# Medically Necessary Food - For Dates Of Service On Or After December 23, 2017

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## 1.0 CPT PROCEDURE CODES

97802 - 97804

## 2.0 HCPCS PROCEDURE CODES

B4034 - B9999, S9433 - S9435

## 3.0 POLICY

**3.1** Medically necessary food and medical equipment and supplies necessary to administer such food are covered by TRICARE when prescribed for dietary management of a covered disease or condition. Medically necessary food includes specialized formulas, a Low Protein Modified Food (LPMF) product or an amino acid preparation product. Medically necessary food and medical equipment and supplies may be covered when it is:

**3.1.1** Furnished pursuant to the prescription of a TRICARE authorized individual professional provider as described in 32 CFR 199.6 (e.g., physician, certified Nurse Practitioner (NP), or a certified Physician Assistant (PA), etc.) acting within the provider's scope of license/certificate of practice for the dietary management of a covered disease or condition as listed in paragraph 3.2; and

**3.1.2** A specifically formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of an individual by means of oral intake, or enteral feeding by tube, or parenteral feeding by IV, or intraperitoneal administration; and

**3.1.3** Intended for the dietary management of an individual 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; and

**3.1.4** Intended to be used under medical supervision, which may include in a home setting; and

**3.1.5** Intended only for an individual receiving active and ongoing medical supervision under which the individual requires medical care on a recurring basis for, among other things, instructions on the use of the food.

**3.2** Covered disease or conditions include:

- Inborn Errors of Metabolism (IEM);
- Medical conditions of malabsorption;
- Pathologies of the alimentary tract or the gastrointestinal tract; and,
- A neurological or physiological condition.

**3.3 Medically Necessary Vitamins And Minerals**

Medically necessary vitamins and minerals, including prenatal vitamins for prenatal care (also see Section 9.1), are covered when used for the management of a covered disease or condition, as listed in paragraph 3.2, pursuant to a prescription or order of a TRICARE authorized individual professional provider acting within the provider's scope of license/certificate of practice as described in 32 CFR 199.6.

**3.4 Specialized Formulas**

**3.4.1** Specialized formulas, to include amino acid based formulas, when covered as medically necessary food under paragraph 3.1, are listed in the "Enteral Nutrition Product Classification List." The list at: https://www.health.mil/rates.

**3.4.2** Specialized formulas included on the Enteral Nutrition Product Classification List are covered for enteral and oral consumption.

**3.5 Low Protein Modified Foods (LPMFs)**

**3.5.1** LPMFs, when covered as medically necessary foods under paragraph 3.1, are those food products that have been modified to be low in protein for use by individuals who have been diagnosed with IEM (e.g., phenylketonuria (PKU), or maple syrup urine disease), and are not typically readily available in grocery stores. LPMFs are primary to the management of IEM, as they help those diagnosed with the condition, avoid organ damage, grow properly, and maintain or improve health status. LPMFs may be covered pursuant to a prescription, when medically necessary and appropriate for the treatment of IEM.

**3.5.2 Contractor Responsibilities - LPMFs**

**3.5.2.1** The contractor shall preauthorize all prescribed LPMFs and ensure the LPMFs are medically necessary and appropriate medical care for the treatment of IEM.

**3.5.2.2** If preauthorization is not obtained and the contractor finds the LPMFs is medically necessary and appropriate and the care otherwise meets the requirements of this policy, the payment reduction provision of the TRICARE Reimbursement Manual (TRM), Chapter 1, Section 28 applies.

**3.5.2.3** If preauthorization is not obtained by the beneficiary and the beneficiary purchases LPMF directly from a vendor, and all policy criteria are met, the appropriate out of network cost-share shall apply.

**3.5.2.4** LPMF products are purchased from vendors who specialize in the distribution of LPMFs. The contractor shall include providers of LPMFs in their network as medical supply firm providers.

### 3.6 Ketogenic Diet

**3.6.1** Inpatient ketogenic diet is covered when it is part of a medically necessary inpatient admission for epilepsy. Services and supplies will be reimbursed under the Diagnosis Related Group (DRG) payment methodology.

**3.6.2** Outpatient services and supplies for ketogenic diet are covered for the treatment of seizures that are refractory to anti-seizure medication. Covered supplies are included on the list maintained by Noridian Administrative Services and can be found at: https://www.health.mil/rates.

### 3.7 Medical Nutritional Therapy/Medical Nutritional Counseling

**3.7.1** Medical nutritional therapy/medical nutritional counseling required in the administration and maintenance of TRICARE covered medically necessary foods, to include low protein foods, for those covered conditions listed in paragraph 3.2, may be covered when medically necessary and appropriate.

**3.7.2** Medical nutritional therapy must be provided by a TRICARE authorized individual professional provider described in 32 CFR 199.6 (e.g., physician, nurse, nutritionist, or Registered Dietician (RD)). If required by 32 CFR 199.6, the authorized provider (e.g., a nutritionist or RD) must be licensed by the state in which the care is provided and must be under the supervision of a physician who is overseeing the episode of treatment or the covered program of services.

### 3.8 Banked Donor Milk (BDM)

**3.8.1** Effective for dates of service on or after January 1, 2019, BDM may be cost-shared as a medically necessary food when all of the following conditions are met:

**3.8.1.1** The infant has one or more of the following conditions:

- Infant born at Very Low Birth Weight (VLBW) (less than 1,500g) or lower (e.g., Extremely Low Birth Weight (ELBW) infants, < 1,000g);
- Gastrointestinal anomaly, metabolic/digestive disorder, or recovery from intestinal surgery where digestive needs require additional support;
- Diagnosed Failure-to-Thrive where other feeding options have been exhausted or are contraindicated;
- Formula intolerance with either (1) documented feeding difficulty or (2) weight loss (where other feeding options have been exhausted or are contraindicated);
- Infant hypoglycemia;

- Congenital heart disease;
- Pre-or post-organ transplant; or
- Other serious health conditions when the use of BDM is medically necessary and will support the treatment and recovery of the infant.

**3.8.1.2** And own mother's milk is contraindicated, unavailable due to medical or psychological condition, or mother's milk is available but is insufficient in quantity or quality to meet the infant's dietary needs.

**Note:** If the birth mother is unavailable due to the physical absence of the birth mother in extraordinary circumstances (i.e., adoption, maternal death, deployment of Active Duty Service Member (ADSM) mother), the own mother's milk is considered to be unavailable for the purposes of this paragraph.

**3.8.2** BDM must be prescribed by a TRICARE authorized individual professional provider described in 32 CFR 199.6 (e.g., physician). As required by 32 CFR 199.6, the authorized provider must be licensed by the state in which the care is provided and must be under the supervision of a physician (if not a physician) who is overseeing the episode of treatment or the covered program of services.

**3.8.3** Coverage shall be extended for as long as medically necessary, not to exceed 12 months of age.

**3.8.4** BDM must be procured through a HMBANA (Human Milk Banking Association of North America) accredited milk bank, and delivered through a TRICARE authorized provider (e.g., pediatrician or inpatient hospital, or the supplier [HMBANA-accredited milk bank]).

**Note:** Currently HMBANA-accredited milk banks only exist in the United States and Canada. Therefore, BDM is not available overseas, except for Canada.

**3.8.5** Coverage shall be limited to no more than 35 ounces per day, per infant.

**3.8.6** Discontinuation of coverage for BDM for ELBW/VLBW infants shall be considered on a case-by-case basis. In general, this is considered to occur concluding the 36th post-menstrual week for otherwise healthy infants; however, continuation of coverage for BDM for healthy but ELBW/VLBW infants after 36 weeks post-menses may be appropriate in certain cases upon medical review. Continuation past 36 weeks post-menses may be covered when BDM is documented as being medically necessary or appropriate and all other conditions of coverage are met.

**3.8.7** The initial prescription shall describe the quantity and frequency of the required BDM, and shall only be valid for 30 days.

**3.8.8** Subsequent prescriptions shall describe the quantity and frequency of the required BDM, and must be renewed every 30 days.

**3.8.9** In accordance with this section, prescriptions for BDM require active medical management by the prescribing provider. The contractor may require medical documentation demonstrating active medical management, as well as documentation of medical necessity to validate both the initial as well

as ongoing prescriptions for BDM, and to validate the frequency, quantity, and duration of treatment with BDM.

**3.8.10** BDM provided during an inpatient stay shall be cost-shared the same as any other medical supply provided during an inpatient stay.

**3.8.11** BDM provided on an outpatient basis shall be subject to the same copays and cost-sharing requirements as other outpatient medical supplies.

## 4.0 REIMBURSEMENT

**4.1** Medical foods shall be reimbursed using the rate on the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) fee schedule. If there is no DMEPOS fee schedule rate, the allowable charge shall be established in accordance with the TRM, Chapter 1, Section 39; Chapter 3, Section 1; and Chapter 5, Sections 1 and 3, for BDM.

**4.2** When reimbursement is made in accordance with the TRM, Chapters 3 and 5, especially when the state prevailing or billed rate is used, the contractor shall ensure the provisions of 32 CFR 199.9(b)(2), (b)(7), (c)(11) and the TRICARE Operations Manual (TOM), Chapter 13, are followed to prevent fraud and abuse.

**4.3** BDM shall be reimbursed in accordance with TRM, Chapter 1, Section 39. The beneficiary may be required to pay out-of-pocket for BDM and submit a claim to the contractor for reimbursement. Provisions are outlined in TOM, Chapter 8, Section 1.

## 5.0 EXCLUSIONS

TRICARE covered medically necessary food and vitamins do not include:

**5.1** Food taken as part of an overall diet designed to reduce the risk of a disease or medical condition, or as weight-loss products, even if the food is recommended by a physician or other health care professional.

**5.2** Food marketed as gluten-free for the management of celiac disease or non-celiac gluten sensitivity.

**5.3** Food marketed for the management of diabetes.

**5.4** Vitamins or mineral preparations, except as provided in paragraph 3.3.

**5.5** Nutritional supplements administered in the absence of a covered disease or a medical condition that is listed in paragraph 3.2.

**5.6** Megavitamin psychiatric therapy, orthomolecular psychiatric therapy.

**5.7** Items used primarily for convenience or for features which exceed that which is medically necessary (for example, prepackaged, liquid vs. powder, etc.).

**5.8** Nutritional products that are marketed for use for individuals without medical conditions.

**5.9** Naturally occurring foodstuff used in its natural state, to include those that are naturally low in protein. Excluded items are those not intended to be used under the direction of a physician for the dietary treatment of an inborn error of metabolism.

**5.10** Healthcare Common Procedure Coding System (HCPCS) code B4104 is an enteral formula additive. The enteral formula codes include all nutrient components, including vitamins, mineral and fiber. As a result B4104 is not separately payable.

**5.11** Specialized formulas, except those covered in paragraph 3.4.

**5.12** BDM from any milk bank not accredited by HMBANA.

**5.13** Peer-to-peer donation or sale of BDM.

**5.14** More than 35 ounces of BDM per day, per infant.

**5.15** BDM for healthy, normal birth weight infants (even if own mother's milk is unavailable).

**5.16** BDM provided for convenience (e.g., to facilitate the mother's return to work).

## 6.0 EFFECTIVE DATES

**6.1** December 23, 2017.

**6.2** Coverage for BDM is effective January 1, 2019.

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