|  |  |  |  |
| --- | --- | --- | --- |
| 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) and authorized for emergency use in pediatric patients (12 to 17 years of age weighing at least 40kg):

* 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. |
| **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% |

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.

**For pediatric patients (12 to 17 years of age and weighing at least 40 kg) and adults prescribed Paxlovid under the EUA: As the healthcare provider, you MUST communicate to your patient or parent/caregiver information consistent with the “Fact Sheet for Patients and Parents/Caregivers” prior to the patient receiving Paxlovid AND MUST document in the patient’s medical record. This order form certifies that:**

* I have confirmed that this patient meets criteria for emergency use of Paxlovid.
* I have reviewed with the patient/current medical decision maker information consistent with that provided by the FDA’s Emergency Use Authorization (EUA) *“Fact Sheet for Patients and Parents/Caregivers”* for Paxlovid and have provided a copy of this fact sheet.
* Communication to the patient/caregiver included:
	+ FDA has authorized the emergency use of Paxlovid for the treatment of mild to moderate COVID-19 who are at high risk of progressing to severe COVID-19 including hospitalization or death.
	+ The patient or parent/caregiver has the option to accept or refuse Paxlovid.
	+ The significant known and potential risks and benefits of Paxlovid, and the extent to which such risks and benefits are unknown.
	+ Information on available alternative treatments and the risks and benefits of those alternatives including clinical trials.
	+ Patients treated with Paxlovid should continue to self-isolate and use infection control measures according to CDC guidelines.
* I have discussed that this medication is an FDA unapproved drug authorized for emergency use only for patients with a current diagnosis of COVID-19.  I have communicated the risks, benefits, and alternatives to use as outlined in the fact sheet and have offered the opportunity for questions.
* The patient/current medical decision maker elected to proceed with treatment and has been Informed to report all adverse reactions to a healthcare provider1

1The prescribing health care provider and/or the provider’s designee are/is responsible for mandatory reporting of all medication errors and serious adverse events potentially related to Paxlovid treatment within 7 calendar days from the onset of the event. The reports should include unique identifiers and the words “Paxlovid use for COVID-19 under Emergency Use Authorization (EUA)” in the description section of the report. Complete and submit the report here: www.fda.gov/medwatch/report.htm

**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/>

 **Patient doesn’t have severe renal impairment (eGFR<30 mL/min)**

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

**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.

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

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