Payment will not be made for any use of these drugs outside of the criteria without prior authorization. The member may not be billed unless the member explicitly agrees in writing to be responsible for the charges in accordance with the contract/provider manual. Prior authorization will only be given if the provider demonstrates the intended use meets Medicare coverage guidelines.

Coverage Guidelines:

FDA
CLINIMIX sulfite-free (Amino Acid in Dextrose) Injections are indicated as a caloric component in a parenteral nutrition regimen and as the protein (nitrogen) source for offsetting nitrogen loss or for treatment of negative nitrogen balance in patients where:
(1) The alimentary tract cannot or should not be used,
(2) Gastrointestinal absorption of protein is impaired, or
(3) Metabolic requirements for protein are substantially increased, as with extensive burns.
Central Vein Administration: Central vein infusion should be used when amino acid solutions are admixed with hypertonic dextrose to promote protein synthesis such as for hypercatabolic or depleted patients or those requiring long term parenteral nutrition. Peripheral Vein Administration: For patients in whom the central vein route is not indicated, amino acid solutions diluted with low dextrose concentrations may be infused by peripheral vein.

<u>Liposyn Products</u>
Intravenous fat emulsion is indicated as a source of calories for patients requiring parenteral nutrition. Where such nutrition is required for extended periods of time (more than 5 days), intravenous fat emulsion is also indicated as a source of essential fatty acids to prevent or reverse biochemical changes in fatty acid composition of plasma lipids (elevated triene/tetraene ration) and the clinical manifestations of EFAD.

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Aminosyn Products

Aminosyn and Aminosyn II products infused with dextrose by peripheral vein infusion are indicated as a source of nitrogen in the nutritional support of patients with adequate stores of body fat, in whom, for short periods of time, oral nutrition cannot be tolerated, is undesirable or is inadequate.

When administered with concentrated dextrose solution with or without fat emulsions they are also indicated for central vein infusion to prevent or reverse negative nitrogen balance in patients where: (a) the alimentary tract by the oral, gastrostomy or jejunostomy route cannot or should not be used; (b) gastrointestinal absorption of protein is impaired; (c) metabolic requirements for protein are substantially increased as with extensive burns and (d) morbidity and mortality may be reduced by replacing amino acids lost from tissue breakdown, thereby preserving tissue reserves, as in acute renal failure.

Coding Information:

HCPCS Code(s)

A5200	PERCUTANEOUS CATHETER/TUBE ANCHORING DEVICE, ADHESIVE SKIN ATTACHMENT
A9270	NON-COVERED ITEM OR SERVICE
B4034	ENTERAL FEEDING SUPPLY KIT; SYRINGE FED, PER DAY, INCLUDES BUT NOT LIMITED TO FEEDING/FLUSHING SYRINGE, ADMINISTRATION SET TUBING, DRESSINGS, TAPE
B4035	ENTERAL FEEDING SUPPLY KIT; PUMP FED, PER DAY, INCLUDES BUT NOT LIMITED TO FEEDING/FLUSHING SYRINGE, ADMINISTRATION SET TUBING, DRESSINGS, TAPE
B4036	ENTERAL FEEDING SUPPLY KIT; GRAVITY FED, PER DAY, INCLUDES BUT NOT LIMITED TO FEEDING/FLUSHING SYRINGE, ADMINISTRATION SET TUBING, DRESSINGS, TAPE
B4081	NASOGASTRIC TUBING WITH STYLET
B4082	NASOGASTRIC TUBING WITHOUT STYLET
B4083	STOMACH TUBE - LEVINE TYPE
B4087	GASTROSTOMY/JEJUNOSTOMY TUBE, STANDARD, ANY MATERIAL, ANY TYPE, EACH
B4088	GASTROSTOMY/JEJUNOSTOMY TUBE, LOW-PROFILE, ANY MATERIAL, ANY TYPE, EACH
B4100	FOOD THICKENER, ADMINISTERED ORALLY, PER OUNCE
B4102	ENTERAL FORMULA, FOR ADULTS, USED TO REPLACE FLUIDS AND ELECTROLYTES

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	(E.G. CLEAR LIQUIDS), 500 ML = 1 UNIT
B4103	ENTERAL FORMULA, FOR PEDIATRICS, USED TO REPLACE FLUIDS AND ELECTROLYTES (E.G. CLEAR LIQUIDS), 500 ML = 1 UNIT
B4104	ADDITIVE FOR ENTERAL FORMULA (E.G. FIBER)
B4149	ENTERAL FORMULA, MANUFACTURED BLENDERIZED NATURAL FOODS WITH INTACT NUTRIENTS, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT
B4150	ENTERAL FORMULA, NUTRITIONALLY COMPLETE WITH INTACT NUTRIENTS, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT
B4152	ENTERAL FORMULA, NUTRITIONALLY COMPLETE, CALORICALLY DENSE (EQUAL TO OR GREATER THAN 1.5 KCAL/ML) WITH INTACT NUTRIENTS, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT
B4153	ENTERAL FORMULA, NUTRITIONALLY COMPLETE, HYDROLYZED PROTEINS (AMINO ACIDS AND PEPTIDE CHAIN), INCLUDES FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT
B4154	ENTERAL FORMULA, NUTRITIONALLY COMPLETE, FOR SPECIAL METABOLIC NEEDS, EXCLUDES INHERITED DISEASE OF METABOLISM, INCLUDES ALTERED COMPOSITION OF PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND/OR MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT
B4155	ENTERAL FORMULA, NUTRITIONALLY INCOMPLETE/MODULAR NUTRIENTS, INCLUDES SPECIFIC NUTRIENTS, CARBOHYDRATES (E.G. GLUCOSE POLYMERS), PROTEINS/AMINO ACIDS (E.G. GLUTAMINE, ARGININE), FAT (E.G. MEDIUM CHAIN TRIGLYCERIDES) OR COMBINATION, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT
B4157	ENTERAL FORMULA, NUTRITIONALLY COMPLETE, FOR SPECIAL METABOLIC NEEDS FOR INHERITED DISEASE OF METABOLISM, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT
B4158	ENTERAL FORMULA, FOR PEDIATRICS, NUTRITIONALLY COMPLETE WITH INTACT

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	NUTRIENTS, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER AND/OR IRON, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT
B4159	ENTERAL FORMULA, FOR PEDIATRICS, NUTRITIONALLY COMPLETE SOY BASED WITH INTACT NUTRIENTS, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER AND/OR IRON, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT
B4160	ENTERAL FORMULA, FOR PEDIATRICS, NUTRITIONALLY COMPLETE CALORICALLY DENSE (EQUAL TO OR GREATER THAN 0.7 KCAL/ML) WITH INTACT NUTRIENTS, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT
B4161	ENTERAL FORMULA, FOR PEDIATRICS, HYDROLYZED/AMINO ACIDS AND PEPTIDE CHAIN PROTEINS, INCLUDES FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT
B4162	ENTERAL FORMULA, FOR PEDIATRICS, SPECIAL METABOLIC NEEDS FOR INHERITED DISEASE OF METABOLISM, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT
B9000	ENTERAL NUTRITION INFUSION PUMP - WITHOUT ALARM
B9002	ENTERAL NUTRITION INFUSION PUMP - WITH ALARM
B9998	NOC FOR ENTERAL SUPPLIES
E0776	IV POLE

ICD-9 Code(s)

No applicable codes listed in the CMS LCD L11553or Article

Indications and Limitations:

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. For the items addressed in this local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act §

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1862(a)(1)(A) provisions, are defined by the following indications and limitations of coverage and/or medical necessity.

For an item to be covered by Medicare, a signed and dated detailed written order must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed detailed written order, the item will be denied as not reasonable and necessary.

GENERAL:

Statutory coverage criteria for enteral nutrition are specified in the related Policy Article. Enteral nutrition products that are administered orally and related supplies are noncovered.

If the coverage requirements for enteral nutrition are met, medically necessary nutrients, administration supplies, and equipment are covered.

Enteral nutrition provided to a patient 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:

Enteral formulas consisting of semi-synthetic intact protein/protein isolates (B4150 or B4152) are appropriate for the majority of patients requiring enteral nutrition.

The medical necessity for special enteral formulas (B4149, B4153-B4157, B4161, and B4162) must be justified in each patient. If a special enteral nutrition formula is provided and if the medical record does not document why that item is medically necessary, it will be denied as not reasonable and necessary.

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

Codes B4102 and B4103 describe electrolyte-containing fluids that are noncovered by

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Medicare.

Self-blenderized formulas are noncovered 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.

EQUIPMENT AND SUPPLIES:

Enteral nutrition may be administered by syringe, gravity, or pump. Some enteral patients may experience complications associated with syringe or gravity method of administration.

If a pump (B9000-B9002) is ordered, there must be documentation in the patient's medical record to justify its use (e.g., gravity feeding is not satisfactory due to reflux and/or aspiration, severe diarrhea, dumping syndrome, administration rate less than 100 ml/hr, blood glucose fluctuations, circulatory overload, gastrostomy/jejunostomy tube used for feeding). If the medical necessity of the pump is not documented, the pump will be denied as not reasonable and necessary.

The feeding supply kit (B4034-B4036) must correspond to the method of administration indicated in question 5 of the DME Information Form (DIF). If it does not correspond, it will be denied as not reasonable and necessary.

If a pump supply kit (B4035) is provided and if the medical necessity of the pump is not documented, it will be denied as not reasonable and necessary.

The codes for feeding supply kits (B4034-B4036) are specific to the route of administration. Claims for more than one type of kit code delivered on the same date or provided on an ongoing basis will be denied as not reasonable and necessary.

More than three nasogastric tubes (B4081-B4083), or one gastrostomy/jejunostomy tube (B4087-B4088) every three months is not reasonable and necessary.

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PROOF OF DELIVERY

For patients in a nursing home, the delivery must be designated for each individual beneficiary, not just as a general delivery to the nursing home.

REFILL REQUIREMENTS

For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes/modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized. (CMS Program Integrity Manual, Internet-Only Manual, CMS Pub. 100-8, Chapter 5, Section 5.2.6).

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the ordering physicians that any changed or atypical utilization is warranted. Regardless of utilization, a supplier must not dispense more than a one (1)-month quantity at a time.

Background:

Enteral nutrition is the provision of nutritional requirements through a tube into the stomach or small intestine.

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Enteral nutrition is covered for a patient who has (a) permanent non-function or disease of the structures that normally permit food to reach the small bowel or (b) disease of the small bowel which impairs digestion and absorption of an oral diet, either of which requires tube feedings to provide sufficient nutrients to maintain weight and strength commensurate with the patient's overall health status.

The patient must have a permanent impairment. Permanence does not require a determination that there is no possibility that the patient's condition may improve sometime in the future. If the judgment of the attending physician, substantiated in the medical record, is that the condition is of long and indefinite duration (ordinarily at least 3 months), the test of permanence is considered met. Enteral nutrition will be denied as non-covered in situations involving temporary impairments.

The patient's condition could be either anatomic (e.g., obstruction due to head and neck cancer or reconstructive surgery, etc.) or due to a motility disorder (e.g., severe dysphagia following a stroke, etc.). Enteral nutrition is non-covered for patients with a functioning gastrointestinal tract whose need for enteral nutrition is due to reasons such as anorexia or nausea associated with mood disorder, end-stage disease, etc.

The patient must require tube feedings to maintain weight and strength commensurate with the patient's overall health status. Adequate nutrition must not be possible by dietary adjustment and/or oral supplements. Coverage is possible for patients with partial impairments - e.g., a patient with dysphagia who can swallow small amounts of food or a patient with Crohn's disease who requires prolonged infusion of enteral nutrients to overcome a problem with absorption.

Enteral nutrition products that are administered orally and related supplies are noncovered.

If the coverage requirements for enteral nutrition are met, medically necessary nutrients, administration supplies, and equipment are covered.

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Enteral nutrition provided to a patient 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.

Black Boxed Warning:

Liposyn products Boxed Warning:

Deaths in preterm infants after infusion of intravenous fat emulsions have been reported in the medical literature. Autopsy findings included intravascular fat accumulation in the lungs. Treatment of premature and low birth weight infants with intravenous fat emulsion must be based upon careful benefit-risk assessment. Strict adherence to the total daily dose is mandatory; hourly infusion rate should be as slow as possible in each case and should not in any case exceed 1 g/kg in four hours. Premature and small for gestational age infants have poor clearance of intravenous fat emulsion and increased free fatty acid plasma levels following fat emulsion infusion; therefore, serious consideration must be given to administration of less than maximum recommended doses in these patients in order to decrease the likelihood of intravenous fat overload. The infant's ability to eliminate infused fat from the circulation must be carefully monitored (such as triglyceride and/or plasma free fatty acid levels). The lipemia must clear between daily infusions.

Definitions:

HCPCS Code—Healthcare Common Procedure Coding System - A system of letter and number codes assigned to procedures, medications, supplies and equipment used for pricing and billing.

ICD-9 Code—International Classification of Disease, 9th edition. A standardized classification of disease, injuries, and causes of death, by etiology and anatomic localization and codified into a

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6-digit number, which allows clinicians, statisticians, politicians, health planners and others to speak a common language, both US and internationally.

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