Local Coverage Article:
Enteral Nutrition - Policy Article (AXXXXX)

Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
CGS Administrators, LLC	DME MAC	17013 - DME MAC	J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
CGS Administrators, LLC	DME MAC	18003 - DME MAC	J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi New Mexico North Carolina Oklahoma Puerto Rico South Carolina Tennessee Texas Virgin Islands Virginia West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut Delaware District of Columbia Maine

				Maryland Massachusetts New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Idaho Iowa Kansas Missouri - Entire State Montana Nebraska Nevada North Dakota Northern Mariana Islands Oregon South Dakota Utah Washington Wyoming

Article Information

General Information

General Article Information Table

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Article Title
Enteral Nutrition - Policy Article

Article Type
Article

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Article Guidance

Article Text:

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary").

Enteral nutrition is covered under the Prosthetic Device benefit (Social Security Act § 1861(s)(8)). In order for a beneficiary's nutrition to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

GENERAL:

Enteral nutrition for temporary impairments will be denied as non-covered, no benefit.

Enteral nutrition for beneficiaries with a functioning gastrointestinal tract whose need for enteral nutrition is not due to reasons related to the non-function or disease of the structures that normally permit food to reach the small bowel will be denied as non-covered, no benefit.

Orally administered enteral nutrition products, related supplies and equipment will be denied non-covered, no benefit.

Enteral nutrition provided to a beneficiary in a Part A covered stay must be billed by the SNF to the fiscal intermediary. No payment from Part B is available when enteral nutrition services are furnished to a beneficiary in a stay covered by Part A. However, if a beneficiary is in a stay not covered by Part A, enteral nutrition is eligible for coverage under Part B and may be billed to the DME MAC by either the SNF or an outside supplier.

NUTRIENTS:

Food thickeners (B4100), baby food, and other regular grocery products that can be blenderized and used with the enteral system will be denied as non-covered.

Electrolyte-containing fluids (B4102 and B4103) are not indicated for the maintenance of weight and strength and are therefore non-covered, no benefit.

Self-blenderized formulas are non-covered by Medicare.

Code B4104 is an enteral formula additive. The enteral formula codes include all nutrient components, including vitamins, mineral, and fiber. Therefore, code B4104 will be denied as not separately payable.

SUPPLIES:

The unit of service (UOS) for the supply allowance (B4034, B4035, or B4036) is one (1) UOS per day. Claims that are submitted for more than one UOS per day for HCPCS codes B4034, B4035, or B4036 will be rejected.

TEST OF PERMANENCE:

Coverage of enteral nutrition under the prosthetic device benefit, as outlined in the Benefit Policy Manual, Chapter 15 §120 (CMS Pub. 100-02), requires that a beneficiary must have a permanent impairment. However, this does not require a determination that there is no possibility that the beneficiary's condition may improve sometime in the future. If the medical record, including the judgment of the treating practitioner, indicates that the impairment will be of long and indefinite duration, the test of permanence is considered met.

REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO Final Rule 1713 (84 Fed. Reg Vol 217)

Final Rule 1713 (84 Fed. Reg Vol 217) requires a face-to-face encounter and a Written Order Prior to Delivery (WOPD) for specified HCPCS codes. CMS and the DME MACs provide a list of the specified codes, which is periodically updated. The link will be located here once it is available.

Claims for the specified items subject to Final Rule 1713 (84 Fed. Reg Vol 217) that do not meet the face-to-face encounter and WOPD requirements specified in the LCD-related Standard Documentation Requirements Article (A55426) will be denied as not reasonable and necessary.

If a supplier delivers an item prior to receipt of a WOPD, it will be denied as not reasonable and necessary. If the WOPD is not obtained prior to delivery, payment will not be made for that item even if a WOPD is subsequently obtained by the supplier. If a similar item is subsequently provided by an unrelated supplier who has obtained a WOPD, it will be eligible for coverage.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

In addition to policy specific documentation requirements, there are general documentation requirements that are applicable to all DMEPOS policies. These general requirements are located in the DOCUMENTATION REQUIREMENTS section of the LCD.

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this Policy Article under the Related Local Coverage Documents section for additional information regarding GENERAL DOCUMENTATION REQUIREMENTS and the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS discussed below.

The supplier must enter a diagnosis code corresponding to the beneficiary's diagnosis on each claim.

Information describing the medical necessity for enteral nutrition must be available upon request. In order to satisfy the test of permanence, there must be documentation to reflect that in the treating practitioner's judgement, the impairment will be of long and indefinite duration.

Documentation in the medical record shall also reflect that the beneficiary has (a) full or partial non-function or disease of the structures that normally permit food to reach the small bowel; or, (b) disease that impairs digestion and/or absorption of an oral diet, directly or indirectly, by the small bowel.

Special nutrient formulas, HCPCS codes B4149, B4153, B4154, B4155, B4157, B4161, and B4162, are produced to meet unique nutrient needs for specific disease conditions. If a special nutrient formula is ordered, the beneficiary's medical records must specify the unfavorable events associated with the standard formula that resulted in prescribing a special enteral formula. A diagnosis alone is not sufficient to support the medical need for a specialty formula. At a minimum, the medical records must include the following:

- Beneficiary's diagnosis
- Formula(s) tried
- Unfavorable events associated with the standard formula

For example, the treating practitioner ordering a diabetes-specific formula may document in the beneficiary's medical record that the beneficiary has a diagnosis of diabetes mellitus and has experienced severe fluctuations of glucose levels on standard formula.

DME INFORMATION FORM (DIF)

A DME Information Form (DIF) which has been completed, signed, and dated by the supplier, must be kept on file by the supplier and made available upon request.

The DIF for Enteral Nutrition is CMS Form 10126. The initial claim must include an electronic copy of the DIF.

A new Initial DIF for enteral nutrients is required when:

- A formula billed with a different code, which has not been previously certified, is ordered, or
- Enteral nutrition services are resumed after they have not been required for two consecutive months.

A new Initial DIF for a pump (B9002) is required when:

- Enteral nutrition services involving use of a pump are resumed after they have not been required for two consecutive months, or
- A beneficiary receiving enteral nutrition by the syringe or gravity method is changed to administration using a pump.

A revised DIF is required when:

- The number of calories per day is changed, or
- The number of days per week administered is changed, or
- The method of administration (syringe, gravity, pump) changes, or
- The route of administration is changed from tube feedings to oral feedings (if billing for denial), or
- The HCPCS code for the current nutrient changes (revised DIF for the pump)

A revised DIF must be submitted when the length of need previously entered on the DIF has expired and the treating practitioner is extending the length of need for the item(s).

If two enteral nutrition products, which are described by the same HCPCS code, are being provided at the same time, they should be billed on a single claim line with the units of service reflecting the total calories of both nutrients.

CODING GUIDELINES

Enteral feeding supply allowances (B4034, B4035, and B4036) include all supplies, other than the feeding tube and nutrients, required for the administration of enteral nutrients to the beneficiary for one day. Only one unit of service may be billed for any one day. Codes B4034, B4035, and B4036 describe a daily supply fee rather than a specifically defined “kit”. The use of individual items may differ from beneficiary to beneficiary, and from day to day. Items included in these codes are not limited to pre-packaged “kits” bundled by manufacturers or distributors. These supply allowances include, but are not limited to, a catheter/tube anchoring device, feeding bag/container, flushing solution bag/container, administration set tubing, extension tubing, feeding/flushing syringes, gastrostomy tube holder, dressings (any type) used for gastrostomy tube site, tape (to secure tube or dressings), Y connector, adapter, gastric pressure relief valve, declogging device, etc.. These items must not be separately billed using the miscellaneous code (B9998) or using a specific code for any individual item, should a unique HCPCS code for item exist (for examples dressing, tape, etc.).

B4105 (IN-LINE CARTRIDGE CONTAINING DIGESTIVE ENZYME(S) FOR ENTERAL FEEDING, EACH) is eligible for separate payment.

When an IV pole (E0776) is used for enteral nutrition administered by gravity or a pump, the BA modifier should be added to the code. Code E0776 is the only code with which the BA modifier may be used.

When enteral nutrients (B4149, B4150, B4152, B4153, B4154, B4155, B4157, B4158, B4159, B4160, B4161, and B4162) are administered by mouth, the BO modifier must be added to the code. Products that are only administered orally should be coded as A9270.

Code B4149 describes formulas containing natural foods that are blenderized and packaged by a manufacturer. B4149 formulas are classified based upon this manufacturer requirement, not on the composition of the enteral formula. Code B4149 must not be used for foods that have been blenderized by the beneficiary or caregiver for administration through a tube.

The only products which may be billed using codes B4149, B4153, B4154, B4155, B4157, B4161, or B4162 are those for which a written Coding Verification Review has been made by the Pricing, Data Analysis and Coding (PDAC) Contractor and subsequently published on the Product Classification List (PCL). If a product is billed to Medicare using a HCPCS code that requires written coding verification review, but the product is not on the PCL for that particular HCPCS code, then the claim line will be denied as incorrect coding.

Suppliers should refer to the Enteral Nutrition Product Classification list on the PDAC Contractor web site or contact the PDAC for guidance on the correct coding for these items.

Coding Information

CPT/HCPCS Codes

N/A

ICD-10 Codes that Support Medical Necessity

Group 1: Paragraph
The presence of an ICD-10 code listed in this section is not sufficient by itself to assure coverage. Refer to the section on "**Coverage Indications, Limitations and/or Medical Necessity**" for other coverage criteria and payment information.
For HCPCS code B4105:

Group 1: Codes

E08.69 Diabetes mellitus due to underlying condition with other specified complication

E09.69 Drug or chemical induced diabetes mellitus with other specified complication

E10.69 Type 1 diabetes mellitus with other specified complication

E11.69 Type 2 diabetes mellitus with other specified complication

E13.69 Other specified diabetes mellitus with other specified complication

E84.19 Cystic fibrosis with other intestinal manifestations

E84.8 Cystic fibrosis with other manifestations

E84.9 Cystic fibrosis, unspecified

K50.018 Crohn's disease of small intestine with other complication

K50.118 Crohn's disease of large intestine with other complication

K50.818 Crohn's disease of both small and large intestine with other complication

K50.918 Crohn's disease, unspecified, with other complication

K51.818 Other ulcerative colitis with other complication

K51.918 Ulcerative colitis, unspecified with other complication

K86.0 Alcohol-induced chronic pancreatitis

K86.1 Other chronic pancreatitis

K86.81 Exocrine pancreatic insufficiency

K90.0 Celiac disease

Q45.3 Other congenital malformations of pancreas and pancreatic duct

Z90.410 Acquired total absence of pancreas

Z90.411 Acquired partial absence of pancreas

ICD-10 Codes that DO NOT Support Medical Necessity

N/A

Additional ICD-10 Information

N/A

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the article,

services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the article should be assumed to apply equally to all Revenue Codes.

N/A

Revision History Information

Revision History DateRevision History NumberRevision History Explanation

Associated Documents

Related Local Coverage Document(s)

Article(s)

A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs

LCD(s)

DL38955 - Enteral Nutrition

Related National Coverage Document(s)

N/A

Statutory Requirements URL(s)

N/A

Rules and Regulations URL(s)

N/A

CMS Manual Explanations URL(s)

N/A

Other URL(s)

N/A