

TRAVEL HEALTH THERAPIES PROTOCOL

PURPOSE

This protocol specifies the criteria and procedures for pharmacists to initiate the dispensing of medications necessary for prevention and treatment of travel-related illness.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating the dispensing of medications required for prevention and treatment of travel-related illness therapies under this protocol, pharmacist(s) must have received education and training in travel health and prevention and treatment of travel-related illness, including review of most current recommendations from the Centers for Disease Control and Prevention (CDC), from a provider accredited by the Accreditation Council for Pharmacy Education, or by a comparable provider approved by the Kentucky Board of Pharmacy.

Provider of Training: _____

Date Training Completed: _____

CRITERIA

Pharmacists authorized to initiate the dispensing of travel health therapies will follow the most current recommendations for the Centers for Disease Control and Prevention (CDC), Health Information for International Travel (commonly called the Yellow Book)¹.

Inclusion criteria:

Any individual who currently is planning travel and is interested in preventive measures who does not meet the exclusion criteria below.

Exclusion criteria:

Individuals who are pregnant are not eligible to receive therapies under this protocol and should be referred to their primary care or Ob/Gyn provider.

MEDICATIONS

This protocol authorizes pharmacists to initiate the dispensing of the following medications as referenced in the CDC Yellow Book and available as an appendix to this protocol (Appendix A):

PROCEDURES FOR INITIATION AND MONITORING OF THERAPIES

Travel health therapy initiation and monitoring will be individualized based on individual history and consideration of contraindications and precautions of therapy as outlined in the CDC Yellow Book¹.

¹ Available at: <https://wwwnc.cdc.gov/travel/page/yellowbook-home>

The pharmacist will assess the individual's travel itinerary, past medical history, current drug therapy, immunization history, and allergies to determine the appropriate travel medications and immunizations.

EDUCATION REQUIREMENTS

During travel health consultations, the pharmacist shall provide verbal and written education on all new medications prescribed, on recommended vaccinations and other travel health precautions (e.g. food/water safety, insect precautions, traveler's diarrhea, sun protection, and altitude sickness) as appropriate to the individual's travel destination to the individual or the individual's parent/guardian/caregiver. The pharmacist may also provide verbal and/or written education regarding chronic health problems as it pertains to travel.

DOCUMENTATION

Pharmacists will document via prescription record each person who receives a travel health medication prescription under this protocol, including:

- (a) Documentation as required in 201 KAR 2:170 for the dispensing of prescription medication
- (b) Documentation that the individual receiving the travel health therapy was provided with the required education pursuant to this protocol
- (c) Documentation of the history and assessment and the plan of care implemented

NOTIFICATION

Pharmacist(s) shall ask all persons receiving travel health therapies under this protocol for the name and contact information of the individual's primary care provider and shall provide notification of the medications dispensed under the protocol to the identified primary care provider within two (2) business days. Any individual affirmatively stating that the individual does not have a primary care provider may still receive travel health therapies under this protocol provided all other applicable requirements of the protocol are met.

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

TERMS

This protocol is effective as of the date all parties execute the document. It shall remain in effect for a period of one year and shall automatically renew for successive one year periods unless otherwise terminated by any party, with or without cause. Any termination without cause shall require prior notice to all parties of no less than sixty days.

SIGNATURES

Practitioner Name

Date

Practitioner Signature

Pharmacist Name

Date

Pharmacist Signature

APPENDIX A: Approved Medications

Traveler's Diarrhea: Prevention & Management

Traveler's diarrhea is defined as the passage of at least 3 unformed stools in a 24-hour period in combination with nausea, vomiting, abdominal pain, cramps, fecal urgency, or the passage of bloody or mucoid stools. Traveler's diarrhea also includes illness during the first 7 to 10 days after returning home.

Prevention

All individuals will be educated regarding food and water precautions to minimize the risk of traveler's diarrhea.

- Food & Drinks to be Avoided
 - Salad
 - Unpeeled raw fruits and vegetables
 - Buffet items
 - Food from street vendors
 - Moist items served at room temperature
 - Ice cubes
 - Reconstituted fruit juices
- Preferred Food & Drinks
 - Dry foods
 - Fruits that can be peeled
 - Foods with high sugar content
 - Bottled carbonated drinks with seal intact
 - Bottled water with seal intact
 - Water boiled or treated with iodine or chlorine

Management of Traveler's Diarrhea Based on Clinical Presentation:

- Mild: loose stools without other symptoms
 - Loperamide alone recommended
 - Oral Rehydration Therapy (ORS)
- Moderate: loose stools with cramps or nausea
 - Antibiotic + loperamide + ORS
- Severe: loose stools with intense cramps, nausea, bloody stools, dehydration, fever, chills
 - Antibiotic + loperamide + ORS
 - Seek medical attention if blood in stool or high fever is present or if symptoms do not rapidly improve

Authorized Medications for the Treatment of Traveler's Diarrhea:

	Adult Dosing Schedule	Pediatric Dosing Schedule	Special Considerations
Fluoroquinolones			
Ciprofloxacin	500 mg BID x 3 days	Not FDA-approved for this indication in children (≤ 18)	<ul style="list-style-type: none"> • Cannot be used during pregnancy • Limited usefulness in some destinations such as Thailand due to increase resistance among <i>Campylobacter</i> isolates
Levofloxacin	500 mg x 1 dose		
Macrolide			
Azithromycin	500 mg daily x 3 days 1000 mg x 1 dose	10 mg/kg daily x 3 days Adolescents ≥ 16 years: Refer to adult dosing	<ul style="list-style-type: none"> • Can be used during pregnancy • Consider if individual is traveling to destination with documented resistance to FQ antibiotics
Anti-Diarrheal			
Loperamide	4 mg after first loose stool, followed by 2 mg with each subsequent stool (max 16 mg/day)	<u>6 to 8 years (22 to 26 kg):</u> 2 mg after first loose stool, followed by 1 mg after each subsequent stool (maximum dose: 4 mg/day) <u>9 to 11 years (27 to 43 kg):</u> 2 mg after first loose stool, followed by 1 mg after each subsequent stool (maximum dose: 6 mg/day) ≥ 12 years: Refer to adult dosing.	<ul style="list-style-type: none"> • Do not use if the individual has abdominal pain without diarrhea • Loperamide is not recommended for children aged <6 years • Avoid use in individuals with acute dysentery and acute ulcerative colitis

Malaria Prophylaxis

All individuals will be educated on insect precautions including:

- Mosquito avoidance (e.g. air conditioned lodging, screened doors/windows, insect netting)
- Insect proof clothing (e.g. long-sleeved shirts, long pants, boots, hats)
- Treatment of clothing with permethrin
- Use of insect repellants containing DEET 25-50%

Authorized Medications for the Malaria Prophylaxis:

	Adult Dosing Schedule	Pediatric Dosing Schedule	Special Considerations
Chloroquine	500 mg PO weekly beginning 2 weeks prior to exposure, weekly while in endemic area, and continuing 4 weeks after leaving endemic area	5 mg/kg base (8.3 mg/kg salt) orally, once/week, up to maximum adult dose of 300 mg base (500mg salt) weekly beginning 2 weeks prior to exposure, weekly while in endemic area, and continuing 4 weeks after leaving endemic area	<ul style="list-style-type: none"> • Cannot be used in areas with documented chloroquine or mefloquine resistance • May exacerbate psoriasis • Can be used during all trimesters of pregnancy • Side effects: gastrointestinal disturbance, headache, dizziness, blurred vision, insomnia, and pruritus
Mefloquine	250 mg (228mg base) PO weekly beginning 2 weeks prior to exposure, weekly while in endemic area, and continuing 4 weeks after leaving endemic area	Weight based dose PO weekly beginning 2 weeks prior to exposure, weekly while in endemic area, and continuing 4 weeks after leaving endemic area: <u>≤9 kg:</u> 4.6 mg/kg base (5 mg/kg salt) orally, once/week <u>>9–19 kg:</u> 1/4 tablet once/week <u>>19–30 kg:</u> 1/2 tablet once/week <u>>30–45 kg:</u> 3/4 tablet once/week <u>>45 kg:</u> tablet once/week	<ul style="list-style-type: none"> • Cannot be used in areas with documented mefloquine resistance • Cannot be used in individuals with a seizure disorder • Cannot be used in individuals with psychiatric conditions • Cannot be used in individuals with cardiac conduction abnormalities • Can be used during pregnancy • Side effects: gastrointestinal disturbance, headache, insomnia, abnormal dreams, visual disturbances, depression, anxiety disorder, and dizziness • Rare side effects: paresthesia, tremor, ataxia, agitation, mood changes, panic attacks, forgetfulness, confusion, hallucinations, aggression, paranoia, and encephalopathy

Doxycycline	100 mg PO daily 2 days prior to exposure, daily while in endemic area, and continuing daily for 4 weeks after leaving endemic area	<u>≥8 years of age:</u> 2.2 mg/kg up to adult dose of 100 mg/day 2 days prior to exposure, daily while in endemic area, and continuing daily for 4 weeks after leaving endemic area	<ul style="list-style-type: none"> • Cannot be used in pregnant women or children < 8 years of age. • Associated with an increased frequency of vaginal yeast infections • Can cause photosensitivity • May cause gastrointestinal side effects
Atovaquone/ Proguanil	250/100 mg PO daily 2 days prior to exposure, daily while in endemic area, and continuing daily for 7 days after leaving endemic area	62.5/25 mg (Pediatric tablets) by weight 2 days prior to exposure, daily while in endemic area, and continuing daily for 7 days after leaving endemic area: <u>5–8 kg:</u> 1/2 pediatric tablet daily <u>>8–10 kg:</u> 3/4 pediatric tablet daily <u>>10–20 kg:</u> 1 pediatric tablet daily <u>>20–30 kg:</u> 2 pediatric tablets daily <u>>30–40 kg:</u> 3 pediatric tablets daily <u>>40 kg:</u> 1 adult tablet daily	<ul style="list-style-type: none"> • Cannot be used in pregnant women or children < 5 kg (11 lb) • Cannot be used in individuals with severe renal impairment (CrCl < 30 mL/min) • May increase the risk of bleeding with warfarin • Well tolerated and side effects are minimal (abdominal pain, nausea, vomiting, headache)

Altitude Illness:

All individuals will be educated on precautions including:

- Ascend gradually (Avoid going more than 9,000 ft (2,750 m) in 1 day. Once > 9,000 ft (2,750 m), move < 1,600 ft (500 m) per day, and plan an extra day for acclimatization every 3,300 ft (1,000 m))
- Consider using acetazolamide to speed acclimatization, if abrupt ascent is unavoidable.
- Avoid alcohol and participate in only mild exercise for the first 48 hours.
- Having an exposure at more than 9,000 ft (2,750 m) for 2 nights or more, within 30 days before the trip, is useful.

Authorized Medications for the Prevention of Altitude Sickness:

	Adult Dosing Schedule	Pediatric Dosing Schedule	Special Considerations
Acetazolamide	125 mg twice a day or 250 mg twice a day if >100 kg; started 1 day before ascent and for first 2 -3 days of altitude	2.5 mg/kg every 12 hr started 1 day before ascent and for first 2-3 days of altitude; maximum dose 125 mg BID	<ul style="list-style-type: none"> • Avoided by people with history of anaphylaxis to any sulfa • People with history of severe penicillin allergy have occasionally had allergic reactions to acetazolamide