

Commercial Claim Payment Bulletin - Pharmacy Benefit

Title: Prescription Vitamins, Dietary Supplements, and Medical Foods

Policy #: Rx.04.5

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

▶ Intent:

The intent of this policy is to communicate the coverage of prescription vitamins, dietary supplements, and medical foods under the member's prescription drug benefit.

▶ Description:

A dietary supplement is defined by the Food and Drug Administration as "a product intended for ingestion that contains a 'dietary ingredient' intended to add further nutritional value to (supplement) the diet. A 'dietary ingredient' may be one, or any combination, of the following substances:

- a vitamin
- a mineral
- an herb or other botanical
- an amino acid
- a dietary substance for use by people to supplement the diet by increasing the total dietary intake
- a concentrate, metabolite, constituent, or extract"

The US Food and Drug Administration (FDA) defines a medical food as a "food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." FDA section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)). The FDA further defines medical foods as "foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in a natural state) for a patient who is seriously ill or who requires use of the product

as a major component of a disease or condition's specific dietary management." Medical foods are "intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone." They also "provide nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation."

Current benefit language states the plan will not cover:

- Dietary supplements
- Amino acid supplements
- Medical foods (exceptions may apply; refer to benefit language for details)
- Prescription vitamins except for pre-natal and pediatric vitamins

Policy:

Coverage is subject to the terms, conditions, and limitations of the member's contract.

Prescription vitamins, dietary supplements, and medical foods are not covered under the pharmacy benefit.

An exception to allow coverage under the member's plan will be in place for prescription medication that are either mandated when used as a preventive medication as described in the Patient Protection and Affordable Care Act (PPACA) or medically necessary for the treatment of a specific illness as determined by the plan.

The following prescription products are covered under the member's prescription benefit:

Products	Clinical Use
Calcitriol oral	Management of secondary hyperparathyroidism and resultant metabolic bone disease in patients with moderate to severe chronic renal failure (creatinine clearance 15 to 55 mL/min) not yet on dialysis.
Cholecalciferol (vitamin D3) 50,000 units	Treatment of hypoparathyroidism, refractory rickets, also known as vitamin D resistant rickets, and familial hypophosphatemia. This is an over the counter preparation included to meet essential health benefit requirements.
Cyanocobalamin inhaled	Maintenance of normal hematologic status in pernicious anemia patients who are in remission following intramuscular (IM) vitamin B12 therapy and who have no nervous system involvement
Dialysis vitamins oral as identified by indication in product label	Wasting syndrome in chronic renal failure, uremia, and impaired metabolic function of the kidney
Doxercalciferol oral	Secondary hyperparathyroidism (dialysis patients): Treatment of secondary hyperparathyroidism in patients with chronic kidney disease on dialysis.

	Secondary hyperparathyroidism (predialysis patients): Treatment of secondary hyperparathyroidism in patients with stage 3 or 4 chronic kidney disease.
Ergocalciferol oral	Treatment of hypoparathyroidism, refractory rickets, also known as vitamin D resistant rickets, and familial hypophosphatemia.
Paracalcitol oral	Hyperparathyroidism: For the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease stage 3 and 4, and chronic kidney disease stage 5 in patients on hemodialysis or peritoneal dialysis.
Pediatric vitamins	Nutritional supplement for children
Phytonadione oral	Anticoagulant-induced prothrombin deficiency caused by coumarin or indandione derivatives. Coagulation disorders: Phytonadione is indicated in the following coagulation disorders which are due to faulty formation of factors II, VII, IX and X when caused by vitamin K deficiency or interference with vitamin K activity.
Potassium aminobenzoate oral	The treatment of scleroderma, dermatomyositis, morphea, linear scleroderma, pemphigus, and Peyronie's disease.
Prenatal vitamins	Nutritional supplement used prior to conception, during pregnancy, and in the postnatal period
Prescription electrolytes	Electrolyte repleters (i.e., potassium) and electrolyte depleters (ie calcium acetate)

References:

Medical food guidance documents & regulatory information. Available from: <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/>. Accessed July 25, 2018.

Preventive Health Services. Available from: <https://www.healthcare.gov/coverage/preventive-care-benefits/>. Accessed July 25, 2018. Dietary supplements. Available from: <https://www.fda.gov/food/dietarysupplements/>. Accessed July 25, 2018.

Cross References:

Formulary Exception policy Rx.06.61

Medical Foods (ie, Enteral Nutrition and Nutritional Formulas) and Low-Protein Modified Food Products 08.00.18j

Non-FDA Approved Products Rx.04.2

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Next Required Review Date:

July 12, 2019

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.