



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Barnett Continent Intestinal Reservoir (BCIR)

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Coverage Policy

CIGNA covers Barnett Continent Intestinal Reservoir (BCIR) as medically necessary for individuals with severe bowel disease, when the individual is not considered to be a candidate for an ileal pouch anal anastomosis (IPAA) or there is failure of a conventional (i.e., Brooke) ileostomy, IPAA or alternative continent (Koch) procedure.

General Background

It is estimated that more than two million Americans suffer from severe bowel disease, including familial adenomatous polyposis (FAP) and ulcerative colitis (UC). The American Society of Colon and Rectal Surgeons (ASCRS) recommends prophylactic colectomy or proctocolectomy in selected patients with FAP, based on their significant risk for colon cancer (ASCRS, 2003). Approximately 25–40% of individuals with UC will require surgery at some time during their illness. Many of these patients are referred for surgical treatment due to disease that is refractory to a medical regimen. Other indications for surgical intervention include hemorrhage, colonic dysplasia, and carcinoma. Total proctocolectomy (TPC), or removal of the entire colon and rectum, is curative for UC in many cases. UC can be difficult to diagnose because its symptoms are similar to those of Crohn's, another chronic disease of the bowel. Approximately 20% of patients presumed to have UC are subsequently diagnosed by postoperative histological findings with either indeterminate colitis or Crohn's disease (CD).

Surgical Procedures

TPC with conventional (Brooke) ileostomy was one of the earliest procedures performed for UC. In this procedure, the ileum or end of the small intestine is brought through an opening in the abdominal wall and sewn to the skin to create a stoma. An external appliance is attached to the abdominal stoma for drainage of fecal matter. Advantages of this procedure include relatively low morbidity and the absence of functional problems that are associated with other procedures. A significant disadvantage is the permanent need for an external appliance.

Total proctocolectomy with ileal pouch-anal anastomosis (IPAA), also referred to as the J-pouch, has become the surgical procedure of choice for patients requiring TPC for UC or familial polyposis. IPAA involves the construction of a pouch from loops of the ileum or small intestine, which is then attached to the anal canal. The ability to defecate via the anus is maintained. A temporary conventional ileostomy is sometimes used with this procedure to allow for healing. Pouchitis, an inflammation of the ileal reservoir, is the most frequent complication after IPAA.

Another surgical option, TPC with continent reservoir, involves the creation of a pouch from the patient's small intestine. The pouch provides internal storage for intestinal contents and is attached to the abdominal wall with a flush stoma. A one-way valve allows for emptying of the pouch by inserting a catheter through the stoma. This continent device eliminates the need for an external appliance, simplifying social and recreational activities. The procedure was devised by Dr. Nils Koch in 1969. Initially, the Koch pouch was associated with a high failure rate, due to significant complications of valve slippage and fistula formation. In addition, the development of pouch anal procedures reduced the demand for this procedure. Subsequent modifications of the procedure have led to improved outcomes. Currently, the use of the continent ileostomy or Koch pouch is limited to those patients who are not candidates for an IPAA and as a modification to an existing conventional ileostomy or alternative to ileostomy for patients requiring ileal pouch excision (ASCRS, 2003).

The Barnett continent intestinal reservoir (BCIR) is a modified version of the continent (Koch pouch) ileostomy. Dr. William Barnett made several design modifications in an attempt to reduce the incidence of the most serious complications of continent slipped valves and fistulae. The method of valve construction was changed, as well as the direction of the flow within the anastomosed portion of the intestine. Initially, a plastic collar was placed around the valve for additional support and stabilization. Rejection of the plastic material caused the formation of fistulae into the valve. The procedure was further modified to construct a collar from the patient's small intestine. The configuration of the pouch was changed in order to decrease the number of suture lines, allowing for faster healing and reduced fistula development. Lastly, the creation of a serosal patch over the suture line decreased the occurrence of leakage. Construction of the BCIR involves taking down a preexisting ileostomy or removing the colon and rectum if this has not been previously done. It is recommended in the literature that surgeons who perform IPAA, Koch or BCIR procedures have specific training or significant experience with those procedures (Society of Surgery of the Alimentary Tract [SSAT], 2001).

BCIR Literature Review

Mullen et al. (1995) conducted a retrospective study of 510 patients with UC or FAP. BCIR was performed at five collaborating centers. Of the 510 patients, 72% were converted from a conventional ileostomy; 18% had TPC with BCIR as a primary procedure; and 9% converted to BCIR from a previously failed IPAA or Koch procedure. The follow-up period ranged from 1–5 years postoperatively. After one year, 92.2% of patients were reported to have fully functioning pouches. Pouch excision was necessary for 33 patients, due to valve slippage and fistula formation. Sixty patients required major subsequent surgical procedures. Responses to questionnaires were reported to reveal a significant improvement in general quality of life, state of mind and overall health. In the opinion of the investigators, study results suggested that the BCIR represents a successful alternative for patients with failed conventional Brooke ileostomies or for those who are not candidates for IPAA.

Behrens and colleagues (1999) reported on 42 patients with conversions from failed IPAA to continent ileostomy (BCIR). This group was compared to a general study population (n=1334) of those undergoing continent ileostomy for reasons other than failed IPAA. During the follow-up period of 3.5 years, 95% of the patients with failed IPAA continued to have functioning continent ileostomies, compared with 88.7% of the general population. The patients with failed IPAA experienced more medical complications than did the general continent ileostomy population (43% versus 22%, respectively). The leading reasons for medical readmissions were similar for both groups and included pouchitis, pouch fistula, and small bowel obstruction. The average number of surgical readmissions was similar for both groups. Two of the failed IPAA patients had pouch excisions due to fistula

development and the emergence of Crohn's disease. All of the patients with failed IPAA's rated their lives after continent ileostomy as improved, compared to 92% of patients in the general population. The authors confirmed previous findings that continent ileostomy should be considered for patients who are not candidates for IPAA procedures and for those with failed IPAA's (Behrens, et al., 1999).

Crohn's Disease

The role of TPC with IPAA or continent reservoir in patients with Crohn's colitis is controversial. Because CD commonly involves the small bowel and anus, the ileal pouch is generally not recommended. In addition, the evidence suggests that pouch procedures produce a high failure rate in patients with CD, and therefore many intestinal surgeons consider CD to be a contraindication to these operations. Recurrence of CD following any surgical intervention is common. Colectomy, or resection of the diseased segment, is usually performed to manage complications of the disease. However, because of the overlap in clinical presentation of UC and CD, some patients undergoing IPAA are subsequently found to have CD (Braveman, et al., 2004).

Literature Review: A number of small, uncontrolled studies evaluating this subset of patients have had variable outcomes. Regimbeau and colleagues (2001) performed ileal pouches in 41 patients with CD who had no evidence of small bowel or anoperineal disease. After a mean follow-up of 10 years, 27% had experienced CD-related complications, and 7% required ileostomies. It has been proposed that IPAA can be performed safely in patients with CD with a complication rate similar to that in patients with UC (McLeod, 2003).

In a retrospective series, Braveman et al. (2004) evaluated the outcome of 32 patients selected from an IPAA registry with a final diagnosis of CD. Patients were followed prospectively to identify potential preoperative predictors of pouch failure. Complications of pouchitis, anal stricture or fistula/abscess formation occurred in 93% of these patients. Pouch failure occurred in nine patients (29%) at a median follow-up of 66 months. Preoperative clinical, endoscopic and pathological features were not found to be predictive of pouch failure or patient outcome. The authors concluded that the risk of IPAA is excessive for a subset of patients with CD and that further study is required to better differentiate among those who will have favorable outcomes with this procedure (Braveman, et al., 2004).

Delaini et al. (2005) assessed the long-term outcomes of a series of patients with CD who had either TPC with a continent ileostomy (n=59) or a conventional ileostomy (n=57). The researchers compared morbidity and mortality rates associated with each type of ileostomy. The median follow-up for the continent ileostomy group was 24 years and 27 years for the conventional ileostomy group. The rates of recurrent disease and reoperation with loss of small bowel were reported to be similar for the 46 surviving patients of each group. The authors contend that to better understand the role of ileal reservoir surgery for patients with CD, long-term outcomes should be compared to CD patients with conventional ileostomy. Based on the results of this study, it was concluded that proctocolitis due to CD should not be an absolute contraindication for continent ileostomy. The generalizability of these observations is limited by the size and retrospective nature of the study (Delaini, et al., 2005).

Professional Societies/Organizations

According to the ASCRS practice parameters for the surgical treatment of UC, surgery is indicated when medical therapy is ineffective. TPC with ileostomy has been the conventional operative approach for patients with UC and may be considered a benchmark procedure to which all other operations are compared. Although restorative TPC with IPAA has become increasingly popular during the past two decades, proctocolectomy with ileostomy can still be considered the first-line procedure for patients who are at significant risk for pouch failure and for those with impaired anal sphincter muscles, previous anoperineal disease, or limited physiological reserve due to comorbidities (ASCRS, 2005).

The SSAT lists four surgical options for patients with ulcerative colitis: 1) TPC and ileostomy; 2) TPC with continent ileostomy (e.g., Koch pouch); 3) TPC with IPAA; or 4) colectomy with ileorectal anastomosis. The Koch pouch is typically reserved for patients with previous TPCs who are experiencing complications with their ileostomies. Advanced age, rectal cancer, and previous anal sphincter damage are relative contraindications for the IPAA procedure. The IPAA is not indicated in patients with Crohn's disease (SSAT, 2005).

Summary

Despite the lack of evaluation via randomized controlled trials (RCTs), the overall body of evidence in the peer-reviewed medical literature is supportive of the Barnett continent intestinal reservoir (BCIR) as a surgical

treatment for a subset of patients with ulcerative colitis (UC) and familial adenomatous polyposis (FAP). In general, Crohn's disease (CD) remains a contraindication to performing a pouch procedure. However, in patients where Crohn's colitis is limited to the colon and rectum, such a procedure may be considered. The type of surgery performed for patients with severe bowel disease should take into account factors such as the patient's overall health, preoperative anorectal function, and the presence of any dysplasia or cancer.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT ^{®*} Codes	Description
44799 [†]	Unlisted procedure, intestine

[†]**Note:** Covered when medically necessary and used to report Barnett continent intestinal reservoir (BCIR).

ICD-9-CM Diagnosis Codes	Description
211.3	Benign neoplasm of colon
211.4	Benign neoplasm of rectum and anal canal
555.0 - 555.9	Regional enteritis
556.0 - 556.9	Ulcerative colitis
569.62	Mechanical complication of colostomy and enterostomy

*Current Procedural Terminology (CPT[®]) © 2008 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	5/15/2007	0360	Barnett Continent Intestinal Reservoir (BCIR)

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