|  |  |  |  |
| --- | --- | --- | --- |
| Date of symptom onset: |  | Date of SARS-CoV-2 diagnosis: |  |
| CHANGE IN BASELINE OXYGEN REQUIREMENTS?  □ No □ Yes (Explain): | | | |

Diagnosis: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Paxlovid is FDA approved for the treatment of **mild-to-moderate** coronavirus disease 2019 (COVID-19) in adults (18 years of age or older):

* With a current diagnosis of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
* Within 5 days of symptom onset and as soon as possible after diagnosis of COVID-19
* Who are at high-risk for progression to severe COVID-19 including hospitalization or death

**Figure 1**

|  |  |
| --- | --- |
| **Severity of Illness** | **Criteria** |
| Asymptomatic or Presymptomatic | Individuals who test positive for SARS-CoV-2 using a virologic test (i.e., a nucleic acid amplification test or an antigen test), but who have no symptoms that are consistent with COVID-19. Paxlovid is not FDA approved for the treatment of asymptomatic or presymptomatic COVID19. |
| **Mild Illness** | Individuals who have any of the various signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste and smell) but who do not have shortness of breath, dyspnea, or abnormal chest imaging. |
| **Moderate Illness** | Individuals who show evidence of lower respiratory disease during clinical assessment or imaging and who have saturation of oxygen (SpO2) ≥94% on room air at sea level. |
| Severe Illness | Individuals who have SpO2 <94% on room air at sea level, a ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (PaO2/FiO2) <300 mmHg, respiratory frequency >30 breaths per minute, or lung infiltrates >50%. Paxlovid is not recommended for use in individuals with severe COVID19. Those with severe illness should be assessed at a hospital. |

Source: COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. Available at https://www.covid19treatmentguidelines.nih.gov/. Accessed 18 Nov 2020.

**Attestation:**

**The provider must review the following:**

**No significant drug-drug interactions exist with Paxlovid for any of the medications patient is currently receiving**

Drug-drug interactions can be assessed at <https://www.covid19-druginteractions.org/> or [NIH recommendations](https://www.covid19treatmentguidelines.nih.gov/therapies/antivirals-including-antibody-products/ritonavir-boosted-nirmatrelvir--paxlovid-/paxlovid-drug-drug-interactions/)

**OR**

**Significant drug-drug interactions exist for Paxlovid for this patient, and their current interacting medication(s) can be adjusted or withheld to manage the interaction(s). Required medication adjustment(s):**

**1.**

**2.**

**3.**

**4.**

**5.**

**Patient doesn’t have severe liver impairment (Child-Pugh Class C)**

**Drug-drug interactions, renal function, and liver function need to be reassessed at the time of diagnosis in case any changes occurred since the initial completion of this form.**

**Order:**

Nirmatrelvir must be co-administered with ritonavir. Initiate PAXLOVID treatment as soon as possible after diagnosis of COVID-19 and within 5 days of symptom onset. Administer orally with or without food. Dosage: 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all three tablets taken together twice daily for 5 days.

Dose reduction for moderate renal impairment (eGFR ≥30 to <60 mL/min): 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet), with both tablets taken together twice daily for 5 days.

Dose reduction for severe renal impairment (eGFR <30 mL/min, not on dialysis): 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet) on day 1, then 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet), with both tablets taken together once daily for 4 days to complete a 5 day course.

**\*\*Note:** Use in this population is not recommended by the manufacturer, however, the risk of toxicity is likely to be minimal with a 5-day course of treatment and is supported by retrospective data in a limited number of patients. If the patient is on dialysis, contact Nebraska ASAP for dosing recommendations.

Medical Director signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical Director name (Please print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_