

## SELF-CARE CONDITIONS PROTOCOL: OVER-THE-COUNTER PROBIOTICS

Approved March 27, 2019

### PURPOSE

This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of over-the-counter probiotic therapies.

### PHARMACIST EDUCATION AND TRAINING

Prior to initiating the dispensing of probiotic therapy under this protocol, pharmacist(s) must have received education and training in probiotic therapies 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

Pharmacist(s) authorized to initiate the dispensing of probiotic therapy will follow the current World Gastroenterology Organisation Global Guidelines on Probiotics and Prebiotics.<sup>1</sup>

#### *Inclusion criteria:*

- Any individual, 18 years or older, who does not meet the exclusion criteria.

#### *Exclusion criteria:*

- Any individual who has an immunocompromised disease state or who is currently on immunocompromising therapies.

### MEDICATIONS

This protocol authorizes pharmacists to initiate the dispensing of over-the-counter probiotic therapy using the doses consistent with the product labeling that meet the following criteria:

- 1) Probiotic product/strain has approval or GRAS (generally recognized as safe) status with the Food and Drug Administration (FDA)<sup>2</sup>,
- 2) Contains no additional active ingredients that would require prescriptive permission, and
- 3) Contains products/strains for the appropriate indication as identified by the current World Gastroenterology Organisation Global Guidelines on Probiotics and Prebiotics<sup>1</sup>.

Sufficient quantities to provide up to a 30-day supply may be dispensed, based on the indication for use.

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<sup>1</sup> Francisco G, Mary Ellen S, Rami E, et al. World Gastroenterology Organisation Global Guidelines: Probiotics and prebiotics. <http://www.worldgastroenterology.org/guidelines/global-guidelines/probiotics-and-prebiotics/probiotics-and-prebiotics-english>. Published February 2017. Accessed March 2019.

<sup>2</sup> Generally recognized as safe (GRAS). U.S. Food and Drug Administration website. <https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GrASNotices>. Accessed March 2019.

## **PROCEDURES FOR INITIATING THERAPY**

Probiotic therapy initiation and monitoring will be individualized based on relevant medical and social history, patient preferences, and consideration of contraindications and precautions of therapy as outlined below.

### Relevant Medical and Social History

- Past medical history
- Current medications
- Allergies and hypersensitivities

### Contraindications and Precautions:

- Known hypersensitivities to probiotic product ingredients (as listed on the product label)

Therapy may be initiated for healthy patients to help regulate bowel movements, patients with a previous history of or to prevent antibiotic associated diarrhea or yeast infection, prevention of Clostridium difficile-associated diarrhea, patients with irritable bowel syndrome (IBS), treatment of acute gastroenteritis, prevention of eczema, and any other clinical application listed in the current World Gastroenterology Organisation Global Guidelines on Probiotics and Prebiotics.<sup>1</sup>

## **PROCEDURES FOR MONITORING AND CONTINUATION OF THERAPY**

Follow-up monitoring and evaluation to determine effectiveness, adverse effects, and patient progress with therapy is required if therapy is to continue following the initial dispensation. If follow-up monitoring and evaluation indicates therapy continuation is warranted, medication refills may be authorized.

Should follow-up evaluation and monitoring indicate an adjustment in therapy is warranted, all procedures as outlined for initiation of therapies, including education, documentation and notification, will be followed.

## **PATIENT EDUCATION REQUIREMENTS**

Patient(s) receiving probiotic therapies under the protocol will receive education regarding:

- Storage requirements
- Directions
- Duration of therapy
- Potential adverse effects

## **DOCUMENTATION**

Pharmacist(s) shall document via prescription record each person who receives any probiotic therapy under this protocol, including:

- Documentation as required in 201 KAR 2:170 for the dispensing of prescription medications, and
- Documentation that the individual receiving the probiotics was provided with the required education pursuant to this protocol
- Documentation of the clinical indication for probiotic therapy, probiotic product/strain dispensed, plan of care implemented, and follow-up monitoring and evaluation

## NOTIFICATION

Pharmacist(s) shall ask all persons receiving probiotics under this protocol for the name and contact information of the individual's primary care provider and shall provide notification of the probiotics 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 probiotics 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 probiotic 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/Practitioner Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Prescriber/Practitioner Signature

\_\_\_\_\_  
Pharmacist Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Pharmacist Signature

*Resources Available Online for Pharmacist Reference and Used in the Development of this Protocol:*

- 1) Francisco G, Mary Ellen S, Rami E, et al. World Gastroenterology Organisation Global Guidelines: Probiotics and prebiotics. <http://www.worldgastroenterology.org/guidelines/global-guidelines/probiotics-and-prebiotics/probiotics-and-prebiotics-english>. Published February 2017. Accessed March 2019.
- 2) Generally recognized as safe (GRAS). U.S. Food and Drug Administration website. <https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GrASNotices>. Accessed March 2019.
- 3) Dragana S, Vivien B, Bradley J, et al. Clinical Guide to Probiotic Products; Indications, dosage forms and clinical evidence to date. *BHSoftInc*. Updated 2019; Valid until December 31, 2019. Available at: [www.usprobioticguide.com](http://www.usprobioticguide.com).