Title: Double Balloon Enteroscopy

Description/Background

Gastrointestinal (GI) bleeding is associated with hospitalization rates of about 100 per 100,000 admissions per year in the United States for upper GI tract bleeding, and 20 per 100,000 per year for bleeding in the lower GI tract. Finding the source of bleeding begins with upper and lower GI radiography and endoscopy (insertion of a lighted tube into the GI tract); however, the cause of GI bleeding remains undetected in approximately 2% to 10% of patients who may then require evaluation of the small bowel. Standard tests for the diagnosis of small bowel disease include barium contrast x-rays, push enteroscopy (PE), Sonde enteroscopy, scintigraphy and angiography, computed tomography, wireless capsule endoscopy (CE), and the gold standard, laparotomy with intraoperative enteroscopy. The double-balloon video enteroscopy (DBE) system is a newer technique for visualizing the small bowel that permits a thorough evaluation and also allows for treatment to be given during the same procedure.

Technology

The DBE system consists of a video enteroscope, an outer tube, an air pump, and two soft balloons. A balloon is attached to the tip of the enteroscope and another balloon fits around the outer tube. After the enteroscope is inserted through the mouth and/or anus, the balloon on the outer tube is inflated, which holds open the bowel wall so that the enteroscope can be pushed more deeply into the bowel. When the enteroscope is in place, its balloon is inflated and the balloon on the outer tube is deflated and the outer tube is moved through the bowel. This process of pushing and pulling back is repeated until most or all of the small bowel is viewed, specimens are collected, and treatment is given. DBE is intended for viewing, diagnosing, and treating diseases of the upper GI tract including the esophagus, stomach, duodenum, and small bowel.

DBE is typically used when upper GI endoscopy and colonoscopy results are normal or unclear in patients with acute or chronic GI bleeding or abdominal pain or other symptoms of small
bowel disease, or when standard tests for small bowel disease suggest the presence of an abnormality that needs further evaluation. DBE is performed using fluoroscopic guidance on outpatients under conscious sedation by a trained gastroenterologist. For some patients, either because of the shape of their colon or because they have had previous abdominal surgery, full colonoscopy is difficult or not possible using standard equipment. A successful examination can often be achieved in this situation using a different colonoscope which has a flexible tube which slides over the instrument, and soft inflatable balloons on the tube and the colonoscope which make passage around the colon easier. The procedure is very similar to the standard procedure, sometimes it can take a little longer, but is often more comfortable.

**Regulatory Status**

**Food and Drug Administration (FDA):** The Fujinon Double Balloon Enteroscopy System (Fujinon Inc., Huntington, CT), a Class II device, received 510(k) approval on June 7, 2004 for the optical visualization of the upper GI tract including the esophagus, stomach, duodenum, and small bowel. It is intended for observation, diagnosis, and endoscopic treatment.\(^7\) The Olympus Small Intestinal Videoscope System (Olympus Medical System Inc., Grand Rapids, MI) received 510(k) approval on June 28, 2005 for endoscopy and endoscopic surgery within the upper and lower GI tract including the esophagus, stomach, duodenum, small bowel, and colon, by either oral or anal insertion.\(^11\) Note: In Europe, a Fujinon DBE enteroscope, model EN-450T, is available. It has an external diameter of 9.5 mm and a 2.8-mm working channel, which would facilitate therapeutic interventions due to its larger working channel compared with the 2.2-mm model.\(^22\) However, this model was not identified during a search of the FDA device database.

**Medical Policy Statement**

The safety and effectiveness of double balloon enteroscopy have been established. It may be considered a useful therapeutic or diagnostic option when indicated.

**Inclusionary and Exclusionary Guidelines**

**Inclusions:**
- Evaluation and treatment/therapeutic interventions for patients with obscure and/or occult gastrointestinal bleeding or suspected small bowel pathology, when esophagogastroduodenoscopy and capsule endoscopy (or if capsule endoscopy is contraindicated) have failed to provide a diagnosis.
- A positive finding on capsule endoscopy requiring a biopsy or therapeutic intervention
- For the removal of entrapped foreign bodies in the small bowel (e.g., retained video capsule)
- For use in conjunction with endoscopic retrograde cholangiopancreatography (ERCP) in individuals with surgically altered upper GI anatomy
- For evaluation of the colon in the case of or history of incomplete colonoscopy
CPT/HCPCS Level II Codes (Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)

**Established codes:**
- 44799*
- 45399*

**Other codes (investigational, not medically necessary, etc.):**
- N/A

*CPT codes may be approved when criteria is met

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

**Rationale**

**Double-Balloon Endoscopy**
May et al (2003) reported on a preliminary experience with double-balloon endoscopy.1 Between the end of March 2003 and August 2003, eight patients (four women, four men; mean age 59 +/- 23 years, range 20 - 90) with chronic gastrointestinal bleeding or abdominal pain, or both, underwent enteroscopy using the double-balloon technique. Seven of the patients had been suffering from chronic gastrointestinal bleeding for 56 +/- 49 months (range 3 - 120 months, median 48 months). The lowest hemoglobin levels ranged from 3.6 g/dl to 8.6 g/dl (mean 6.7 +/- 1.7 g/dl), and a mean of 7.6 +/- 5.6 (range 1 - 15) blood units had been transfused. Capsule endoscopy was carried out in six patients, revealing angiodysplasias in three, suspected Crohn's disease in one, fresh blood in the small bowel without a lesion in one, and a focal enanthema in another patient. Enteroscopy with the double-balloon technique was carried out using the oral approach in all patients and additionally with the anal approach in four patients. In two patients with multiple angiodysplasias, it was possible to examine the whole small bowel and to treat the angiodysplasias. All of the capsule endoscopy findings were confirmed; a definite bleeding source was found and treated in two patients with unclear bleeding, and in another patient the real bleeding source was found (not angiodysplasia). The enteroscopy system was easy to handle in all cases. No complications occurred. It was possible to carry out the procedure with the patients under conscious sedation.

In 2005, Ell et al evaluated the feasibility, safety, and clinical impact of push-and-pull enteroscopy (PPE) in patients with suspected or documented small-bowel diseases, in a prospective trial in three European medical centers.2 A total of 100 patients (mean age 56 +/- 16 years; range 13 - 90) were included at the three institutions between July and November 2004. The leading symptoms were: acute recurrent or chronic gastrointestinal bleeding (n = 64), polyposis syndrome (n = 8), chronic abdominal pain (n = 7), chronic diarrhea (n = 7), and others (n = 14). No major PPE-associated complications such as perforation, bleeding, or relevant injury to the small-bowel tissue or mesentery were encountered. Minor complications occurred in 12 %. The mean time required to carry out the procedure from the oral and anal approaches was 75 +/- 19 min (32 - 150 min). The average insertion depths into the small...
bowel were 200 +/- 70 cm per PPE session (220 +/- 90 cm with the oral approach and 130 +/- 80 cm with the anal approach). The average radiation exposure (including diagnostic and therapeutic interventions) was 2.1 +/- 2.4 min and 155 +/- 159 dGy/cm². PPE was fully diagnostic in 72 % of cases. The majority of the patients (34 %) were suffering from angiodysplasias; ulcerations and erosions of various etiologies were seen in 16 %, and polyps and tumors in 13 %. The PPE findings played a role in the subsequent treatment in 62 % of the patients. Endoscopic treatments, including argon plasma coagulation, polypectomy, dilation, and foreign-body extraction, were carried out in 42 %. Medical treatment was given in 12 %, and patients were referred for surgery in 8 % of cases.

Sunada et al (2005) evaluated the outcome of enteroscopy, using the double-balloon method, focusing on the involvement of neoplasms in strictures of the small intestine. Enteroscopy, using the double-balloon method, was performed between December 1999 and December 2002 at Jichi Medical School Hospital, Japan and strictures of the small intestine were found in 17 out of 62 patients. These 17 consecutive patients were subjected to analysis. The double-balloon enteroscopy contributed to the diagnosis of small intestinal neoplasms found in 3 out of 17 patients by direct observation of the strictures as well as biopsy sampling. Surgical procedures were chosen for these three patients, while balloon dilation was chosen for the strictures in four patients diagnosed with inflammation without involvement of neoplasm. The authors concluded that double-balloon enteroscopy was a useful method for the diagnosis and treatment of strictures in the small bowel.

Matsumoto et al (2005), in a retrospective study, compared the performance and the diagnostic value of antegrade DBE with those of push enteroscopy (PE). We reviewed endoscopic and histologic findings in 118 patients examined by PE or antegrade DBE during a period 1980 to 2004. The maximal length of insertion under plain radiograph was compared between patients examined by PE and those examined by antegrade DBE. Diagnostic yield was compared among patients stratified by indication for enteroscopy and the duodenal pathology. Ninety-one patients were examined by PE and 27 patients by antegrade DBE. Length of insertion from the ligament of Treitz was significantly greater in antegrade DBE (median, 92 cm; range, 40-144 cm) than in PE (median, 22 cm; range, 0-98 cm; p < 0.0001). In 90 nonbleeding patients with inflammatory or miscellaneous diseases or polyposis, the diagnostic yield was not different between PE and antegrade DBE (64% vs. 82%, p = 0.13). However, it was higher in antegrade DBE (79%) than in PE (31%, p = 0.012) in nonbleeding patients without duodenal pathology. In bleeding patients, the diagnostic yield was 40% in antegrade DBE and 36% in PE (p = 0.61).

May et al (2005) evaluated the feasibility and the diagnostic and therapeutic yield of double-balloon enteroscopy in comparison with current imaging methods. Between March 2003 and November 2004, 248 consecutive double-balloon enteroscopies (push-and-pull enteroscopies) were performed in a prospective study in 137 patients with suspected small-bowel disease (60 women, 77 men; mean age 56.6 +/- 17.8 years), most with chronic GI bleeding (66%). The examinations were carried out after negative evaluations with other methods or to allow biopsy or treatment in patients with known small-bowel findings. There were no relevant technical problems or severe complications. On average, 240 +/- 100 cm of the small bowel was visualized by using the oral route and 140 +/- 90 cm was visualized by using the anal route. The investigation time averaged 73.5 +/- 25 minutes. The overall diagnostic yield was 80% (109/137 patients). The main diagnosis was angiodysplasia (40/109; 37%); erosions and
ulcerations of various etiologies were found in 27% (29/109). Polyps and tumors were identified, including malignancy, in 25% (27/109). Other findings were detected in a further 11%. No relevant pathology was found in 20%. Subsequent treatment was influenced by the results in 104 patients (76%): endoscopic therapy in 57 (41.5%), medical treatment in 23 (17%), and surgery in 24 (17.5%). The authors concluded that visualization and tissue sampling are possible in the entire small bowel by using the oral and anal approaches, and treatment is possible in the same way as in standard endoscopy, avoiding open surgery.

Matsumoto et al (2005) compared the value of capsule endoscopy (CE) and DBE in the diagnosis of small-intestinal pathology.6 Thirteen patients with gastrointestinal bleeding of obscure origin and nine patients with known gastrointestinal polyposis were examined using antegrade or retrograde DBE, and the most distal or proximal site in the explored small intestine was marked by submucosal injection of sterilized ink. The patients were then evaluated by CE. Video images obtained by CE were reviewed by an observer who was blinded to the DBE findings. DBE identified positive findings in 12 patients (54.5 %). CE identified positive findings in the area explored by DBE in eight patients (36.4 %), and in the unexplored area in 11 patients (50.0 %). The overall diagnostic yield in the area explored by DBE did not differ between the two procedures. The enteroscopic findings in the area explored by DBE were concordant in 12 of 13 patients with gastrointestinal bleeding of obscure origin. In patients with polyposis, the diagnoses were discordant in three patients, in whom CE failed to detect any polyp. In two of three polyposis patients with discordant positive findings, DBE detected a larger number of polyps than CE did.

**Double-Balloon Colonoscopy**

Pasha et al (2007), in a retrospective chart review, evaluated the completion rate of double-balloon endoscopy for colon evaluation (i.e., double-balloon colonoscopy) and therapeutic interventions after a prior incomplete colonoscopy by conventional colonoscope.7 Sixteen patients (11 women and 5 men; mean age, 69 years) had retrograde double-balloon endoscopy between April 20, 2005, and February 8, 2006, after a prior incomplete colonoscopy. The main outcomes measurement is the completion rate of double-balloon colonoscopy, therapeutic success of standard procedures, and postprocedure complications. A completion rate of 88% (14 patients), successful performance of standard therapeutic procedures, and no procedure-related complications. Double-balloon colonoscopy was generally performed with the patient under conscious sedation in a mean (standard deviation) total procedure time (including therapeutics) of 50.6 minutes (SD, 15.2 minutes). Double-balloon colonoscopy had a high rate of effectiveness for completion of colon evaluation in patients with incomplete conventional colonoscopy. It allowed diagnostic and therapeutic interventions and can be performed with the patient under conscious sedation within a reasonable time.

Gay and Delvaux (2007) reported on a pilot series in which a new colonoscope was tested that utilized a double-balloon principle.8 A total of 29 patients (5 men, 24 women; mean age 54 years) in whom conventional colonoscopy had failed were included in this study. Both the failed colonoscopy and the double-balloon colonoscopy procedures were performed under general anesthesia, the usual practice in France. A prototype instrument (working length 152 cm, diameter 9.4 mm) designed to incorporate the principles of double-balloon enteroscopy was used. The completeness of colonoscopy was assessed according to conventional criteria by the achievement of a stable position in the cecum. The indications for the procedure, the time to reach the cecum, the need for fluoroscopic control, and adverse
events were recorded. The previous colonoscopy failed due to adhesions (n = 16), or too long or fixed loops (n = 13). Complete colonoscopy using the balloon method was achieved in 28/29 patients, taking an average time of 18 +/- 14 minutes; a long sigmoid loop limited the examination to the left flexure in one patient. Balloon colonoscopy using double-balloon methodology was used in 24 patients and the instrument was used without an overtube (i.e., using a single-balloon technique) in five patients. Fluoroscopy was used in 16 patients to monitor endoscope progression. No complications were reported.

Becx and Al-Toma (2014) evaluated the success rate of caecal intubation, the reasons for its failure and the therapeutic consequences of using DBE after incomplete conventional colonoscopy. We report our single-centre experience of using DBE to complete an otherwise incomplete colonoscopy. A total of 114 consecutive patients, 45 male and 69 female, with a mean age of 64.8 years, who had undergone 116 procedures, were evaluated retrospectively by a review of their medical records. The main causes for failed caecal intubation using a conventional colonoscope were loop formation in 70 patients (61.4%) and an adhesive angulated sigmoid in 33 (28.9%). Caecal intubation by DBE was successful in 101 patients (88.6%). The rate of failure was not associated with the cause of failure of the previous colonoscopy. In 55 patients (48.2%) a relevant new diagnosis was made in the previously inaccessible part of the colon: carcinoma (n=4; 3.5%), one or more adenomas (n=48; 42.1%) and caecal flat hyperplastic polyps (n=4; 3.5%). Endoscopic polypectomy was performed in 51 patients (44.7%); two complications occurred, both being mild postpolypectomy bleedings. In seven patients (6.1%) a subsequent surgical resection was performed. The authors concluded that colonoscopy by DBE were useful in most patients in whom conventional colonoscopy was incomplete, irrespective of the cause of the failure.

Despott et al (2017) compared the time taken to achieve caecal intubation during conventional colonoscopy (CC) and DBC in patients with a technically difficult (TD) colonoscopy. In a prospective, randomized study, patients were screened for parameters predictive of TD colonoscopy using an original scoring system and randomized to DBC or CC. Pain, sedation dose, colonoscopy completeness, time taken for cecal intubation, procedure completion, recovery time and patient satisfaction were recorded. Forty-four patients were recruited (DBC=22; CC=22). DBC facilitated total colonoscopy in 22 cases whereas 9 CC procedures were incomplete (P=0.019). Median pre-procedure difficulty scores were equal for both groups (4.0 vs. 4.0). Mean patient discomfort, pain scores and recovery time were significantly lower for the DBC group (2.3 vs. 5.5, P=0.001; 2.0 vs. 5.9, P=0.005; 5 vs. 20min, P=0.014 respectively). Mean time taken for cecal intubation was similar (17.5 vs. 14min, P=0.18). The authors concluded that DBC facilitates colonoscopy completion and might be a more comfortable alternative to CC for TD cases although the time taken to achieve caecal intubation was similar.

Hermans et al (2018) evaluated cecal intubation rate and pathology detection rate in the previously unexplored part of the colon, complication rate of DBC, and CTC results after incomplete colonoscopy. Sixty-three DBCs were performed after incomplete colonoscopy. Cecal intubation rate was 95%. Detection rate was 58% (5% carcinoma and 3% high-grade dysplastic adenoma). CTC preceded 54% of DBCs and 62% of CTC findings were confirmed. In 16%, a biopsy was taken, and in 60%, an intervention (mostly polypectomy) was performed. One major complication (1.5%) occurred, i.e., arterial bleeding due to polypectomy necessitating right hemicolecotomy. CTC (n=213) showed a possible lesion in 35%, and could be confirmed by follow-up endoscopy or surgery in 65%. DBC is effective and safe for
completion of colon inspection in incomplete colonoscopy. In patients with a high likelihood of pathology, DBC is preferred over CTC.

In a retrospective, single-center study, Niu et al (2022) compared the clinical features and DBE characteristics of ISBCD with those of other small bowel ulcerative diseases (OSBUD).12 Patients with coexisting colonic and/or ileal valve lesions (n = 45) or whose final diagnosis was not determined (n = 29) were excluded. A total of 139 patients with ISBCD and 62 patients with OSBUD found by DBE were analyzed. The age of ISBCD onset was lower than that of OSBUD (odds ratio [OR] 0.957, 95 % CI: 0.938 to 0.977, p < 0.001). Abdominal pain was more common in ISBCD (OR 4.986, 95 % CI: 2.539 to 9.792, p < 0.001). Elevated fibrinogen levels (OR 1.431, 95 % CI: 1.022 to 2.003, p = 0.037) and lower levels of D-dimer (OR 0.999, 95 % CI: 0.999 to 1.000, p = 0.017) were also more supportive of the diagnosis of ISBCD. NSAIDs used for more than 2 weeks decreased the probability of a diagnosis of ISBCD (OR 0.173, 95 % CI: 0.043-0.695, p = 0.013). Abdominal CT revealed a higher proportion of skip lesions in ISBCD than in OSBUD (OR 9.728, 95 % CI: 3.676 to 25.742, p < 0.001). The ulcers of ISBCD were more distributed in the ileum (111 (79.9 %) versus 29 (46.8 %), p < 0.001), and their main morphology differed in different intestinal segments. Longitudinal ulcers (OR 14.293, 95 % CI: 4.920 to 41.518, p < 0.001) and large ulcer (OR 0.128, 95 % CI: 0.044 to 0.374, p < 0.001) contributed to the differentiation of ISBCD from OSBUD. These investigators constructed a diagnostic model, ISBCD index (AUROC = 0.877, 95 % CI: 0.830 to 0.925), using multi-factorial binary logistic regression to help distinguish between these 2 groups of diseases. The authors concluded that clinical features, laboratory tests, abdominal CT, DBE characteristics, and pathology aided in differentiating ISBCD from OSBUD. Moreover, these researchers stated that the conclusions from this retrospective, single-center trial had several drawbacks and the possibility of bias; thus, a large, multi-center study on the ulcerative characteristics of ISBCD observed by DBE is needed.

SUMMARY OF EVIDENCE
The available evidence focuses on the diagnostic yield of this technique in relation to alternative diagnostic tests, particularly wireless CE and PE/PPE. DBE was relatively safe and no major complications were reported. Insertion depth was greater by the oral than by the anal route and the combination of both routes was often needed to view the largest portion of the small bowel. The overall diagnostic yield of DBE ranged from about 50% to 80% and its therapeutic yield ranged from about 60% to 70%. DBE findings guided treatment decisions in most patients (drugs, endoscopic therapy, or surgery), resulting in beneficial effects over the short term. DBE can be a useful adjunct to wireless CE when CE shows a lesion(s) that requires biopsy and/or is potentially treatable during enteroscopy or when CE results are unclear. The evidence is sufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements
No position or policy statements regarding DBE have been released by any major GI disease organization.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.
Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT04585516</td>
<td>Diagnostic usefulness of different types of gastrointestinal endoscopic investigations</td>
<td>5000</td>
<td>Jan 2028</td>
</tr>
<tr>
<td>Unpublished</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT03942965</td>
<td>Registry evaluation of a double balloon accessory device.</td>
<td>165</td>
<td>Mar 2021</td>
</tr>
</tbody>
</table>

NCT: national clinical trial

**Government Regulations**

**National:**
While there is no specific coverage decision regarding DBE, endoscopy is covered within a longstanding and undated National Coverage Determination for indications involving diagnosis and therapy when it is deemed necessary for an individual patient.23

**Local:**
No local coverage determination was found specifically addressing DBE.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

**Related Policies**

- Virtual Colonoscopy
- Wireless Capsule Endoscopy

**References**


*The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through March 2023, the date the research was completed.*
# Joint BCBSM/BCN Medical Policy History

<table>
<thead>
<tr>
<th>Policy Effective Date</th>
<th>BCBSM Signature Date</th>
<th>BCN Signature Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>7/1/21</td>
<td>4/20/21</td>
<td></td>
<td>Joint policy established</td>
</tr>
<tr>
<td>7/1/22</td>
<td>4/19/22</td>
<td></td>
<td>Routine policy maintenance, no change to policy status.</td>
</tr>
<tr>
<td>7/1/23</td>
<td>4/18/23</td>
<td></td>
<td>Routine policy maintenance, added reference 12. No change in policy status. Vendor managed: N/A. (ds)</td>
</tr>
</tbody>
</table>

Next Review Date: 2nd Qtr. 2024

# Pre-Consolidation Medical Policy History

<table>
<thead>
<tr>
<th>Original Policy Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCN:</td>
<td>Revised:</td>
</tr>
<tr>
<td>BCBSM:</td>
<td>Revised:</td>
</tr>
</tbody>
</table>
I. **Coverage Determination:**

<table>
<thead>
<tr>
<th>Category</th>
<th>Coverage Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial HMO (includes Self-Funded groups unless otherwise specified)</td>
<td>Per policy criteria</td>
</tr>
<tr>
<td>BCNA (Medicare Advantage)</td>
<td>See government section</td>
</tr>
<tr>
<td>BCN65 (Medicare Complementary)</td>
<td>Coinsurance covered if primary Medicare covers the service.</td>
</tr>
</tbody>
</table>

II. **Administrative Guidelines:**

- The member’s contract must be active at the time the service is rendered.
- Coverage is based on each member’s certificate and is not guaranteed. Please consult the individual member’s certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member’s PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.