Pharmacy Name: _____

Pharmacy Permit Number: _____

SARS-CoV-2 INFECTION PROTOCOL
V1
Approved 09/25/2024

PURPOSE

This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of medication therapies for the treatment of SARS-CoV-2 infection. The purpose of this protocol is to ensure appropriate and timely therapy for individuals with SARS-CoV-2 following diagnostic confirmation via nucleic acid amplification test (NAAT) or rapid antigen detection test (RADT).

PHARMACIST EDUCATION AND TRAINING

Prior to initiating testing and dispensing antivirals under this protocol, pharmacist(s) must have received education and maintain knowledge of the Centers for Disease Control current guidelines for the treatment of SARS-CoV-2 from a provider accredited by the Accreditation Council for Pharmacy Education, or by a comparable provider approved by the Kentucky Board of Pharmacy.

CRITERIA

Pharmacist(s) authorized to initiate the dispensing of antivirals to treat acute COVID-19 infection will treat individuals in accordance with guidance issued by the Center for Disease Control and Prevention.

Inclusion criteria:

Any individual who presents to the pharmacy and meets ALL of the following inclusion criteria:

- ≥ 12 years old (with consent of a parent/guardian if <18 years old)
- Documentation of positive SARS-CoV-2 viral testing within the last 5 days from a CLIA-waived NAAT or RADT ordered and conducted onsite as authorized by this protocol or documented as being performed by a healthcare professional offsite **[Note: antibody tests are NOT considered to be direct SARS-CoV-2 tests]**
- Underlying conditions associated with increased risk for progression to severe COVID-19 per CDC guidance[1]

[1] Available at: https://www.cdc.gov/covid/hcp/clinical-care/underlying-conditions.html?CDC_AAref_Val=https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html

Exclusion criteria:
Any individual who meets ANY of the following criteria:

- Pregnant or breastfeeding
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than 2 weeks, HIV/AIDS)
- Other pharmacologic therapy prescribed for upper respiratory conditions within the previous 30 days
- Clinically unstable based on the clinical judgment of the pharmacist or any of the following criteria:
  - Acute altered mental status
  - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg
  - Pulse > 125 beats/min
  - Respiratory rate > 30 breaths/min
  - Temperature ≥ 103 °F
- Symptoms indicating developing or progressing pulmonary involvement, including:
  - Persistent or progressive dyspnea
  - SpO2 ≤ 94% on room air at sea level
  - Other high acuity symptoms, including:
    - Chest pain or tightness
    - Dizziness
    - Confusion or other mental status changes

All individuals who do not qualify for antiviral dispensing under this protocol will be referred to a primary care provider or urgent/emergent treatment facility if clinically appropriate.

MEDICATIONS
This protocol authorizes pharmacist(s) to initiate the dispensing of one of the following antiviral agents. The pharmacists may dispense any dosage form deemed appropriate for the individual:

First-line Treatments
Oral **Nirmatrelvir with Ritonavir** dosing:

- Adults and Children (≥ 12 years old, ≥ 40 kg):
  - eGFR ≥ 60 mL/min.: Nirmatrelvir 300 mg with Ritonavir 100 mg administered together twice a day x 5 days
  - eGFR ≥ 30 to < 60 mL/min.: Nirmatrelvir 150 mg with Ritonavir 50 mg administered together twice a day x 5 days

Alternate Treatments
Oral **Molnupiravir** dosing:

- Adults: 800 mg every 12 hours x 5 days
- Children (<18 years old): Contraindicated due to the potential for bone and cartilage toxicity

Adjunctive Treatments

Adjunctive therapy may be useful for treatment of symptoms, including fever, headache, myalgias, and cough associated with COVID-19 infection. Treatment of symptoms includes using over-the-counter antipyretics, analgesics, or antitussives. Patients should be advised to drink fluids regularly and to rest as needed.

PROCEDURES FOR INITIATION OF THERAPY

Evaluate CLIA-waived point-of-care nucleic acid amplification test (NAAT) or rapid antigen detection test (RADT) results

- If positive: continue to evaluate with protocol
- If negative:
  - Evaluate for other minor acute illnesses such as influenza or bacterial infections

Antiviral therapy will be initiated only in carefully selected individuals based on relevant medical and social history and considerations of contraindications and precautions as identified through assessment and screening (see Appendix 1).

Assess for Relevant Medical and Social History

- Patient demographics
- Weight if <18 y/o using scale in pharmacy
- Medical history
- Relevant social history
- Current medications
- Medication allergies and hypersensitivities

Medication Specific Contraindications and Precautions

- Known hypersensitivity to nirmatrelvir, ritonavir, or molnupiravir
- Coadministration with drugs that are highly dependent on CYP3A for clearance or are CYP3A inducers (nirmatrelvir with ritonavir)
- Severe renal dysfunction (nirmatrelvir with ritonavir)
- Reduced efficacy of combination hormonal contraceptives (nirmatrelvir with ritonavir)
- Reproductive considerations (molnupiravir)

PROCEDURES FOR MONITORING AND CONTINUATION OR ADJUSTMENT OF THERAPIES

Telephone follow-up within 48 to 72 hours of dispensing to assess for clinical stability, symptom burden, and adverse effects to treatment. Referral to a primary care provider or urgent/emergent treatment facility will occur if any of the following are reported:

- New onset of dyspnea or persistent/worsening dyspnea (particularly if dyspnea occurs while resting or if it interferes with daily activities); dizziness; and mental status changes, such as confusion.
- Significant deterioration in condition or new evidence of clinical instability
- Lack of improvement in symptoms or onset of symptoms indicative of serious complications
- Medication adverse effects severe enough to warrant discontinuation

EDUCATION REQUIREMENTS

Individuals with a positive test will receive counseling on the following:

- Appropriate self-care, including symptom control, hygiene, and infection control measures.
- Per CDC guidance, people with acute COVID-19 infection should stay home from work, school, or daycare until they are afebrile without pharmacologic intervention AND symptoms are improving overall for at least 24 hours.
- After ending self-isolation, practice additional precautions over the next 5 days, such as:
  - Wearing a well-fitting mask
  - Maintaining distance from others
  - Enhanced hygiene practices
- Medication counseling consistent with state and federal requirements for prescription drug products
- Instructions on signs or symptoms that warrant emergent medical care
- Follow-up details

DOCUMENTATION

Pharmacist(s) will document the dispensing event for each person who is treated for COVID-19 under this protocol in the pharmacy management system, including:

- Documentation as required in 201 KAR 2:171 if dispensing a prescription medication
- Documentation that the individual (or caregiver) received the required education

Upon request, documentation for work/school absence

NOTIFICATION

Pharmacist(s) shall ask all persons receiving treatment under this protocol for the name and contact information of a primary care provider. If an individual (or caregiver) identifies a primary care provider, the pharmacist will provide that provider with a summary of the encounter, including at least the individual's name, date of birth, COVID-19 test results, medication dispensed, and follow-up plan, within 2 business days.

[If directed by the authorizing prescriber, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing prescriber of persons receiving medications under this protocol within 7 days of initiating dispensing.]

TERMS

This protocol is authorized pursuant to 201 KAR 2:380 and is effective when it is submitted to the registry. Any termination shall require prior notice to all parties no later than 30 days after discontinuing the protocol.

SIGNATURES

Prescriber Name _____ Date _____

Prescriber Kentucky License Number _____

Prescriber Signature _____

Pharmacist Name _____ Date _____

Pharmacist Kentucky License Number _____

Pharmacist Signature _____

Course Taken For Training: _____

Provider of Training: _____

Date Training Completed: _____

Any pharmacist not party to the protocol will be subject to discipline should they utilize the protocol. A pharmacist utilizing the protocol must be employed by or contracted with the permit listed in the executed protocol.

For additional pharmacists party to this protocol, the pharmacy should keep a list of the additional pharmacists and their training at the pharmacy.

ADDITIONAL SIGNATURE PAGE

By signing below, I attest that I read and understand the Board-authorized protocol, entitled: _____
and that I will follow all guidelines and requirements included in the Board-authorized protocol.

_____ _____
Pharmacist Name Date

_____
Pharmacist Kentucky License Number

_____
Pharmacist Signature

Course Taken for Training: _____

Provider of Training: _____

Date Training Completed: _____