

SELF-CARE CONDITIONS PROTOCOL: OVER-THE COUNTER DIETARY SUPPLEMENT PROTOCOL
Approved January 26, 2022

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

PHARMACIST EDUCATION AND TRAINING

Prior to initiating the dispensing of over-the-counter dietary supplements under this protocol, pharmacist(s) must have received education and training in dietary supplement therapy 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 over-the-counter dietary supplement therapy will follow the current World Gastroenterology Organizational Global Guidelines on Probiotics and Prebiotics¹ and the Dietary Guidelines for Americans 2015-2020².

Inclusion criteria for over-the-counter dietary supplement therapy:

- Individuals, who do not meet any of the exclusion criteria and could benefit from dietary supplement therapy due to any of the following:
 - Are at risk for a dietary deficiency and could benefit from an over-the dietary supplement with the following conditions or history of:
 - Alcoholism
 - Tobacco Use
 - Poor-quality diets with low fruit and vegetable intake
 - Malabsorption
 - Bariatric surgery
 - Vegan diet
 - Those with nonhealing wounds
 - On a medication known for drug-induced nutrient depletion including but not limited to:
metformin, orlistat, beta agonists, corticosteroids, diuretics (loop or thiazide), proton pump inhibitors, H2 blockers, and statins
 - Supplementation that satisfies the physiological needs or deficiencies for a specific disease state or condition
 - Any other known or suspected dietary deficiency
- Patients that may benefit from probiotic therapy or adjunct probiotic therapy with history of or for prevention of the following conditions:
 - Acute gastroenteritis

- Antibiotic associated diarrhea or yeast infections
- Clostridium difficile associated diarrhea
- Eczema
- Irritable bowel syndrome
- Regulate bowel movements
- Any other clinical application listed in the current World Gastroenterology Organizational Global Guidelines on Probiotics and Prebiotics.¹

Exclusion criteria for over-the-counter dietary supplements:

- Any individual who has an allergy or contraindication to therapy due to drug-drug interactions
- Any individual who has an immunocompromised disease state or who is currently on immunocompromising therapies.
- Any individual who does not meet one of the previous inclusion criteria

MEDICATIONS

This protocol would authorize pharmacists to initiate the dispensing of an over-the-counter dietary supplement therapy using doses consistent with package labeling and clinical guidelines through professional judgement. Products would include only over-the-counter dietary supplements that:

- 1) Have been manufactured in an FDA registered facility
- 2) Contains no additional active ingredients that would require prescriptive permission
- 3) Probiotic product/strain has approval of GRAS (generally recognized as safe) status with the Food and Drug Administration (FDA)
- 4) Probiotics contain products/strains for the appropriate indications as identified by the current World Gastroenterology Organisation Global Guidelines on Probiotics and Prebiotics
- 5) Contains products/ingredients for appropriate indications as identified by the Dietary Guidelines for Americans 2015-2020² or the National Institute of Health (NIH) Office of Dietary Supplements⁶.

PROCEDURES FOR INITIATING THERAPY

Dietary supplement therapy initiation would be individualized based on relevant medical and social history, preferences, and consideration of contraindications of therapy as outlined below.

- Relevant medical and social history
 - ✦ Past medical and social history
 - ✦ Current medications
 - ✦ Allergies and hypersensitivities
- Contraindications
 - ✦ Known hypersensitivities to any component of the formulation (as listed on the product label)
 - ✦ Pre-existing hypervitaminosis
 - ✦ Potential drug-drug interactions based on current medications

PROCEDURES FOR MONITORING AND CONTINUATION OF DISPENSING OVER-THE-COUNTER DIETARY SUPPLEMENTS

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 dispensing. If follow-up monitoring and evaluation indicates therapy continuation is warranted, medication refills may be authorized.

If signs of an allergic reaction occur, such as hives, itching, rash, red and swollen skin, difficulty breathing, medication will be discontinued, and the patient referred to an emergency care or primary care provider.

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

PATIENT EDUCATION REQUIREMENTS

Patient(s) receiving over-the-counter dietary supplement therapy under this protocol will receive education regarding:

- Potential adverse effects
- Directions
- Duration of therapy
- Storage requirements
- Action if dose is missed

DOCUMENTATION

Pharmacist(s) shall document, via prescription record, each person who receives any over-the-counter dietary supplement 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 over-the-counter dietary supplement with the required education in accordance with this protocol, and
- Documentation of the clinical indication for supplementation, product/strain dispensed, plan of care implemented, and follow-up monitoring and evaluation

NOTIFICATION

Pharmacist(s) shall ask all persons receiving over-the-counter dietary supplements under this protocol for the name and contact information of the individual's primary care provider. If a primary care physician is identified, the pharmacist(s) shall provide that physician with a summary of the encounter and notification of the supplement(s) dispensed under this protocol within two (2) business days. Any individual affirmatively stating that the individual does not have a primary care provider may still receive over-the-counter dietary supplement therapy 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 nutrition supplementation under this protocol within 7 days of initiating dispensing.]

TERMS

This protocol is effective as of the date that 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/Prescriber Name

Date

Practitioner/Prescriber Signature

Pharmacist Name

Date

Pharmacist Signature

Resources used to develop this protocol:

- 1) Francisco G, Mary Ellen S, Rami E, et al. World Gastroenterology Organization Global Guidelines: Probiotics and prebiotics. <http://www.worldgastroenterology.org/guidelines/global-guidelines/probiotics-and-prebiotics/probiotics-and-prebioticsenglish>. Published February 2017. Accessed June 2020.
- 2) Millen B, Lichtenstein A, Abrams S, et al. 2015-2020 Dietary guidelines for Americans. 8th Edition. U.S. Department of Health and Human Services and U.S. Department of Agriculture. Published 2015 Dec.
- 3) Generally recognized as safe (GRAS). U.S. Food and Drug Administration website. <https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GrASNotices>. Accessed June 2020.
- 4) Dragana S, Vivien B, Bradley J, et al. Clinical Guide to Probiotic Products; Indications, dosage forms and clinical evidence to date. BHSofInc. Updated 2019; Valid until December 31, 2019. Available at: www.usprobioticguide.com.
- 5) National Center for Complementary and Integrative Health. Vitamins and minerals. U.S. Department of Health and Human Services. <https://nccih.nih.gov/health/vitamins>. Updated 2018 Feb 09; Accessed June 2020.
- 6) The National Institutes of Health (NIH) Office of Dietary Supplements. Dietary Supplement Fact Sheets. <https://ods.od.nih.gov/factsheets/list-all/>