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*. Additional eligibility will be considered for immunosuppressed patients with persistent SARS-CoV-2 infection characterized by persistent/progressive respiratory symptoms and prolonged viral shedding. **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.**

Mild-Moderate Acute COVID-19 Infection	**Persistent Covid-19 Infection**
• 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.[1] 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.[2,3] 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.

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

References:

1. Gottlieb RL et al. Early Remdesivir to Prevent Progression to Severe COVID-19 in Outpatients NEJM 2022; 386:305-15.
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.

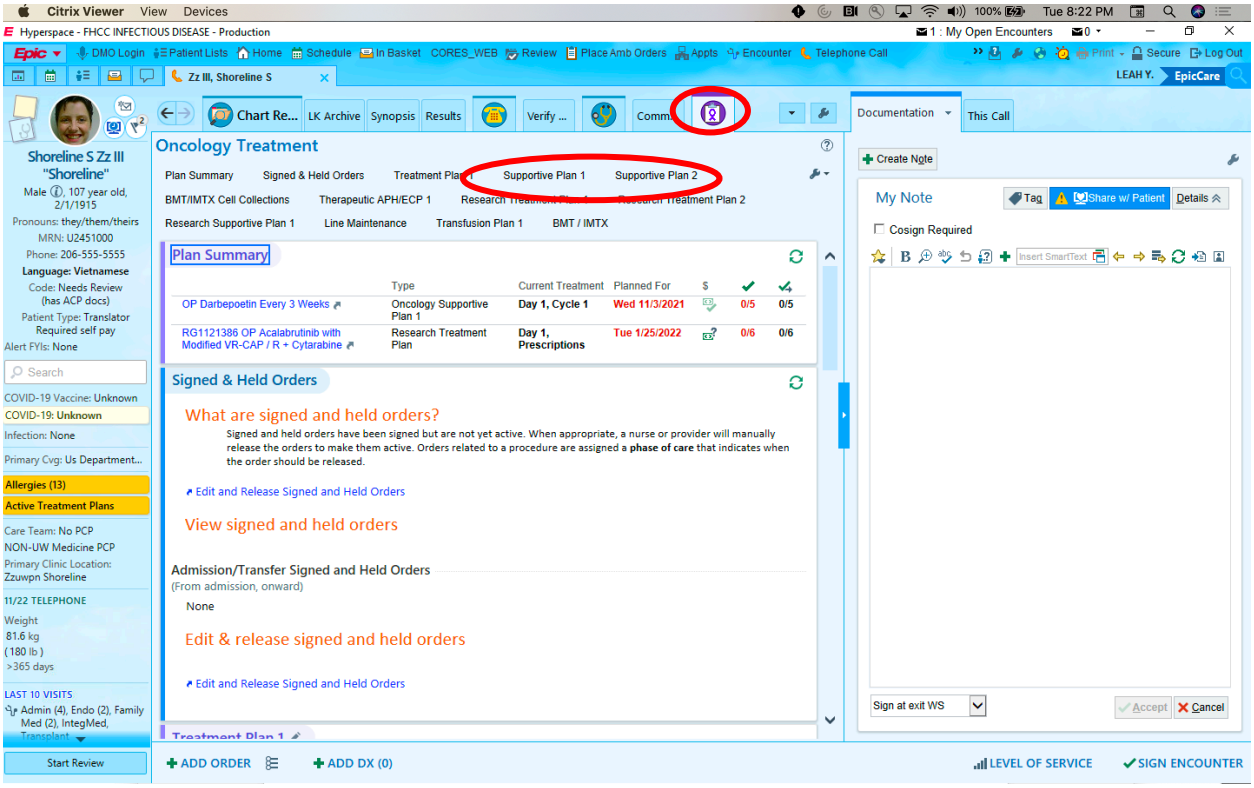
Tier 1 (mAb or Paxlovid)	**Immunocompromised** individuals not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to their underlying conditions, regardless of vaccine status (see Immunocompromising Conditions below); or Unvaccinated individuals **at the highest risk of severe disease** (anyone aged ≥75 years or anyone aged ≥65 years with additional risk factors).
Tier 2 (mAb or Paxlovid)	Unvaccinated individuals at risk of severe disease not included in Tier 1 (anyone aged ≥65 years or anyone aged <65 years with clinical risk factors*)
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

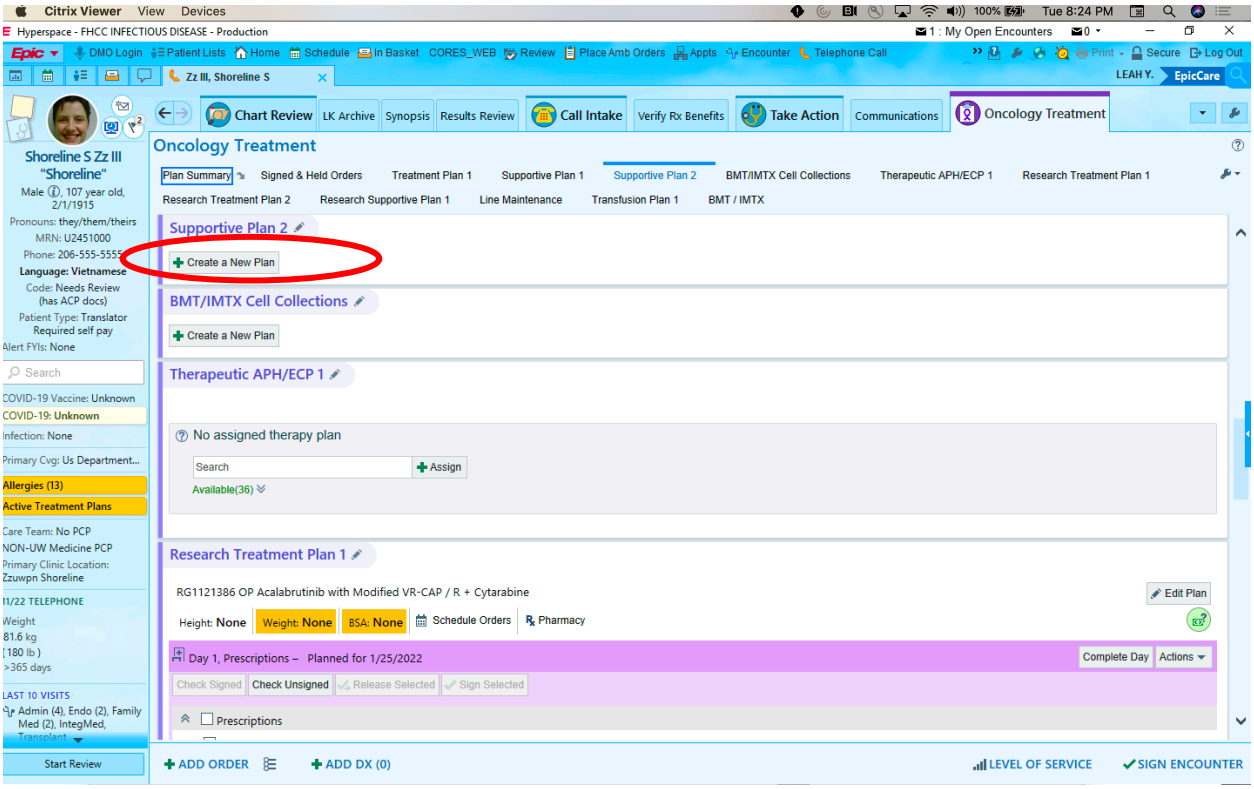
Tier 1 immunocompromising conditions*

Moderate to Severe Immunosuppression	Severe Immunosuppression
• Been receiving active cancer treatment for tumors or cancers of the blood • Received an organ transplant and are taking medicine to suppress the immune system • Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system • Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott- Aldrich syndrome) • Advanced or untreated HIV infection • 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)	• Patients who are within 1 year of receiving B-cell depleting therapies (e.g., rituximab, ocrelizumab, ofatumumab, alemtuzumab) • Patients receiving Bruton tyrosine kinase inhibitors (Acalabrutinib, Ibrutinib, Zanubrutinib) • Chimeric antigen receptor T cell recipients (CAR-T cells) • Post-hematopoietic cell transplant recipients who have chronic graft versus host disease or who are taking immunosuppressive medications for another indication • Patients with hematologic malignancies who are on active therapy • Lung transplant recipients • Patients who are within 1 year of receiving a solid-organ transplant (other than lung transplant) • Solid-organ transplant recipients with recent treatment for acute rejection with T or B cell depleting agents • Patients with severe combined immunodeficiencies • Patients with untreated HIV who have a CD4 T lymphocyte cell count <50 cells/mm3

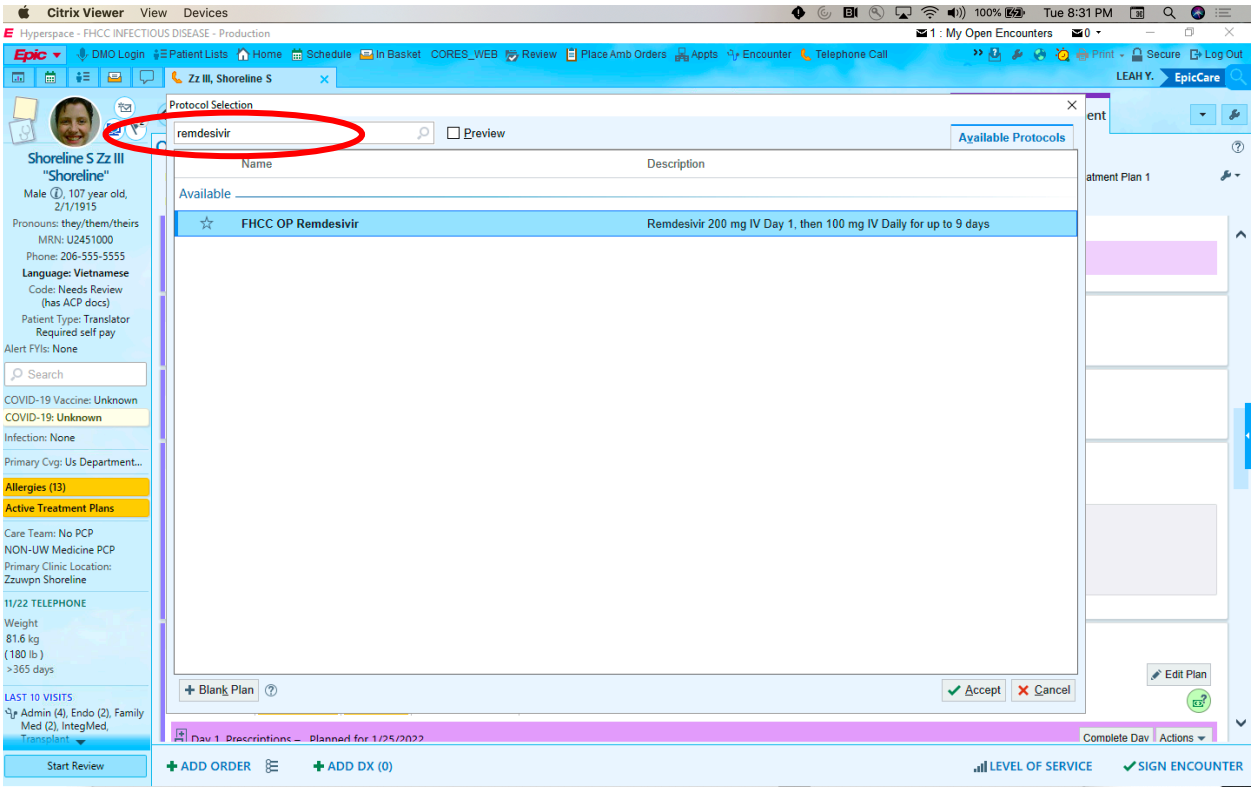
EPIC TIP SHEET:

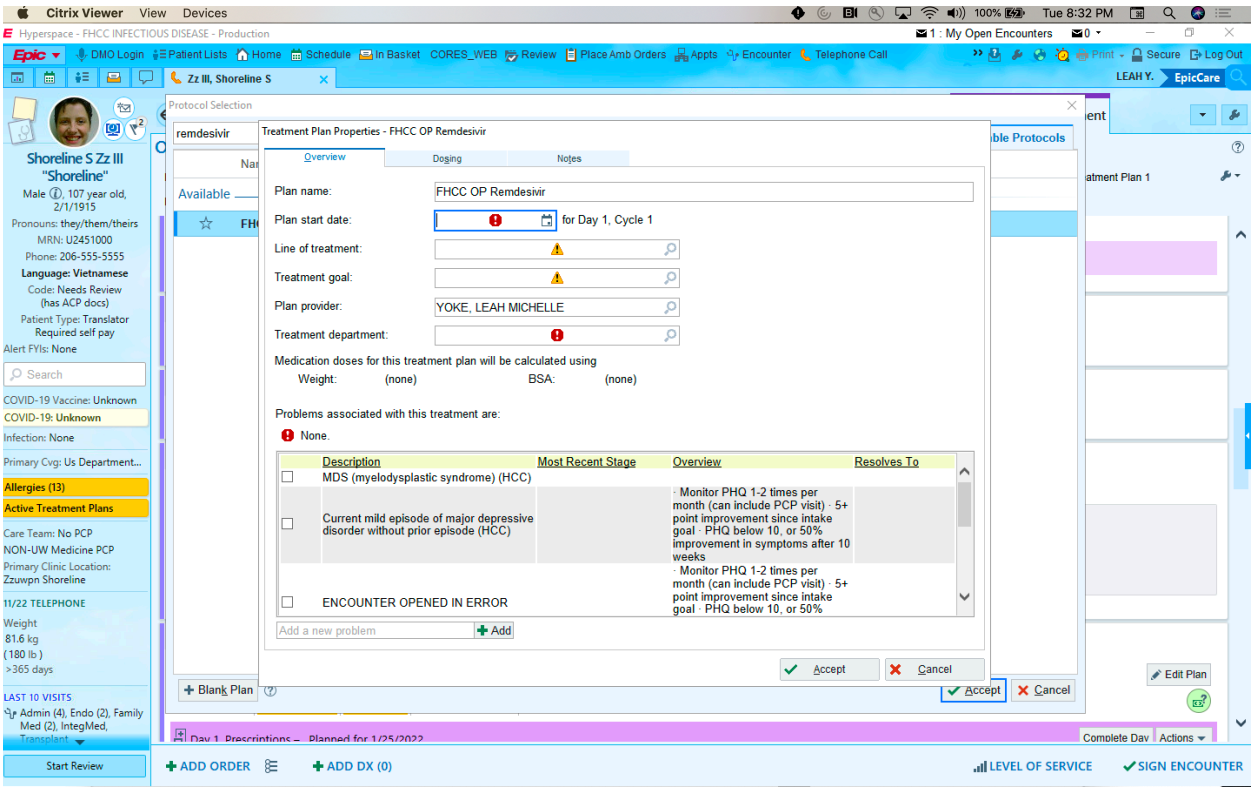


-Click on "supportive plan 1". You may need to use "supportive plan 2" dependent on if patient already has existing supportive treatment plans.



-Click on “Create a new plan”
-Type “Remdesivir”




Protocol Selection
remdesivir
Treatment Plan Properties - FHCC OP Remdesivir
Overview
Dosing
Notes
Plan name: FHCC OP Remdesivir
Plan start date: for Day 1, Cycle 1
Line of treatment:
Treatment goal:
Plan provider: YOKE, LEAH MICHELLE
Treatment department:
Medication doses for this treatment plan will be calculated using
Weight: (none) BSA: (none)
Problems associated with this treatment are:
None.
Description
Most Recent Stage
Overview
Resolves To
MDS (myelodysplastic syndrome) (HCC)
Current mild episode of major depressive disorder without prior episode (HCC)
· Monitor PHQ 1-2 times per month (can include PCP visit) · 5+ point improvement since intake goal · PHQ below 10, or 50% improvement in symptoms after 10 weeks
ENCOUNTER OPENED IN ERROR
· Monitor PHQ 1-2 times per month (can include PCP visit) · 5+ point improvement since intake goal · PHQ below 10, or 50%
Add a new problem
Add
Accept
Cancel
Blank Plan
Edit Plan
ADD ORDER
ADD DX (0)
LEVEL OF SERVICE
SIGN ENCOUNTER

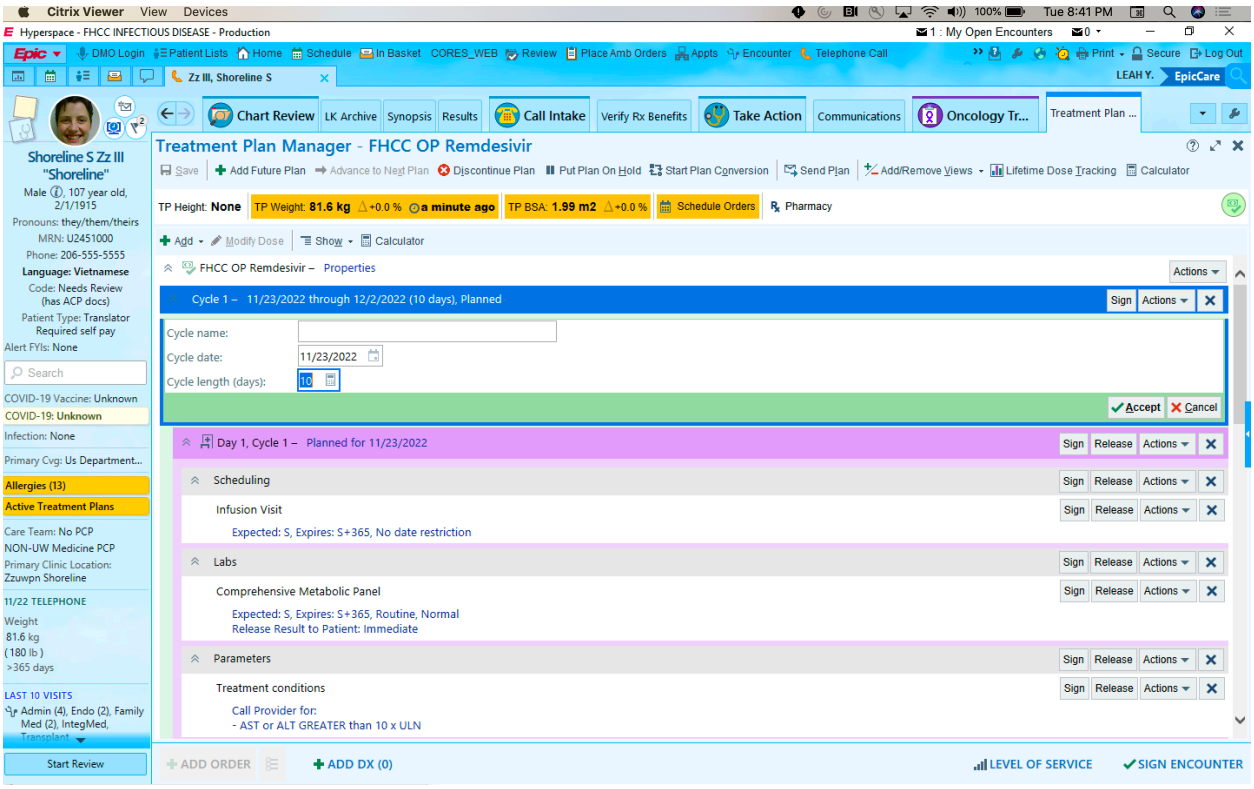
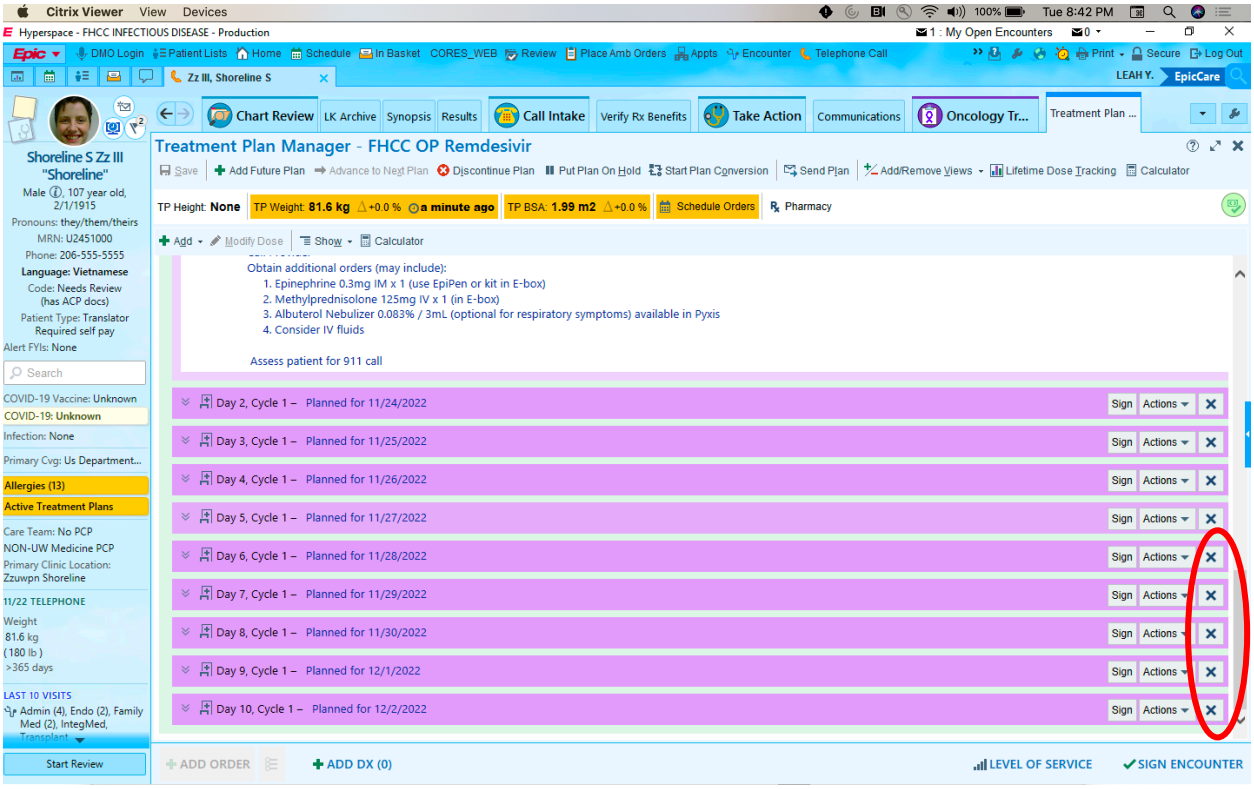
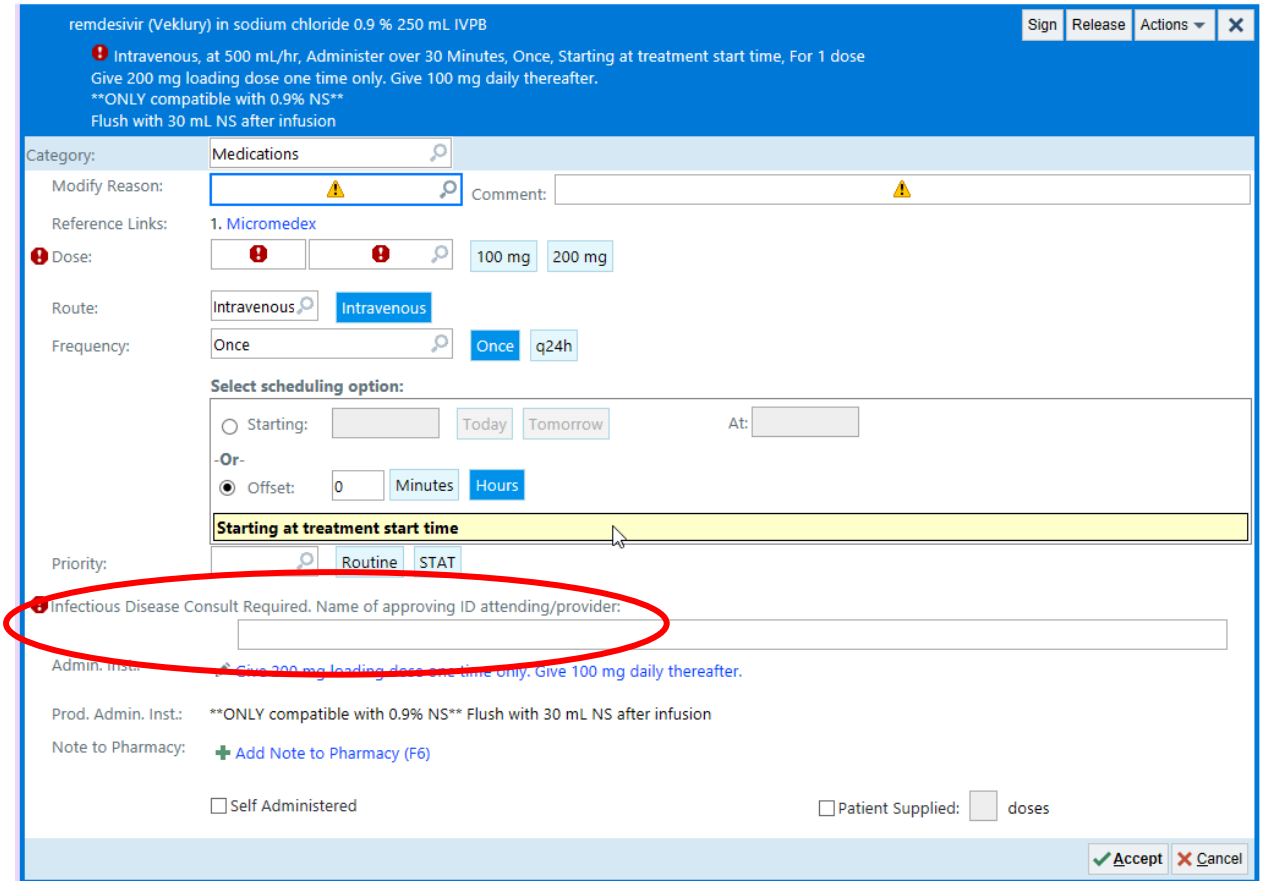


Chart Review
Call Intake
Take Action
Oncology Tr...
Treatment Plan ...
Treatment Plan Manager - FHCC OP Remdesivir
Save
Add Future Plan
Discontinue Plan
Put Plan On Hold
Start Plan Conversion
Send Plan
Lifetime Dose Tracking
Calculator
TP Height: None
TP Weight: 81.6 kg
TP BSA: 1.99 m2
Schedule Orders
Pharmacy
Add
Modify Dose
Show
FHCC OP Remdesivir – Properties
Cycle 1 – 11/23/2022 through 12/2/2022 (10 days), Planned
Cycle name:
Cycle date: 11/23/2022
Cycle length (days): 10
Accept
Cancel
Day 1, Cycle 1 – Planned for 11/23/2022
Scheduling
Infusion Visit
Expected: S, Expires: S+365, No date restriction
Labs
Comprehensive Metabolic Panel
Expected: S, Expires: S+365, Routine, Normal
Release Result to Patient: Immediate
Parameters
Treatment conditions
Call Provider for:
- AST or ALT GREATER than 10 x ULN
Sign
Release
Actions
ADD ORDER
ADD DX (0)
LEVEL OF SERVICE
SIGN ENCOUNTER

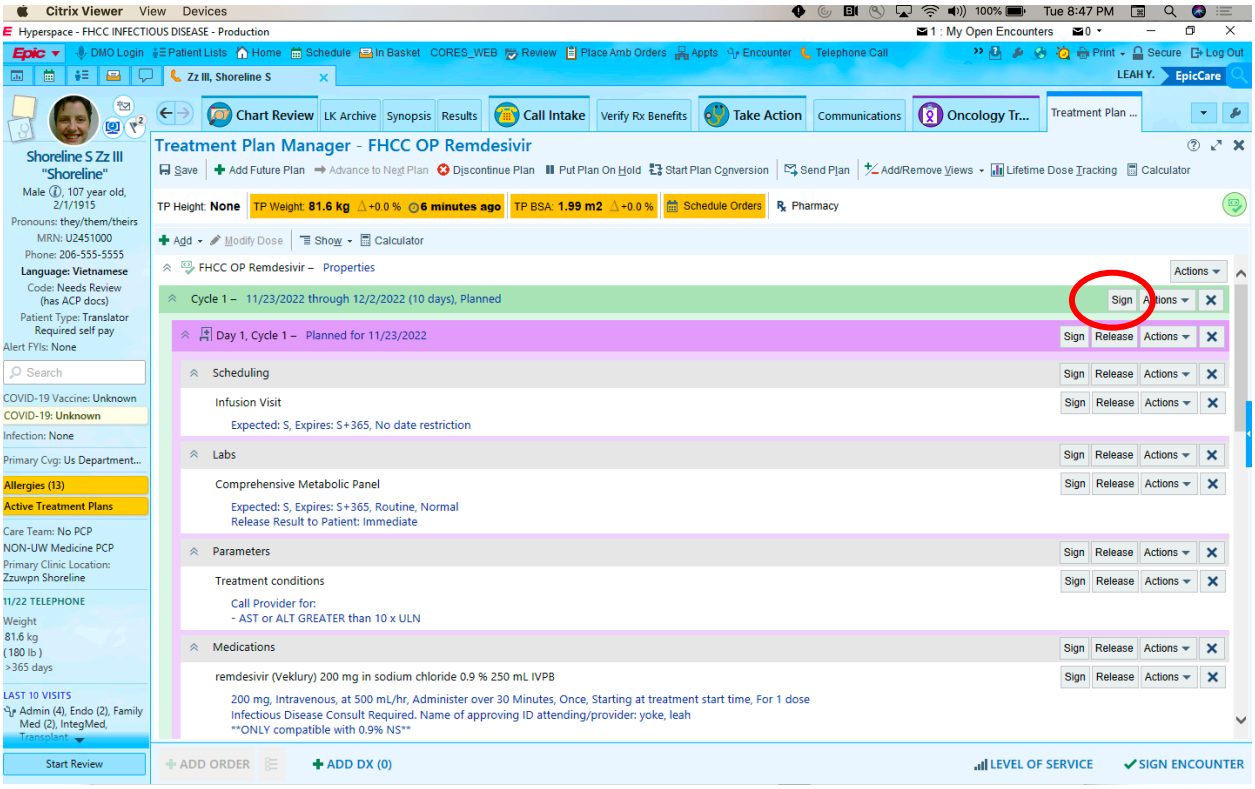


-Plan will automatically populate into a "10 day" course. Please delete additional days at the bottom using the "x" bottom on the far right. Scroll down to start deleting on day 10.

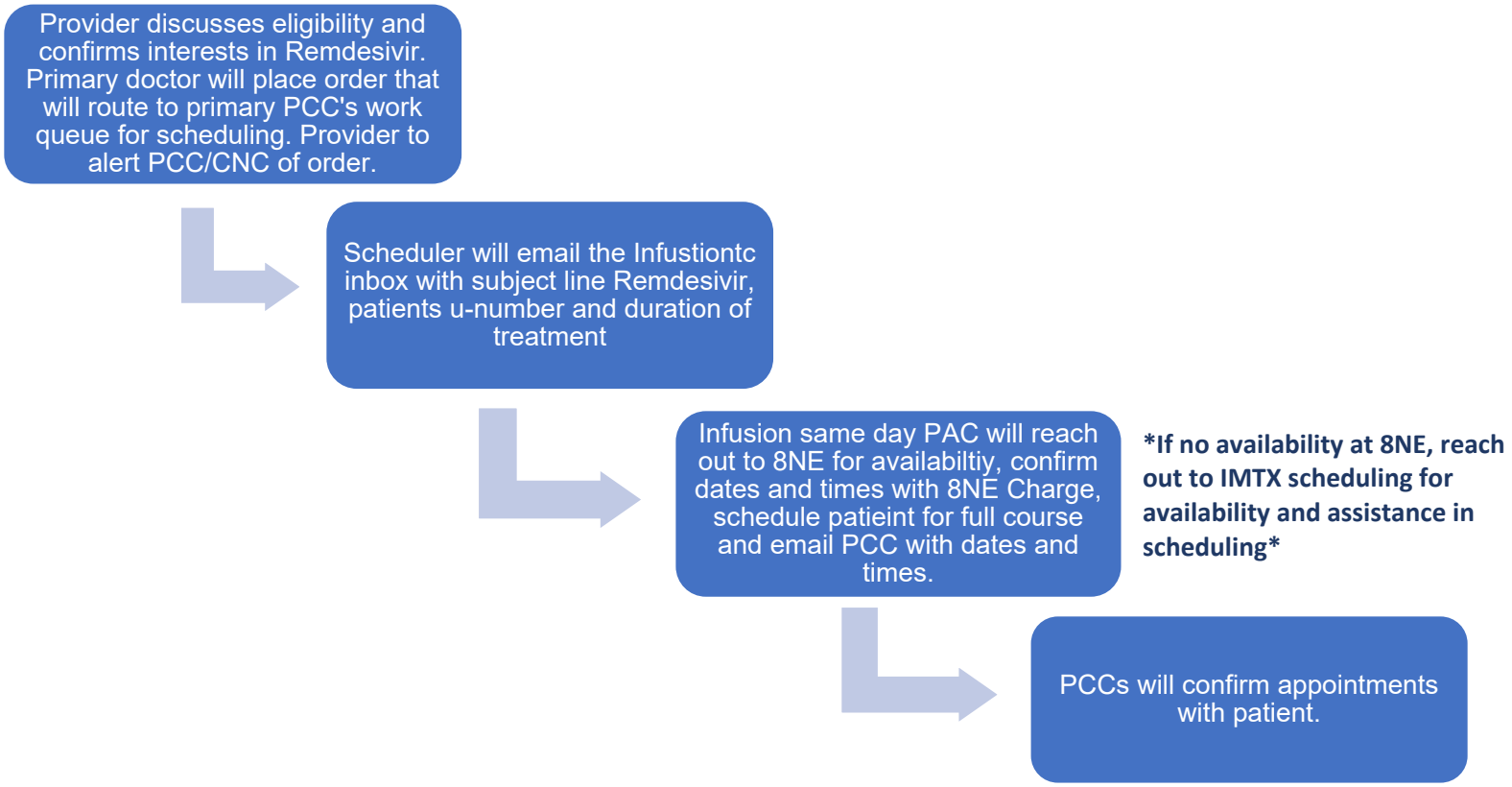


- The 200 mg dose should only be given as the initial loading dose, all subsequent doses should be the 100 mg dose. If a patient has already received the 200 mg loading dose while inpatient and is completing the remaining doses as an outpatient, the 100 mg dose should be selected.

- 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.


Citrix Viewer View Devices
Tue 8:47 PM
Hyperspace - FHCC INFECTIOUS DISEASE - Production
1 : My Open Encounters
Epic
DMO Login
Patient Lists
Home
Schedule
In Basket
CORES_WEB
Review
Place Amb Orders
Appts
Encounter
Telephone Call
Print
Secure
Log Out
LEAH Y.
EpicCare
Zz III, Shoreline S
Chart Review
LK Archive
Synopsis
Results
Call Intake
Verify Rx Benefits
Take Action
Communications
Oncology Tr...
Treatment Plan ...
Shoreline S Zz III
"Shoreline"
Male, 107 year old, 2/1/1915
Pronouns: they/them/theirs
MRN: U2451000
Phone: 206-555-5555
Language: Vietnamese
Code: Needs Review (has ACP docs)
Patient Type: Translator Required self pay
Alert FYIs: None
Search
COVID-19 Vaccine: Unknown
COVID-19: Unknown
Infection: None
Primary Cvg: Us Department...
Allergies (13)
Active Treatment Plans
Care Team: No PCP
NON-UW Medicine PCP
Primary Clinic Location: Zzuwpn Shoreline
11/22 TELEPHONE
Weight
81.6 kg
(180 lb)
>365 days
LAST 10 VISITS
Admin (4), Endo (2), Family Med (2), IntegMed, Transplant
Start Review
Treatment Plan Manager - FHCC OP Remdesivir
Save
Add Future Plan
Advance to Next Plan
Discontinue Plan
Put Plan On Hold
Start Plan Conversion
Send Plan
Add/Remove Views
Lifetime Dose Tracking
Calculator
TP Height: None
TP Weight: 81.6 kg +0.0 % 6 minutes ago
TP BSA: 1.99 m2 +0.0 %
Schedule Orders
Pharmacy
Add
Modify Dose
Show
Calculator
FHCC OP Remdesivir – Properties
Actions
Cycle 1 – 11/23/2022 through 12/2/2022 (10 days), Planned
Sign
Actions
Day 1, Cycle 1 – Planned for 11/23/2022
Sign
Release
Actions
Scheduling
Infusion Visit
Expected: S, Expires: S+365, No date restriction
Labs
Comprehensive Metabolic Panel
Expected: S, Expires: S+365, Routine, Normal
Release Result to Patient: Immediate
Parameters
Treatment conditions
Call Provider for:
- AST or ALT GREATER than 10 x ULN
Medications
remdesivir (Veklury) 200 mg in sodium chloride 0.9 % 250 mL IVPB
200 mg, Intravenous, at 500 mL/hr, Administer over 30 Minutes, Once, Starting at treatment start time, For 1 dose
Infectious Disease Consult Required. Name of approving ID attending/provider: yoke, leah
ONLY compatible with 0.9% NS
ADD ORDER
ADD DX (0)
LEVEL OF SERVICE
SIGN ENCOUNTER

Remdesivir workflow



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