

TRAVEL HEALTH THERAPIES PROTOCOL

v3

Approved 07/27/2021

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 prescriber, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing prescriber 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

Prescriber Name

Date

Prescriber 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 or bismuth subsalicylate 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 years)	Limited usefulness in particular regions, such as Southeast Asia or India with high prevalence of <i>Campylobacter</i> .
Levofloxacin	500 mg daily x 1-3 days (if symptoms not resolved after 24 hours following single dose therapy, continue for a total of 3 days)		
Ofloxacin	400 mg BID x 1-3 days (if symptoms not resolved after 24 hours following single dose therapy, continue for a total of 3 days)		
Macrolide			
Azithromycin	500 mg daily x 3 days OR 1000 mg as a single dose or divided dose	10 mg/kg daily x 3 days (maximum dose: 500 mg) Adolescents ≥ 16 years: Refer to adult dosing	<ul style="list-style-type: none"> • Consider if individual is traveling to destination with documented resistance to FQ antibiotics • Preferred regimen for dysentery or febrile diarrhea
Rifamycins			
Rifamycin SV	388 mg BID x 3 days	Not FDA-approved for this indication in children (≤ 18 years)	Do not use if clinical suspicion for <i>Campylobacter</i> , <i>Salmonella</i> , <i>Shigella</i> , or other causes of invasive diarrhea. Use may be reserved for patients unable to receive fluoroquinolones or azithromycin.
Rifaximin	200 mg TID x 3 days	Children and Adolescents ≥ 12 years: Refer to adult dosing	
Anti-Diarrheal			

Loperamide	4 mg after first loose stool, followed by 2 mg with each subsequent stool (maximum dose: 16 mg/day)	<p><u>2 to 5 years (13 to < 21 kg):</u> 1 mg after first loose stool, followed by 1 mg after each subsequent loose stool (maximum dose: 3 mg/day)</p> <p><u>6 to 8 years (21 to 27 kg):</u> 2 mg after first loose stool, followed by 1 mg after each subsequent stool (maximum dose: 4 mg/day)</p> <p><u>9 to 11 years (27.1 to 43 kg):</u> 2 mg after first loose stool, followed by 1 mg after each subsequent stool (maximum dose: 6 mg/day)</p> <p>12 to 18 years: 2mg after first loose stool, followed by 2mg after each subsequent stool (maximum dose: 8 mg/day)</p>	<ul style="list-style-type: none"> • Do not use if the individual has abdominal pain without diarrhea • May be used in combination with antibiotic regimen • Avoid use in individuals with acute dysentery and acute ulcerative colitis • Limit use to \leq 48 hours
Bismuth subsalicylate	524 mg every 30 to 60 minutes or 1,050 mg every 60 minutes as needed (maximum: 4,200 mg/24 hours)	<p><u>For children do not exceed 8 doses/24 hours</u></p> <p><u>3 to < 6 years: 87 mg every 30 minutes to 1 hour as needed</u></p> <p><u>6 to < 9 years: 175 mg every 30 minutes to 1 hour as needed</u></p> <p><u>9 to < 12 years: 262 mg every 30 minutes to 1 hour as needed</u></p> <p><u>\geq 12 years: Refer to adult dosing</u></p>	<ul style="list-style-type: none"> • Do not use if patient is allergic to salicylates (including aspirin) or are taking other salicylates • Do not use if patient has an ulcer, bleeding problem, or bloody/black stool

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 salt (300 mg base) PO weekly beginning 1 to 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 1 to 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
Hydroxychloroquine	400 mg salt (310 mg base) PO, once weekly beginning 1 to 2 weeks prior to exposure, weekly while in endemic area, and continuing 4 weeks after leaving endemic area	5 mg/kg base (6.5 mg/kg salt) orally, once/week, up to a maximum adult dose of 310 mg base beginning 1 to 2 weeks prior to exposure, weekly while in endemic area, and continuing 4 weeks after leaving endemic area	<ul style="list-style-type: none"> • May exacerbate psoriasis • May be better tolerated than chloroquine • Side effects: gastrointestinal disturbance, headache, dizziness, blurred vision, insomnia, and pruritus • If patients are already taking hydroxychloroquine for rheumatoid arthritis or other conditions, patients may not require additional prophylaxis

<p>Mefloquine</p>	<p>250 mg (228mg base) PO weekly beginning \geq 2 weeks prior to exposure, weekly while in endemic area, and continuing 4 weeks after leaving endemic area</p>	<p>Weight based dose PO weekly beginning \geq 2 weeks prior to exposure, weekly while in endemic area, and continuing 4 weeks after leaving endemic area:</p> <p><u>\leq9 kg:</u> 4.6 mg/kg base (5 mg/kg salt) orally, once/week <u>$>$9–19 kg:</u> $\frac{1}{4}$ of 250 mg tablet once/week <u>$>$19–30 kg:</u> $\frac{1}{2}$ of 250 mg tablet once/week <u>$>$30–45 kg:</u> $\frac{3}{4}$ of 250 mg tablet once/week <u>$>$45 kg:</u> 250 mg tablet once/week</p>	<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
<p>Primaquine</p>	<p>30 mg PO daily 1 to 2 days prior to travel and continue while in the malaria-endemic area and for 7 days after departure from endemic areas</p>	<p>0.5 mg/kg base (0.8 mg/kg salt) up to adult dose orally, daily 1 to 2 days prior to travel and continue while in the malaria-endemic area and for 7 days after departure from the area</p>	<ul style="list-style-type: none"> • Recommended for primary prophylaxis of malaria when the travel is of short duration to areas with principally <i>P. vivax</i> malaria and last-minute travelers and for presumptive antirelapse therapy • Before tafenoquine is used, G6PD deficiency MUST be ruled out by laboratory testing; If a patient has NOT been tested G6PD deficiency, this medication cannot be used • Contraindicated in pregnancy and avoid during breastfeeding

<p>Tafenoquine</p>	<p>200 mg PO daily 3 days prior to travel to endemic areas. Then, take once weekly starting 7 days after loading dose while at the endemic area, and for 1 week after leaving the endemic area</p>	<p>Not indicated in children < 16 years old</p>	<ul style="list-style-type: none"> • Before tafenoquine is used, G6PD deficiency MUST be ruled out by laboratory testing; If a patient has NOT been tested G6PD deficiency, this medication cannot be used • Contraindicated in pregnancy and during breastfeeding • Tafenoquine should not be used as prophylaxis in people with a history of psychotic disorder
<p>Doxycycline</p>	<p>100 mg PO daily 1 to 2 days prior to exposure, daily while in endemic area, and continuing daily for 4 weeks after leaving endemic area</p>	<p><u>≥8 years of age:</u> 2.2 mg/kg up to adult dose of 100 mg/day 1 to 2 days prior to exposure, daily while in endemic area, and continuing daily for 4 weeks after leaving endemic area</p>	<ul style="list-style-type: none"> • Cannot be used in 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 1 to 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 1 to 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 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)
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Altitude Illness:

Acute Mountain Sickness (AMS): The most common form of altitude illness, affecting, for example, 25% of all visitors sleeping above 8,000 ft (2,500 m) in Colorado. Symptoms are similar to those of an alcohol hangover: headache is the cardinal symptom, sometimes accompanied by fatigue, loss of appetite, nausea, and occasionally vomiting. Headache onset is usually 2–12 hours after arrival at a higher elevation and often during or after the first night. Preverbal children may develop loss of appetite, irritability, and pallor. AMS generally resolves with 12–48 hours of acclimatization.

High-Altitude Cerebral Edema (HACE): A severe progression of AMS and is rare; it is most often associated with HAPE. In addition to AMS symptoms, lethargy becomes profound, with drowsiness, confusion, and ataxia on tandem gait test, similar to alcohol intoxication. A person with HACE requires immediate descent; if the person fails to descend, death can occur within 24 hours of developing ataxia.

High-Altitude Pulmonary Edema (HAPE): HAPE can occur by itself or in conjunction with AMS and HACE; incidence is 1 per 10,000 skiers in Colorado and up to 1 per 100 climbers at more than 14,000 ft (4,270 m). Initial symptoms are increased

breathlessness with exertion, and eventually increased breathlessness at rest, associated with weakness and cough. Oxygen or descent is lifesaving. HAPE can be more rapidly fatal than HACE.

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 (500m) 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 (AMS, HACE prevention)	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
Dexamethasone (AMS, HACE prevention)	2 mg every 6 hours or 4mg every 12 hours; may be discontinued after staying at the same elevation for 2 to 4 days or if descent is initiated	Should not be used for prophylaxis in children	<ul style="list-style-type: none"> • Due to adverse effects, limit duration to ≤ 10 days • Acetazolamide is the treatment of choice and use of dexamethasone should be reserved as adjunct treatment if patient is unable to tolerate or for specific situations including rapid decent.

Cholera Prophylaxis

Cholera in travelers is extremely rare, and the vaccine is not routinely recommended for most travelers because most travelers do not visit areas of active transmission. Although still rare, cholera appears to be more common in travelers who are visiting friends and relatives and those performing humanitarian aid work in outbreak settings. Outbreak settings include areas of Africa, Asia, Haiti, and the Phillipines. Additional information can be found on the CDC website (<https://wwwnc.cdc.gov/travel/news-announcements/cholera-vaccine-for-travelers>).

All individuals will be educated on precautions including:

- Choosing food and drinks
 - Only eat foods that are cooked and served hot
 - Avoid food that has been sitting on a buffet
 - Eat raw fruits and vegetables only if you have washed them in clean water or peeled them
 - Only drink beverages from factory-sealed containers
 - Avoid ice because it may have been made from unclean water
 - Only drink pasteurized milk
- Washing hands
 - Wash hands often with soap and water for 20 seconds, especially after using the bathroom and before eating
 - If soap and water aren't available, use an alcohol-based hand sanitizer that contains at least 60% alcohol
 - Keep your hands away from your face and mouth

Authorized Medications/Immunizations for Cholera Prophylaxis:

	Adult Dosing Schedule	Pediatric Dosing Schedule	Special Considerations
Vaxchora	100 mL (single dose) administered ≥ 10 days prior to potential cholera exposure	Not FDA-approved in children (≤ 18)	<ul style="list-style-type: none">• Contraindicated in people with a history of severe allergic reaction to any ingredient of Vaxchora or to a previous dose of any cholera vaccine• Should not be administered to patients who have received antibiotics in the previous 14 days• Patients should not eat or drink 1 hour before or after administration

			<ul style="list-style-type: none"> • Patients need to receive the immunization at the pharmacy within 15 minutes of constitution • Both the buffer and active components need to be stored refrigerated at 36°F to 46°F
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Typhoid Fever Prophylaxis

Typhoid fever can be a life-threatening disease. Symptoms of infection include persistent high fever, weakness, stomach pain, headache, diarrhea or constipation, cough, and loss of appetite. Typhoid fever is common in many regions of the world, including parts of East and Southeast Asia, Africa, the Caribbean, and Central and South America. Additional information can be found on the CDC website (<https://www.cdc.gov/vaccines/hcp/vis/vis-statements/typhoid.html>).

All individuals will be educated on precautions including:

- Choosing food and drinks
 - Only eat foods that are cooked and served hot
 - Avoid food that has been sitting on a buffet
 - Eat raw fruits and vegetables only if you have washed them in clean water or peeled them
 - Only drink beverages from factory-sealed containers
 - Avoid ice because it may have been made from unclean water
 - Only drink pasteurized milk
- Washing hands
 - Wash hands often with soap and water for 20 seconds, especially after using the bathroom and before eating
 - If soap and water aren't available, use an alcohol-based hand sanitizer that contains at least 60% alcohol
 - Keep your hands away from your face and mouth

Authorized Medications/Immunizations for Typhoid Prophylaxis:

	Adult Dosing Schedule	Pediatric Dosing Schedule	Special Considerations
Vivotif	Primary immunization: One capsule on alternative days (Day 1, 3, 5, 7) for a total of 4 doses; all doses should be complete at least 1 week prior to potential exposure	FDA-approved for children ≥ 6 years: Refer to adult dosing	<ul style="list-style-type: none"> • This is a live vaccine; however, it can be administered with oral polio or yellow fever vaccines • Must be refrigerated between 35.6°F-46.6°F to maintain optimal potency • Should not be administered in immunocompromised patients

	<p><u>Reimmunization:</u> Repeat full course of primary immunization every 5 years</p>		<ul style="list-style-type: none">• Swallow whole soon after placing into mouth; do not chew or open capsule• Take 1 hour prior to food with cool or lukewarm water• Avoid alcohol 1 hour before and 2 hours after administration• Reimmunization recommended with repeated or continued exposure to typhoid fever
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