Name of Policy:
Inpatient Intestinal Rehabilitation Therapy

Policy #: 152
Category: Medical
Latest Review Date: March 2010
Policy Grade: Active Policy but no longer scheduled for regular literature reviews and updates.

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:
1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
**Description of Procedure or Service:**
Short bowel syndrome (SBS) is a malabsorption syndrome that occurs after extensive intestinal resection which results in massive loss of intestinal surface area. It is characterized by chronic diarrhea, dehydration, electrolyte abnormalities, and malnutrition as a result of severe maldigestion and malabsorption. Common causes of SBS in adults include resection due to Crohn’s disease, a catastrophic vascular event such as mesenteric arterial embolism or venous thrombosis, volvulus, trauma, or tumor. Most patients are initially fed with total parenteral nutrition (TPN) to help prevent the development of malnutrition. Some patients may be difficult to wean from TPN. This includes patients with very short remaining small bowel segments (< 60 cm), loss of colon, loss of ileocecal valve, or small bowel strictures. This parenteral nutrition provides protein, calories, other macronutrients, and micronutrients until the bowel has had time to adapt.

After massive enterectomy, the intestine adapts to ensure more efficient absorption per unit length. There is slight lengthening, but also diameter and villus height increase, which increases the absorptive surface. This intestinal adaptation process continues for up to two years. The exact mechanisms are not known, but various factors have been shown to enhance adaptation, including growth hormone, glutamine, epidermal growth factor, certain peptides and interleukins, soluble fiber, short chain fatty acids, and pancreaticobiliary secretions. There has been a great deal of research interest in methods to increase intestinal adaptation as a nonsurgical alternative to intestinal transplantation. Specifically, the combination of the amino acid glutamine and human recombinant growth hormone (GH), in conjunction with a high carbohydrate, low fat diet, has been studied. Glutamine, administered either enterally or parenterally, and growth hormone, administered subcutaneously, is thought to have trophic affects on the bowel.

There are some inpatient programs specifically designed for patients with short bowel syndrome who are dependent on TPN for their nutritional needs. The programs offer intensive counseling and tailored regimens of diet modification, glutamine, and growth hormone therapy to these patients. The goal of these programs is to help patients either eliminate or reduce the need for total parenteral nutrition.

In 1993, the Nutritional Restart Center (NRC) for intestinal rehabilitation was started in Boston. In 2001, the NRC transferred its treatment methodologies to the Nebraska Medical Center in Omaha, NE. It offers patients with intestinal failure comprehensive treatment options to help them transition from TPN to a more normal oral diet. They offer inpatient and outpatient services. The inpatient program lasts 2-4 weeks and the patient undergoes detailed metabolic evaluations to determine the feasibility of an oral diet, intestinal adaptation therapy with dietary modification (a high-carbohydrate, low-fat diet), glutamine and growth hormone, and a gradual weaning of TPN, if possible. Patients also undergo extensive counseling and education and participate in a physical rehabilitation program. Each patient’s treatment plan is individualized to meet their specific needs to improve bowel function. At completion of the program, patients are discharged on only the diet and supplemental glutamine.
**Policy:**

An inpatient program of intestinal rehabilitation, consisting of metabolic evaluation, patient counseling and education, nutritional counseling, physical therapy, and treatment with growth hormone and glutamine does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for patients with short bowel syndrome who are dependent on total parenteral nutrition and is considered investigational.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

**Key Points:**

The early published data are almost exclusively derived from researchers working at the NRC near Boston. Most reports were small case series with overlapping patients.

In 1995 and 1997, Wilmore, Byrne, et al, published the results of a study of 47 TPN-dependent short-bowel patients who underwent specific treatment for 28 days. The patients received either a high-carbohydrate low fat diet alone or in combination with the amino acid glutamine and growth hormone. The results showed that in the group that received all three treatments (diet, GLN & GH), there was a 39% improvement in protein absorption and 33% decrease in stool output. The major side effect was fluid retention, manifested by peripheral edema and arthralgia. At the end of 4 weeks, 27 of 47 patients (57%) did not require TPN, 14 (30%) had reduced TPN requirements and 6 (13%) had the same TPN requirement. At 1 year, 40% remained off TPN, 40% received reduced TPN, and 20% were on TPN similar to their initial requirement.

The relative contributions of the pharmacologic, dietary, and counseling/education aspects of the overall inpatient program of intestinal rehabilitation cannot be determined. Specifically, some researchers have questioned whether the treatment effect was primarily due to meticulous dietary counseling as opposed to any effect from glutamine or growth hormone.

Scolapio, et al (1997), looked at the effects of parenteral GH, glutamine (GLN) supplementation, and a high carbohydrate low fat diet (HCLF) on gut adaptation in 8 patients with SBS. The patients were treated for 21 days. The results showed that active treatment transiently increased body weight, improved electrolyte absorption, and delayed gastric emptying. However, there were no improvements in small bowel morphology, stool losses, or macronutrient absorption. Scolapio also published more results in 1999 on these same 8 patients. He reported that active treatment significantly increased body weight and lean body mass and decreased percent body fat. They felt the positive findings are most likely a reflection of increased extracellular fluid because all 8 patients developed peripheral edema on active treatment. Also, the positive effects were not sustained once treatment was discontinued. The authors did not advocate the use of this treatment.
Szkudlarck, et al (2000), looked at 8 short bowel patients to see if GH with GLN and no change in diet improved intestinal function. The results showed that GH with GLN did not improve intestinal absorption of energy, carbohydrate, fat, nitrogen, net weight, sodium, potassium, calcium, or magnesium compared with placebo or baseline 5 days after treatment was terminated.

An additional research question is the contribution of an intensive inpatient program, compared to similar elements of the program offered in an outpatient setting. This issue has not been addressed in the published literature.

Jeppesen, et al (2001), looked at the changes in body weight (BW) and composition, 24-h urine creatinine excretion, intestinal fatty acid absorption, and EFA status in relation to treatment with GH and GLN in 8 short bowel patients. The results showed that active treatment did not increase BW, lean body mass (LBM), fat mass (FM), and bone mass significantly compared with placebo. There were no changes in intestinal absorption of fatty acids and no changes in essential fatty acids measured in plasma phospholipids.

Li-Ling and Irving (2001), did a review of published trials and found only a marginal, if any, benefit for SBS patients from administering GH alone or with GLN with or without a low-fat high-carbohydrate (fiber) diet.

There have been several more recently published studies that had varied treatment and contrasting results. Some of these are highlighted below.

Zhu, et al (2002), looked at 27 SBS patients who received rehabilitation therapy, including enteral or parenteral nutrition, glutamine, growth hormone, and rehabilitative diet. At 1 year, 10 of 13 patients were weaned from TPN. At 2 years, 4 of 8 patients were weaned from TPN. The authors felt that therapeutic effects were related to many factors, including length of residual small intestine, patient’s age, and duration between resection and start of treatment. The early initiation of treatment increased the patient’s ability to wean from TPN.

Fishbein, et al (2002), evaluated 59 patients with intestinal failure, and recommended 68% have transplantation, 10% have rehabilitation, and 17% have long-term parenteral nutrition. All patients managed with rehabilitation were weaned from parenteral nutrition within 6 months.

Seguy (2003) reported on 12 adult HPN- dependent patients with SBS who received daily low dose GH and placebo for two 3-week periods separated by a 1-week washout period. Patients were on an unrestricted hyperphagic diet. The results showed that treatment with GH increased intestinal absorption of energy, nitrogen, carbohydrates, and fat. Patients showed an increase in body weight, lean body mass, D-xylose absorption, insulin-like growth factor, and insulin-like growth factor binding protein and a decrease in GH binding protein.

Wu, et al (2003), looked at the effects of bowel rehabilitation and combined trophic therapy on intestinal adaptation in 38 patients with SBS on TPN treatment. Enteral feedings were given as soon as possible after resection. Eight patients were treated with GH and GLN for 3 weeks. The
average follow-up time was 6 ± 4 years. Twenty-two patients were weaned from TPN with an average TPN time of 9.5 ± 6.6 months. Patients who received GH and GLN had increased nutrient absorption, but the effects were transient and not sustained beyond the treatment period.

**March 2008**
Byrne (2005) and colleagues followed up 41 patients with short bowel syndrome dependent on parenteral nutrition for 3 months after participating in a 4-week inpatient intestinal rehabilitation program in which patients were randomized in a double-blind, controlled trial to evaluate growth hormone, glutamine, and optimal diet. Parenteral nutrition volume, calories, and infusions were most reduced in patients who received growth hormone plus glutamine and diet. This group was also the only treatment group to maintain reductions in parenteral nutrition significantly after 3 months. However, how reductions in parenteral nutrition translated into health outcomes was not reported.

**March 2010 Update**
This policy will remain active but is no longer scheduled for regular peer-reviewed updates. There will continue to be no coverage for this therapy.

**Key Words:**
Intestinal rehabilitation, short bowel syndrome (SBS), growth hormone (GH), glutamine (GLN), and high carbohydrate, low fat diet (HCLF), Zorbtive™

**Approved by Governing Bodies:**
Zorbtive™—FDA approved December 1, 2003.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.
Pre-certification/Pre-determination requirements: Not applicable

**Coding:**
CPT: There are currently no CPT codes for this service
References:

17. Wilmore DW. Indications for specific therapy in the rehabilitation of patients with the short-bowel syndrome, Best Practice and Research Clinical Gastroenterology, December 2003; 17(6): 895-906.


**Policy History:**
Medical Policy Group, March 2004
Medical Policy Administration Committee, March 2004
Available for comment April 6-May 20, 2004
Medical Policy Group, March 2006 (1)
Key Points updated, March 2008 (1)
Medical Policy Group, March 2010 (1) Policy retired, no further updates, non-covered

**Medical Policy Group, March 31, 2010:** Active Policy but no longer scheduled for regular literature reviews and updates.

*This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

*This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.*