

	Standard Formula Intolerance	Initial Specific Medical Need	Possible ICD-9 Codes	Nutritional Assessment Indicating Formula Need	Clinical/Physical Findings Indicating Formula Needs	
	Patient shows evidence of failure to tolerate a standard formula	Patient has a specific medical condition and the need for the specialty nutrients formulated for that condition	Patient has a medical diagnosis (ICD-9 code) that is appropriate for a specialized nutritional product/formula	Patient has laboratory results that demonstrate the need for a specialty product/formula and documentation is included in patient's medical record	Patient has clinical/physical findings that demonstrate the need for a specialty product/formula	
PEDIATRIC	EleCare®/ EleCare® Jr Amino acid-based formulas for infants (under 12 months) and children (over 1 year of age) who cannot tolerate intact or hydrolyzed protein	<ul style="list-style-type: none"> Persistent diarrhea, steatorrhea Persistent nausea and/or vomiting Abdominal pain Weight loss 	<ul style="list-style-type: none"> Protein maldigestion Malabsorption Severe food allergies Short-bowel syndrome Eosinophilic GI disorders GI-tract impairment 	<ul style="list-style-type: none"> Sensitivity to Intact Protein, Allergic Colitis (558.3) GI Conditions (536.9) Eosinophilic GI Disorder (558.4) Short Bowel Syndrome (579.3) Fat Malabsorption, Protein Maldigestion (579.9) Food Allergy (693.1) Lactose Sensitivity (271.3) Galactosemia (271.1) Celiac Disease (579.0) 	<ul style="list-style-type: none"> Laboratory tests documenting malnutrition (e.g. serum albumin, prealbumin, transferrin, vitamin levels) Laboratory tests confirming malabsorption (e.g. fecal fat, d-xylose) 	<ul style="list-style-type: none"> Unsuccessful trials of other formulas Justification for / results of tube placement/administration method changes Negative nitrogen balance Weight loss Stool or ostomy output (I & O) Evidence of skin breakdown due to diarrhea Radiographic reports of enteritis Progress notes ruling out infections or medication induced diarrhea (if medication change not possible, document formula use to ameliorate diarrhea) Surgery or pathology reports confirming gastric, pancreatic, or bowel resection or bypass
	PediaSure® Peptide 1.0 Cal/PediaSure® Peptide 1.5 Cal Peptide-based nutrition for children ages 1-13 years with malabsorption, maldigestion and other GI conditions	<ul style="list-style-type: none"> Symptoms of GI intolerance <ul style="list-style-type: none"> Diarrhea Nausea/Vomiting Abdominal Pain/Cramping Bloating/Distension Poor weight gain and growth 	<ul style="list-style-type: none"> Maldigestion Malabsorption Impaired GI function 	<ul style="list-style-type: none"> Intestinal Malabsorption (579.0-579.9) Regional enteritis (Crohn's Disease) (555.0-555.1) Ulcerative Colitis (556.0-556.9) Pancreatitis (577.0-577.9) Short bowel syndrome (579.3) Cystic Fibrosis (277.0) Celiac Disease (579.0) Lactose sensitivity (271.3) Human Immunodeficiency Virus infection (042) Liver Transplant (996.82) Trauma (959.0-959.9) Sepsis (995.91) Burn (949.0-949.5) Functional digestive disorders, not elsewhere classified (564.0-564.9) Other and unspecified noninfectious gastroenteritis and colitis (558.1-558.9) Other conditions in which a peptide-based formulation would be beneficial (e.g., tube feeding-associated GI intolerance, critical illness-associated GI dysfunction, early enteral feeding, transition from TPN) 	<ul style="list-style-type: none"> Laboratory tests documenting malnutrition (e.g. serum albumin, prealbumin, transferrin, vitamin levels) Laboratory tests confirming malabsorption (e.g. fecal fat, d-xylose) 	<ul style="list-style-type: none"> Unsuccessful trials of other formulas Justification for / results of tube placement/administration method changes Maldigestion (e.g., pancreatic enzyme insufficiency) Malabsorption (e.g., cystic fibrosis, inflammatory bowel disease) Symptoms of GI intolerance Intolerance to standard formula Intolerance to intact protein Acute GI dysfunction GI disease Other situations based on clinical judgment that would benefit from a peptide-based formula
ADULT	Vital® 1.0 Cal/ Vital® 1.5 Cal/ Vital® High Protein/ Vital AF 1.2 Cal® Therapeutic, peptide-based elemental nutrition to promote GI tolerance	<ul style="list-style-type: none"> Symptoms of GI intolerance <ul style="list-style-type: none"> Diarrhea Nausea/Vomiting Abdominal Pain/Cramping Bloating/Distension Elevated Gastric Residuals Delayed Gastric Emptying 	<ul style="list-style-type: none"> Maldigestion Malabsorption Impaired GI function 	<ul style="list-style-type: none"> Intestinal Malabsorption (579.0-579.9) Regional enteritis (Crohn's Disease) (555.0-555.1) Ulcerative Colitis (556.0-556.9) Pancreatitis (577.0-577.9) Short bowel syndrome (579.3) Cystic Fibrosis (277.0) Celiac Disease (579.0) Lactose sensitivity (271.3) Human Immunodeficiency Virus infection (042) Liver Transplant (996.82) Trauma (959.0-959.9) Sepsis (995.91) Burn (949.0-949.5) Functional digestive disorders, not elsewhere classified (564.0-564.9) Other and unspecified noninfectious gastroenteritis and colitis (558.1-558.9) Other conditions in which an elemental peptide-based formulation would be beneficial (e.g., tube feeding-associated GI intolerance, critical illness-associated GI dysfunction, early enteral feeding, transition from TPN) 	<ul style="list-style-type: none"> Nutritional status assessment Documentation of pertinent laboratory tests to aid malnutrition diagnosis (e.g., serum albumin, prealbumin, transferrin, vitamin levels, C-reactive protein) Malabsorption assessment (e.g., fecal fat, d-xylose) 	<ul style="list-style-type: none"> Unsuccessful trials of other formulas Justification for / results of tube placement/administration method changes Maldigestion (e.g., pancreatic enzyme insufficiency) Malabsorption (e.g., cystic fibrosis, inflammatory bowel disease) Symptoms of GI intolerance Intolerance to standard formula Intolerance to intact protein Acute GI dysfunction GI disease Other situations based on clinical judgment that would benefit from a peptide-based formula
	Nepro® with Carb Steady/Suplena® with Carb Steady Therapeutic nutrition for patients with renal disease (e.g. acute kidney injury, chronic kidney disease, and chronic kidney disease requiring dialysis)	<ul style="list-style-type: none"> Elevated electrolyte levels (e.g. potassium, sodium) Elevated serum phosphorus levels Elevated BUN/Cr levels Worsening renal disease (e.g. decreased eGFR level) 	<ul style="list-style-type: none"> Acute kidney injury Chronic kidney disease (stages 3-5) Chronic kidney disease requiring dialysis (end-stage renal disease or renal failure) 	<ul style="list-style-type: none"> Acute kidney failure (584) Chronic kidney disease (585) Renal failure (586) 	<ul style="list-style-type: none"> Hyperkalemia Hyperphosphatemia Elevated BUN Elevated Cr Elevated eGFR 	<ul style="list-style-type: none"> Unsuccessful trials of other formulas
	Glucerna® 1.0 Cal/ Glucerna® 1.2 Cal/ Glucerna® 1.5 Cal Specialized nutrition for patients with abnormal glucose tolerance	<ul style="list-style-type: none"> Elevated blood glucose levels Increased antihyperglycemic medication needed to manage blood glucose levels At risk or experiencing hypoglycemia (potentially due to the need for increased insulin) 	<ul style="list-style-type: none"> Type 1 and type 2 diabetes Hyperglycemia/ abnormal glucose tolerance resulting from metabolic stress, such as illness, trauma or infection 	<ul style="list-style-type: none"> Secondary diabetes mellitus (249) Diabetes mellitus (250) 	<ul style="list-style-type: none"> Hyperglycemia 	<ul style="list-style-type: none"> Unsuccessful trials of other formulas Poorly controlled blood glucose levels Hyperglycemia and/or hypoglycemia episodes based on blood glucose monitoring

Specialty Nutrients - Documentation

Some payers require additional documentation to justify coverage of specialty enteral formulas because they are produced to meet unique nutrient needs for individual patients. Failure to substantiate the medical necessity of specialty enteral formulas (HCPCS codes B4149, B4153-B4157, B4161, and B4162) may result in a claim being denied as not medically necessary. The sample documentation grid is provided as an educational tool to help providers capture information specific to the patient's medical condition.

Disclaimer: This document offers examples of clinical information and medical diagnoses that may be relevant for specific products in seeking enteral coverage. It is not intended to be an exhaustive list of all the potentially applicable codes for all diagnoses. Abbott Nutrition is not recommending a product based on medical necessity determination or providing documentation associated with a specific patient or claim. The health care professional should make their own nutritional product determination and assessment based on the patient's condition and care plan. In addition, each health care provider is ultimately responsible for verifying codes, coverage and payment policies used to ensure that they are accurate and appropriate for the services and items provided. Abbott Nutrition does not guarantee reimbursement by any third-party payer and will not reimburse physicians or providers for claims denied by third-party payers. This document does not take the place of documentation which may be required to support a claim submission. Providers should consult with the payer for complete and accurate details concerning documentation for enteral claims. Documentation requirements may vary among payers.