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DEFENSE
HEALTH AGENCY

HPOD

CHANGE 42
6010.60-M
MARCH 12, 2019

PUBLICATIONS SYSTEM CHANGE TRANSMITTAL FOR TRICARE POLICY MANUAL (TPM), APRIL 2015

The Defense Health Agency has authorized the following addition(s)/revision(s).

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SUMMARY OF CHANGE(S): See page 2.

EFFECTIVE DATE: See page 2.

IMPLEMENTATION DATE: April 12, 2019.

This change is made in conjunction with Apr 2015 TRM, Change No. 34, and Apr 2015 TSM, Change No. 22.

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WHEN PRESCRIBED ACTION HAS BEEN TAKEN, FILE THIS TRANSMITTAL WITH BASIC DOCUMENT.

CHANGE 42
6010.60-M
MARCH 12, 2019

SUMMARY OF CHANGES

CHAPTER 8

1. Section 2.6. Updates policy for Breast Pumps, Breast Pump Supplies and Breastfeeding Counseling. EFFECTIVE DATE: 07/05/2018.

2. Section 7.2. Clarifies language regarding Medically Necessary Foods. EFFECTIVE DATE: As Stated in Issuance.

Chapter 8 Section 2.6

Breast Pumps, Breast Pump Supplies, And Breastfeeding Counseling

Issue Date: August 8, 2005
Authority: 32 CFR 199.4(d)(1) and (f)(12)

Revision: C-42, March 12, 2019

1.0 CPT PROCEDURE CODES

99401 - 99404

2.0 HCPCS PROCEDURE CODES

Level II Codes E0602 - E0604, A4281 - A4286, A9900, A9999

3.0 BACKGROUND

3.1 Effective August 8, 2005, TRICARE began covering heavy-duty hospital grade breast pumps and associated supplies for mothers of premature infants. However, heavy-duty hospital grade breast pumps for other conditions, as well as manual and standard electric breast pumps, were excluded from coverage.

3.2 On December 19, 2014, the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2015 was signed into effect. Section 706 of this Law allows expanded coverage of breast pumps and supplies, as well as coverage of breastfeeding counseling. Therefore, effective for services rendered on or after December 19, 2014, breast pumps (including manual and standard electric breast pumps), breast pump supplies, and breastfeeding counseling obtained in accordance with this policy are covered. This coverage is extended to all pregnant TRICARE beneficiaries beginning at the 27th week of pregnancy (third trimester) or birth of a child if prior to 27 weeks, as well as for a female beneficiary who legally adopts an infant and intends to personally breastfeed the adopted infant. This will subsequently be referred to in this policy as a "birth event".

3.3 In general, the equipment, supplies, and counseling authorized by Section 706 of the FY 2015 NDAA are considered to be preventive. Therefore, in accordance with the authority provided by the FY 2009 NDAA, Section 711, cost-shares, copays, and deductibles are waived for breast pumps, breast pump supplies, and breastfeeding counseling services rendered on or after December 19, 2014.

4.0 POLICY

4.1 Heavy-Duty Hospital Grade Breast Pumps And Supplies

4.1.1 For services rendered between August 8, 2005, and December 18, 2014, a heavy-duty hospital grade breast pump (E0604) is covered (including services and supplies related to the use of the pump) for mothers of premature infants only.

4.1.1.1 A premature infant is defined as a newborn with International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) codes 765.0 (extreme immaturity), 765.1 (other preterm infants), or 765.21 through 765.28 (up to 36 weeks gestation) for services provided before the mandated date, as directed by Health and Human Services (HHS), for International Classification of Diseases, 10th Revision (ICD-10) implementation or ICD-10-CM codes P07.00 - P07.03 (extremely low birth weight (unspecified weight-999 grams)), P07.10 - P07.18 (other low birth weight (unspecified weight, 1000-2499 grams)), P07.20 - P07.26 (extreme immaturity (unspecified weeks-27 completed weeks)), P07.30 - P07.39 (other preterm (unspecified, 28-36 completed weeks)) for services provided on or after the mandated date, as directed by HHS, for ICD-10 implementation.

4.1.1.2 A heavy-duty hospital grade breast pump is covered while the premature infant remains hospitalized during the immediate postpartum period.

4.1.1.3 After the premature infant (as defined in paragraph 4.1.1.1) is discharged, continued use of a hospital-grade breast pump may be covered when a physician documents the medical reason for continued use.

4.1.1.4 Regular Durable Medical Equipment (DME) and supply cost-sharing rules apply.

4.1.2 For services rendered on or after December 19, 2014, a heavy-duty hospital grade breast pump (E0604) and associated supplies are covered when required to support initiation of lactation for mothers and infants who are separated due to illness or who are unable to feed directly from the breast due to maternal or infant medical complications, congenital anomalies, induced lactation, relactation, adoption, or other medical conditions for mother or infant which preclude effective feeding at the breast.

4.1.2.1 A prescription from a TRICARE-authorized physician, physician assistant, nurse practitioner, or nurse midwife is required for coverage of a heavy-duty hospital grade breast pump.

4.1.2.2 Use of a heavy-duty hospital grade breast pump may be covered for as long as use of a heavy-duty hospital grade breast pump is determined to be medically necessary and appropriate medical care.

4.1.2.3 If/when a heavy-duty hospital grade breast pump is determined to no longer be medically necessary and appropriate medical care, a manual or standard electric breast pump may be covered.

4.1.2.4 The supply limitations established for the manual and standard electric breast pumps in paragraphs 4.2 through 4.2.9 apply to heavy-duty hospital grade pumps.

4.1.2.5 Cost-shares, copays, and deductibles do not apply to heavy-duty hospital grade breast pumps and associated supplies for services rendered on or after December 19, 2014.

4.2 Manual/Standard Electric Breast Pumps And Supplies

4.2.1 Manual or standard electric breast pumps and associated supplies are covered for services rendered on or after December 19, 2014, the date of the FY 2015 NDAA.

4.2.2 One manual (E0602) or one standard electric (E0603) breast pump may be covered per birth event.

4.2.3 For dates of service prior to July 5, 2018, standard power adapters, tubing and tubing adaptors, locking rings, bottles, bottle caps, shield/splash protectors, and storage bags used with the breast pump are covered as necessary for up to 36 months post birth event.

4.2.4 Breast pump kits are also covered. Pump kits, which are specific to each breast pump manufacturer's requirements, provide the necessary supplies/accessories to allow expression of breast milk from both breasts simultaneously (double-pumping). For dates of service prior to July 5, 2018, up to two breast pump kits are covered per birth event. Effective July 5, 2018, one breast pump kit is covered per birth event, but may not be separately reimbursed. See paragraph 5.5.

4.2.5 A prescription from a TRICARE-authorized physician, physician assistant, nurse practitioner, or nurse midwife is required for coverage of the breast pump. In addition, the prescription must, at a minimum, indicate the type of breast pump prescribed (manual or standard electric).

4.2.6 To be covered, the breast pump and supplies must be obtained from a TRICARE-authorized provider, supplier, or vendor. For manual or standard electric breast pumps and associated supplies (includes breast pump kits), this includes any civilian retail store or pharmacy (please reference Chapter 11, Section 9.1, paragraph 2.2.1).

4.2.7 Effective for dates of service on or after July 5, 2018, only the following replacement supplies are available without an additional prescription:

- Bottles: Two replacement bottles and caps/locking rings every 12 months following a birth event;
- Power Adapters: One power adapter per birth event, and not within the first 12 months following purchase;
- Valves: Twelve valves/membranes for each 12 months period following a birth event;
- One set (2) of flanges/breast shields per birth event;
- One set of tubing per birth event;
- Ninety breast milk bags every 30 days following the birth event.

4.2.8 Effective July 5, 2018, two sets (2) of nipple shields and one Supplemental Nursing System (SNS) per birth event may be covered when prescribed by a TRICARE-authorized provider.

4.2.9 Effective July 5, 2018, additional replacement supplies, in addition to those detailed in paragraphs 4.2.7 and 4.2.8, may be covered when a new prescription from an authorized individual

professional provider is obtained, describing the specific supplies required. Only those replacement supplies in excess of the limits described in paragraphs 4.2.7 and 4.2.8, which are essential for breast feeding and are accompanied by a new prescription from a TRICARE-authorized individual professional provider, shall be reimbursed.

4.2.10 In the event a beneficiary pays out-of-pocket for a covered breast pump and/or supplies, the beneficiary may request reimbursement from the appropriate contractor. To request reimbursement from the contractor, the beneficiary must submit an approved and properly completed claim form with a copy of the prescription for the breast pump and an itemized receipt(s). An approved claim form is either a Department of Defense Document (DD) Form 2642 (http://www.dtic.mil/whs/directives/forms/eforms/dd2642.pdf) or a Centers for Medicare and Medicaid Services (CMS) 1500 Claim Form. Effective July 5, 2018, limitations on the maximum amount of reimbursement available for beneficiary-purchased breastfeeding supplies may result in out-of-pocket expenses. The contractor shall ensure appropriate beneficiary education regarding the maximum amount of reimbursement available under the program as detailed in the TRICARE Reimbursement Manual (TRM), Chapter 1, Addendum D and in this section.

4.2.11 Cost-shares, copays, and deductibles do not apply to manual or standard electric breast pumps and supplies for covered services provided on or after December 19, 2014.

4.3 Breastfeeding/Lactation - Counseling

4.3.1 Breastfeeding/Lactation counseling is generally considered an expected component of good clinical practice. Therefore, reimbursement of breastfeeding/lactation counseling rendered during the inpatient maternity stay or an outpatient OB or well-child care visit is included in the allowance for the primary service. However, for services rendered on or after December 19, 2014, up to six individual outpatient breastfeeding/lactation counseling sessions (Current Procedural Terminology (CPT) procedure codes 99401-99404), per birth event, may be covered. These counseling sessions are **in addition to** breastfeeding/lactation counseling that may be provided during an inpatient maternity stay, outpatient OB visit, or well-child visit. However, these additional counseling sessions are only covered and separately reimbursed when **all** of the following are met:

- The breastfeeding/lactation counseling is billed using one of the preventive counseling CPT procedure codes 99401-99404; and
- Breastfeeding/Lactation counseling is the only service being provided; and
- The breastfeeding/lactation counseling is rendered by a TRICARE-authorized individual professional provider (e.g., physician, physician assistant, nurse practitioner, nurse midwife, or registered nurse), outpatient hospital, or clinic.

4.3.2 Cost-shares, copays, and deductibles do not apply to covered breastfeeding/lactation counseling sessions for services rendered on or after December 19, 2014.

5.0 EXCLUSIONS

5.1 The following products associated with breast pump use are specifically excluded:

- Breast pump batteries, battery-powered adapters, and battery packs;

- Regular "baby bottles" (Bottles not specific to pump operation), including associated nipples, caps, and lids;
- Travel bags and other similar carrying accessories;
- Breast pump cleaning supplies;
- Baby weight scales;
- Garments and other products that allow hands-free pump operation;
- Ice packs, labels, labeling lids, and other similar products;
- Nursing bras, bra pads, and other similar products; and
- Over-the-counter (OTC) creams and ointments.

5.2 Individual outpatient breastfeeding/lactation counseling sessions rendered by an individual professional provider, outpatient hospital or clinic that is not TRICARE-authorized.

5.3 Rental of breast pumps for personal use (the rental of hospital-grade breast pumps is covered when medically necessary).

5.4 Breast pumps with "luxury or deluxe" features, such as smartphone connectivity, Bluetooth connectivity, enhanced/expanded rechargeable batteries, or unnecessary accessories, such as luxury tote bags, car adapters, or nipples for use with bottle feeding are excluded. Beneficiaries may elect to purchase luxury or deluxe pumps and pay for the difference between TRICARE's maximum benefit and the actual cost of the pump.

5.5 Parts and supplies (i.e., kits, pump, tubing, valves/membranes, flanges/breast shields, locking rings, power adapters, bottles, bottle caps, and other required accessories) that are billed in conjunction with the breast pump are excluded. These components shall be included in the overall reimbursement for the initial breast pump and are not separately payable. Unbundling of a breast pump kit for the purposes of billing items individually to maximize reimbursement is considered an abusive billing practice in accordance with 32 CFR 199.9.

6.0 EFFECTIVE DATES

6.1 The effective date for coverage of heavy-duty hospital grade breast pumps and supplies is August 8, 2005.

6.2 The effective date for coverage of a manual or standard electric breast pump and associated supplies, and counseling services covered under this policy is December 19, 2014.

6.3 The effective date for elimination of cost-shares, copays, and deductibles for the equipment, supplies, and services covered under this policy is December 19, 2014.

6.4 The effective date for limitations on replacement supplies, and coverage for SNS and nipple shields is July 5, 2018.

- END -

Chapter 8 Section 7.2

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

Issue Date: August 25, 2017
Authority: 32 CFR 199.4(a)(1)(i), (d)(3)(iii), (g)(39), (g)(57), (g)(66), 32 CFR 199.5(c), 32 CFR 199.6(c)(3)(iii)(L), (c)(3)(iii)(M), and National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2017, Section 714

Revision: C-42, March 12, 2019

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 is maintained by Noridian Administrative Services and can be found at: https://www.health.mil/rates.

3.4.2 Specialized formulas included on the Noridian 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.

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 3, Section 1 and Chapter 5, Sections 1 and 3.

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.

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 Banked breast milk.

5.12 Specialized formulas, except those covered in paragraph 3.4.

6.0 EFFECTIVE DATE

December 23, 2017.

- END -