

**Nutritional Supplementation Protocol**  
**Approved July 29, 2020**

**PURPOSE**

This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of nutritional supplementation with non-controlled, prescription multi-vitamins, minerals and/or probiotics.

**PHARMACIST EDUCATION AND TRAINING**

Prior to initiating the dispensing of nutritional supplementation with non-controlled, prescription multi-vitamins, minerals and/or probiotics under this protocol, pharmacist(s) must have received education and training in nutritional supplementation 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 nutritional supplementation with non-controlled, prescription multi-vitamins, minerals and/or probiotics will follow the current World Gastroenterology Organisation Global Guidelines on Probiotics and Prebiotics<sup>1</sup> and the Dietary Guidelines for Americans 2015-2020<sup>2</sup>.

Inclusion criteria for non-controlled, prescription multi-vitamins, minerals, and/or probiotics:

- Patients at risk for vitamin and/or mineral deficiency 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

- 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 Organisation Global Guidelines on Probiotics and Prebiotics.<sup>1</sup>

Exclusion criteria for non-controlled, prescription multi-vitamins, minerals and/or probiotics:

- 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 nutritional supplementation with non-controlled, prescription multi-vitamins, minerals and/or probiotics using doses consistent with package labeling and clinical guidelines through professional judgement. The products would include any medication assigned by the FDA as a nutritional supplement.

## **PROCEDURES FOR INITIATING THERAPY**

Nutritional supplementation 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 NUTRITIONAL SUPPLEMENTATION WITH NON-CONTROLLED, PRESCRIPTION MULTI-VITAMINS, MINERALS AND/OR PROBIOTICS**

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 nutritional supplementation with non-controlled, prescription multi-vitamins, minerals, and/or probiotics 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 nutritional supplementation with non-controlled, prescription multi-vitamins, minerals and/or probiotics 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 nutritional supplementation with non-controlled, prescription multi-vitamins, minerals, and/or probiotics was provided with the required education in accordance to 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 nutritional supplementation with non-controlled prescription multi-vitamins, minerals and/or probiotics 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 nutritional supplementation 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 Organisation Global Guidelines: Probiotics and prebiotics. <http://www.worldgastroenterology.org/guidelines/global-guidelines/probiotics-and-prebiotics/probiotics-and-prebiotics-english>. Published February 2017. Accessed June 2020.
- 2) Millen B, Lichtenstein A, Abrams S, et al. 2015-2020 Dietary guidelines for Americans. 8<sup>th</sup> 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](http://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.