
</tr>
<tr>
<td>• Received an organ transplant and are taking medicine to suppress the immune system</td>
<td>• Patients receiving Bruton tyrosine kinase inhibitors (Acalabrutinib, Ibrutinib, Zanubrutinib)</td>
</tr>
<tr>
<td>• Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system</td>
<td>• Chimeric antigen receptor T cell recipients (CAR-T cells)</td>
</tr>
<tr>
<td>• Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)</td>
<td>• Post-hematopoietic cell transplant recipients who have chronic graft versus host disease or who are taking immunosuppressive medications for another indication</td>
</tr>
<tr>
<td>• Advanced or untreated HIV infection</td>
<td>• Patients with hematologic malignancies who are on active therapy</td>
</tr>
<tr>
<td>• Active treatment with high-dose corticosteroids or other drugs that may suppress immune response (e.g., prednisone 20mg daily or equivalent x 14 days, tacrolimus, sirolimus, MMF, TNF- alpha inhibitors)</td>
<td>• Lung transplant recipients</td>
</tr>
<tr>
<td></td>
<td>• Patients who are within 1 year of receiving a solid-organ transplant (other than lung transplant)</td>
</tr>
<tr>
<td></td>
<td>• Solid-organ transplant recipients with recent treatment for acute rejection with T or B cell depleting agents</td>
</tr>
<tr>
<td></td>
<td>• Patients with severe combined immunodeficiencies</td>
</tr>
<tr>
<td></td>
<td>• Patients with untreated HIV who have a CD4 T lymphocyte cell count &lt;50 cells/mm3</td>
</tr>
</tbody>
</table>
EPIC TIP SHEET:

-Click on “supportive plan 1”. You may need to use “supportive plan 2” dependent on if patient already has existing supportive treatment plans.
- Click on “Create a new plan”
- Type “Remdesivir”
Plan will automatically populate into a “10 day” course. Please delete additional days at the bottom using the “x” bottom on the far right. Scroll down to start deleting on day 10.
- The 200 mg dose should only be given as the initial loading dose, all subsequent doses should be the 100 mg dose. If a patient has already received the 200 mg loading dose while inpatient and is completing the remaining doses as an outpatient, the 100 mg dose should be selected.
- The remdesivir portion of the order requires an ID provider name. Enter the name of the ID provider you spoke with in the appropriate box.
### Treatment Plan Manager - FHCC OP Remdesivir

**Patient Information:**
- **Name:** Shoshonee S. Zillas
- **Age:** 102 years old
- **DOB:** 2/17/1937
- **Weight:** 81.6 kg
- **Height:** 5.6 ft
- **BMI:** 21.4

**Medications:**
- **Remdesivir (Reclatis):** 200 mg in sodium chloride 0.9% 250 ml IV PB
  - 200 mg administered every 8 hours for 5 days. Once started, treatment cannot be suspended, and dosing cannot be reduced. This dose is calculated based on a body surface area of 0.5 m². It is only compatible with 0.9% NaCl.

**Infusion Order:**
- **Signature:**
  - Date: 1/11/2023
  - Signature: [Signature]
  - Date: 1/15/2023

**Scheduling:**
- **Cycle 1:** 1/12/2023 through 1/16/2023 (5 days) Planned
- **Day 1, Cycle 1:** Planned for 1/13/2023

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**Side Effects:**
- **Mild:** Headache, Fatigue, Nausea
- **Severe:** Severe headache, rash, flushing, angioedema, hepatitis

**Allergies:**
- **Hypersensitivity:** None

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**General Instructions:**
- **Infusion:** Over 30 minutes, starting at treatment start time. For 1 dose, Infectious Disease Consult Required. Name of referring provider, order, and patient data.
- **Vital Signs:** None needed.
- **Labor:** Comprehensive metabolic panel, ESR, CRP, LFTs, PT/PTT

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**Other:**
- **Medication:** Remdesivir (Reclatis) 200 mg in sodium chloride 0.9% 250 ml IV PB

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**Signatures:**
- [Signature] 1/11/2023
- [Signature] 1/15/2023

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**Other Information:**
- **DOSING:** Administer every 8 hours for 5 days.
- **VITAL SIGNS:** None needed.
- **LABS:** Comprehensive metabolic panel, ESR, CRP, LFTs, PT/PTT

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**Notes:**
- **Dosing:** Administer every 8 hours for 5 days.
- **VITAL SIGNS:** None needed.
- **LABS:** Comprehensive metabolic panel, ESR, CRP, LFTs, PT/PTT

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**Signatures:**
- [Signature] 1/11/2023
- [Signature] 1/15/2023
Remdesivir workflow

Provider discusses eligibility and confirms interests in Remdesivir. Primary doctor will place order that will route to primary PCC’s work queue for scheduling. Provider to alert PCC/CNC of order.

Scheduler will email the InfusionTC inbox with subject line Remdesivir, patients u-number and duration of treatment.

Infusion same day PAC will reach out to 8NE for availability, confirm dates and times with 8NE Charge, schedule patient for full course and email PCC with dates and times.

*If no availability at 8NE, reach out to IMTX scheduling for availability and assistance in scheduling*

PCCs will confirm appointments with patient.

*If infusion TC does not reply within an hour of Remdesivir request please escalate to the infusion-ctu-leadership@seattlecca.org email*