Double Balloon Enteroscopy

Number: 0737

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Aetna considers double balloon enteroscopy (DBE) medically necessary for the following indications:

- For evaluating suspected small bowel malignancies (e.g., adenocarcinoma, lymphoma, GI stromal tumors, metastatic tumors); or
- For evaluating the colon in the case of incomplete colonoscopy; or
- For investigating suspected small intestinal bleeding in persons with objective evidence of recurrent, obscure gastro-intestinal (GI) bleeding (e.g., iron-deficiency anemia, positive fecal occult blood test, or visible bleeding) who have had upper and lower GI endoscopies (esophagogastroduodenoscopy (EGD) and colonoscopy) that have failed to identify a bleeding source; or
- For initial diagnosis in persons with suspected Crohn's disease (abdominal pain, diarrhea, elevated erythrocyte sedimentation rate, elevated white blood cell count, fever, GI bleeding, or weight loss) without evidence of disease on conventional diagnostic tests, including small-bowel follow-through and upper and lower endoscopy (EGD and

Policy History

Last Review 08/24/2016
Effective: 10/05/2007
Next Review: 08/24/2017

Definitions

Additional Information

Clinical Policy Bulletin Notes
colonoscopy); or

- For removing entrapped foreign bodies in the small bowel (e.g., retained video capsule); or
- For removing large polyps (greater than 10 mm) of the small bowel in persons with Peutz-Jeghers syndrome; or
- For treating members with GI bleeding when the small intestine has been identified as the source of bleeding; or
- For use in conjunction with endoscopic retrograde cholangio-pancreatography (ERCP) in individuals with surgically altered upper GI anatomy.

Aetna considers DBE experimental and investigational for all other indications including the following (not an all-inclusive list) because its effectiveness for indications other than the ones listed above has not been established:

- Detection of neuroendocrine tumors of the small bowel
- Diagnosis of pyogenic granuloma
- Treatment of intussusception

See also CPB 0588 - Capsule Endoscopy (../500_599/0588.html)

Background
Examination of the small intestine (small bowel) has always been hindered by its long (about 650 cm) and convoluted configurations. Currently, push enteroscopy is the most commonly used method for endoscopic examination of the small bowel. Recent advent in technology has led to development of double balloon enteroscopy/double balloon endoscopy (DBE, also known as push-pull enteroscopy) and capsule endoscopy (CE) making visualization of the small intestine possible. Double balloon enteroscopy, developed by Yamamoto and associates in co-operation with Fujinon Corporation (Saitama, Japan), employs a 200-cm enteroscope with 2 latex balloons -- one attached to the tip of the enteroscope and the other at the distal end of a 140-cm overtube. By inflating the overtube balloon enough to grip the intestinal wall (which can occur at a balloon pressure of 45 mm
Hg), the endoscope can be inserted further without forming redundant loops in the small intestine. Double balloon endoscopy is unique in that it allows for visualization of the entire small bowel without advancing an excessive length of the endoscope into the patient; it can also measure the depth of insertion of the endoscope. The endoscope can be inserted via an oral (anterograde) or anal (retrograde) approach depending on the suspected location of the lesion. In general, two types of endoscope are available for DBE: (i) a thin endoscope for observation of the entire small intestine in steps of 20 to 40 cm, and (ii) a therapeutic double balloon endoscope with a larger accessory channel (Gerson, 2005; Heine et al, 2006).

Double balloon enteroscopy can provide both diagnostic as well as therapeutic intervention to the entire small bowel. Observation of an affected area with controlled movement of the endoscope enables interventions (e.g., biopsies, endoscopic hemostasis using injection and argon plasma coagulation (APC), balloon dilatation, polypectomy, stent placement, foreign-body extraction, and endoscopic mucosal resection) to be carried out. The advantages of DBE over CE and push enteroscopy are as follows: (i) while CE can be used to examine the entire small bowel, it can not be used to obtain a biopsy, precisely localize a lesion, or perform therapeutic intervention for small bowel lesions; (ii) push enteroscopy can examine only a relatively short portion of the proximal small bowel estimated to be between 50 and 150 cm distal to the pylorus; whereas DBE can evaluate an extensive area of the small bowel reaching approximately 300 cm in the oral direction. The entire small bowel can be examined when a DBE is performed with the conjunctive use of the oral and anal approaches (Heine et al, 2006; Concha et al, 2007). On the other hand, the disadvantages of DBE include long procedural time (averaging approximately 90 mins compared to 45 mins for CE), additional sedative medication, extended anesthesia support, and the need for fluoroscopy for direction of loop reduction and to aid in ileal intubation during the retrograde approach (Lo and Mehdizadeh, 2006).
Preliminary findings suggested that DBE is useful in the management of patients with small bowel lesions, especially for individuals with obscure gastro-intestinal bleeding (OGIB). The complication rate of DBE is low; severe complications such as pancreatitis and perforation have been reported in approximately 1% of all diagnostic DBEs. Moreover, the complication rate of therapeutic DBEs is higher than diagnostic DBEs, but is comparable with the conventional endoscopy (May and Ell, 2006).

Sunada and associates (2005) evaluated the clinical outcome of DBE focusing on the involvement of neoplasms in strictures of the small intestine. By means of DBE, strictures of the small intestine were found in 17 out of 62 patients. These 17 consecutive patients were subjected to analysis -- DBE contributed to the diagnosis of small intestinal neoplasms in 3/17 patients by direct observation of the strictures as well as by biopsy sampling. Surgical procedures were chosen for these 3 patients, while balloon dilation was chosen for the strictures in 4 patients diagnosed with inflammation without neoplasm. The authors concluded that DBE is a useful method for the diagnosis and treatment of strictures in the small bowel.

In a retrospective analysis, Di Caro and colleagues (2005) assessed the indications, safety, as well as clinical impact of DBE. A total of 62 patients with suspected or documented small bowel diseases were investigated by DBE. A total of 89 procedures were performed (26 and 9 patients from the oral or the anal route, respectively; 27 patients from both). The main outcome measures were depth and time of insertion, diagnostic and therapeutic yields, as well as complication rates. Mean time of insertion was 70 +/- 30 mins and 90 +/- 35 mins from the oral and the anal route, respectively. Length of insertion was 254 +/- 174 cm beyond the pylorus, 180 +/- 150 cm beyond the ileo-cecal valve, whereas the entire small bowel was completely explored in 10 patients. Double balloon enteroscopy was diagnostic in 80% of the patients: in 29/33 of patients with GI bleeding, in 1/5 patients with iron deficiency anemia and positive fecal occult blood testing, in 3/5 patients
with chronic diarrhea, in 2/3 patients with abdominal pain, in 2/3 patients with GI cancer (follow-up), in all patients with suspected or refractory celiac disease, and in 2/3 patients with Crohn's disease. Treatment was performed in 41.9% of patients (22 polyps and 29 angioectasias). No complications occurred. The authors concluded that DBE is a safe and feasible diagnostic and therapeutic tool for suspected or documented small bowel diseases. They claimed that at present, the best candidates for the procedure appear to be those with OGIB.

Matsumoto et al (2005a) compared the value of CE and DBE in the diagnosis of small intestinal pathology. A total of 13 patients with OGIB and 9 patients with known GI 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. Patients were then evaluated by CE. Video images obtained by CE were reviewed by an observer who was blinded to DBE findings. Double balloon enteroscopy identified positive findings in 54.5% (12/22) patients. Capsule endoscopy identified positive findings in the area explored by DBE in 36.4% (8/22) patients, and in the unexplored area in 50.0% (11/22) patients. 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 12/13 patients with OGIB. In patients with polyposis, the diagnoses were discordant in 3 patients, in whom CE failed to detect any polyp. In 2/3 polyposis patients with concordant positive findings, DBE detected a larger number of polyps than CE did. The authors concluded that DBE appears to be superior to CE in the diagnosis of small intestinal polyps, whereas the value for diagnosing OGIB is similar in the two procedures. Furthermore, Matsumoto et al (2005b) stated that DBE is superior to push enteroscopy in exploration of the small intestine and in diagnostic yield for small intestinal pathology.

Nakamura et al (2006) evaluated the clinical effects of CE and DBE to consider their roles as well as the indications for the procedures in patients with suspected small bowel bleeding. A
total of 32 patients with OGIB were enrolled in the study; and 28 were examined with both methods. Bleeding sources were categorized as A1 lesions (immediate hemostatic procedures required) or A2 lesions (close observation required). Capsule endoscopy and DBE were evaluated with regard to whether or not they were capable of accessing the entire small bowel and provided a diagnosis, and the access and diagnostic rates were calculated. On CE, 13 patients were diagnosed with A1 lesions and 6 with A2 lesions; on DBE, 11 had A1 lesions and 1 had an A2 lesion. The access rate for the entire small intestine on CE was 90.6 % (29/32), significantly higher than with DBE at 62.5 % (10/16; p < 0.05). The diagnostic rate on CE was 59.4 % (19/32), higher than with DBE at 42.9 % (12/28; p = 0.30), but not significantly different. Among patients with A1 lesions who were diagnosed by means of DBE, histological diagnoses were obtained in 6/11, and 3 patients were treated. The authors concluded that in many suspected small bowel bleeding cases, CE should be selected for the initial diagnosis and DBE for treatment or histopathological diagnosis after detection of the bleeding site on CE.

In a prospective study, Hadithi and colleagues (2006) compared the diagnostic detection rate of small bowel lesions using wireless video capsule endoscopy (VCE) with that using DBE in patients with OGIB. Tolerance, adverse events, endoscopic interventions, and prognosis were used as secondary outcomes. A total of 35 consecutive patients with OGIB were assessed (13 females and 22 males; mean age of 63.2 years; range of 19 to 86 years). Small bowel abnormalities were detected using VCE in 80 % (28/35) patients with OGIB, compared with 60 % (21/35) patients using DBE (p = 0.01). Both examinations were well-tolerated, but VCE was more acceptable to patients. No major complication occurred after either examination. Biopsies (n = 27), APC (n = 19), tattoo injection (n = 8), and polypectomy (n = 2) were feasible with DBE when indicated in 77 % (27/35) patients. During a follow-up period of 5 months (range of 2 to 12 months), 74 % (26/35) patients remained clinically stable and did not require blood transfusions after DBE. Eighteen (51 %) of those who
remained clinically stable had received APC therapy. The authors concluded that high detection rates of the causes of OGIB are feasible with VCE and DBE. They noted that although the detection rate of VCE was superior, the findings of this study indicated that the procedures are complementary; and that an initial diagnostic imaging employing VCE might be followed by therapeutic and interventional DBE.

Monkemuller and associates (2006) examined the diagnostic yield of DBE, measured the frequency of management changes based on the results, and assessed the clinical outcome for patients undergoing the procedure. Subjects included patients undergoing DBE using a Fujinon enteroscope (length 200 cm, diameter 8 mm) during a 11-month period. All patients had previously undergone esophago-gastro-duodenoscopy and colonoscopy. They underwent small bowel cleansing on the day before the procedure using a standard colon lavage solution. A total of 70 DBE procedures were performed in 53 patients (19 women; 34 men, mean age of 60 years, range of 24 to 80 years) by the oral route in 46 cases and the anal route in 24 cases. The indications for the examination were GI bleeding (n = 29), suspected Crohn’s disease (n = 6), abdominal pain (n = 4), polyp removal or evaluation in polyposis syndromes (n = 6), chronic diarrhea (n = 4), and surveillance or tumor search (n = 4). The mean duration of the procedure was 72 mins (range of 25 mins to 3 hrs). The mean radiation exposure was 441 dGy/cm (range of 70 to 1462 dGy/cm), and the mean depth of small bowel insertion was 150 cm (range of 1 to 470 cm). It was possible to evaluate the entire small bowel in 4 patients (8 %). A new diagnosis was obtained in 26/53 patients (49 %). The findings in the 70 procedures were angiodysplasia (n = 13), ulcerations or erosions (n = 5), jejunitis or ileitis (n = 5), tumors (n = 5), stenosis (n = 4), polyps (n = 5), Crohn's disease (n = 4), lymphangietasias (n = 4), and normal (n = 17). Double balloon enteroscopy resulted in a therapeutic intervention (endoscopic, medical or surgical, excluding blood transfusions) in 57 % (30/53) of the patients. The only complication (1.4 %) observed was a single case of intra-procedural post-polypectomy bleeding, which resolved with injection of epinephrine. The
authors concluded that in almost 2/3 of the patients examined, DBE was clinically useful for obtaining a new diagnosis and starting new treatments, changing existing treatments, carrying out surgical intervention, or providing therapeutic endoscopy. They stated that DBE is a useful and safe method of obtaining tissue for diagnosis, providing hemostasis, and carrying out polypectomy.

May et al (2007) stated that DBE is a new endoscopic tool that allows both diagnostic work-up as well as therapeutic interventions of small bowel diseases. However, for a variety of reasons, endoscopic therapy appears to be more difficult to carry out deep in the small bowel than in the upper or lower GI tract. These researchers evaluated the acute technical success and complication rates of DBE. A total of 353 patients (152 women, 201 men; mean age of 60.3 +/- 17.1 years) with suspected or known small bowel disease underwent 635 consecutive DBE procedures. The majority of the patients were suffering from mid-GI bleeding (n = 210, 60 %). The overall diagnostic yield was 75 % (265/353) for relevant lesions in the small bowel. The overall therapeutic yield was 67 % (236/353). Endoscopic therapy was performed in 59 % of these patients (139/236). All therapeutic interventions were performed in an inpatient manner. The majority of the procedures were carried out with the patients under conscious sedation (n = 130, 73 %); sedation with propofol was administered in 37 (20.8 %) and with a combination of propofol and meperidine in 11 (6.2 %) investigations. A total of 178 therapeutic procedures was carried out. A median of 270 cm of the small bowel was visualized using the oral route and a median of 150 cm using the anal route. The investigation time averaged 78 +/- 30 minutes. The endoscopic treatments included APC (n = 102 treatment sessions), injection therapy (n = 2), a combination of APC and injection (n = 6), polypectomies (n = 46), dilation therapy (n = 18), and foreign-body extraction (n = 3). In 6/178 cases (3.4 %), polypectomy (n = 2), dilation (n = 3), and implantation of a self-expanding metal stent (n = 1) could not be performed successfully for technical or anatomical reasons. Severe treatment-related complications occurred in 6/178
therapeutic procedures (3.4 %) and 4/139 patients (2.9 %), consisting of bleeding (n = 2) and perforation (n = 3) during and after polypectomy of large polyps (greater than 3 cm in size), as well as one case of segmental enteritis after APC. The authors concluded that endoscopic therapeutic interventions can be performed safely even in the more difficult conditions of the small bowel in the majority of patients. Furthermore, polypectomy of large polyps appears to be the procedure associated with the highest risk.

Cazzato et al (2007) prospectively evaluated the diagnostic and therapeutic impact of DBE in patients with suspected or documented small bowel disease (n = 100). Starting insertion route (anal or oral) of DBE was chosen according to the estimated location of the suspected lesions based on the clinical presentation and on the findings, when available, of previous endoscopic or radiological investigations. Major indications for the procedures were acute recurrent or chronic mid-GI bleeding (n = 71), suspected GI tumors (n = 10), suspected Crohn's disease (n = 6), chronic abdominal pain and/or chronic diarrhea (n = 8), refractory celiac disease (n = 5). A total of 118 DBE procedures were performed. Oral and anal route DBE were performed in 54 and 28 patients, respectively, while 18 patients underwent a combination of both approaches. The overall diagnostic yield of DBE was 69 %. Most common pathological findings included angiodysplasias (n = 39), ulcerations and erosions of various etiologies (n = 21), tumors (n = 7) and ileal stenosis in patients with suspected Crohn's disease (n = 2). In the 65 % of the patients examined, DBE findings influenced the subsequent clinical management (endoscopic, medical or surgical treatment). No major adverse events related to the procedure occurred. The authors concluded that DBE is a useful, safe and well-tolerated new method with a high diagnostic and therapeutic impact for the management of suspected or documented small bowel diseases.

Kita et al (2007) performed 419 enteroscopic examinations in 250 patients using the Fujinon DBE system. Total enteroscopy
was successfully achieved by the combination of both oral and anal approaches in 55 out of 71 cases in whom total enteroscopy was intended. Of 250 patients, ulcerative and/or erosive lesions were found in 49 cases and tumors/polyps were found in 49 cases. These investigators also found 26 cases of vascular lesion, including angiodysplasia. Endoscopic treatments, including hemostasis using either clipping devices or electro-coagulation, polypectomy, endoscopic mucosal resection, balloon dilation, and stent placement was successfully carried out. They concluded that DBE is an useful technique for the diagnosis as well as treatment of small intestinal disorders.

While Gurudu and Leighton (2006) stated that the ultimate role of DBE in the diagnosis and management of OGIB remains to be explored, Gerson (2005), in an editorial, stated that based on preliminary data in patients with OGIB, the diagnostic yield from DBE appears to surpass other imaging modalities while also allowing the opportunity for therapeutic intervention. Moreover, Martins and Wassef (2006) noted that a number of prospective studies have reported that CE is the most sensitive imaging modality for identifying lesions in the small bowel and that DBE is the least invasive modality available for the management of these lesions. Also, May and Ell (2006) noted that the diagnostic yield of DBE is high, at about 75%, as is the therapeutic yield; and the key indication of DBE is mid-GI bleeding. Concha et al (2007) stated that DBE may be the method of choice when therapeutic objectives are considered after wireless CE or whenever wireless CE is contra-indicated in patients with OGIB.

Additionally, an assessment by the Australian Medical Services Advisory Committee (MSAC, 2006) reached the following conclusions about DBE: "Double Balloon Enteroscopy (DBE) is a safe, minimally invasive technique for examining endoscopically the whole of the small intestine, allowing biopsy and certain therapeutic procedures at the same time. The most appropriate comparator is intraoperative enteroscopy. While there is no direct comparative data, it is likely to be safer to
perform than the alternative, intraoperative enteroscopy. DBE is effective in allowing enteroscopic assessment and some treatment of the entire small intestine. Although more costly to Medicare than intraoperative enteroscopy, DBE is potentially cost saving for the entire health funding system. MSAC recommends public funding for DBE for the diagnosis and treatment of patients with obscure gastrointestinal bleeding.

In a meta-analysis, Pasha and colleagues (2008) compared the diagnostic yield of CE with DBE in small bowel (SB) disease. Data on diagnostic yield of CE and DBE were extracted, pooled, and analyzed. The weighted incremental yield (IY(W)) (yield of CE−yield of DBE) of CE over DBE and 95 % confidence intervals (CIs) for pooled data were calculated using a fixed-effect model (FEM) for analyses without, and a random-effect model (REM) for analyses with, significant heterogeneity. Eleven studies compared CE and DBE; the pooled overall yield for CE and DBE was 60 % (n = 397) and 57 % (n = 360), respectively (IY(W), 3 %; 95 % CI: -4 % to 10 %; p = 0.42; FEM). Ten studies reported vascular findings; the pooled yield for CE and DBE was 24 % (n = 371) and 24 % (n = 364), respectively (IY(W), 0 %; 95 % CI: -5 % to 6 %; p = 0.88; REM). Nine studies reported inflammatory findings; the pooled yield for CE and DBE was 18 % (n = 343) and 16 % (n = 336), respectively (IY(W), 0 %; 95 % CI: -5 % to 6 %; p = 0.89; FEM). Nine studies reported polyps/tumors; the pooled yield for CE and DBE was 11 % (n = 343) and 11 % (n = 336), respectively (IY(W), -1 %; 95 % CI: -5 % to 4 %; p = 0.76; FEM). The authors concluded that CE and DBE have comparable diagnostic yield in SB disease, including OGIB. Capsule endoscopy should be the initial diagnostic test because of its non-invasive quality, tolerance, ability to view the entire SB, and for determining the initial route of DBE. Because of its therapeutic capabilities, DBE may be indicated in patients with a positive finding on CE requiring a biopsy or therapeutic intervention, if suspicion for a SB lesion is high despite a negative CE, and in patients with active bleeding.

In a multi-center prospective study, Marmo et al (2009) evaluated diagnostic agreement between CE and DBE in
patients with OGIB, and secondarily the diagnostic gain of DBE when CE detected only blood or clots in the small-bowel lumen. A total of 193 patients (119 men, mean age of 61.6 +/- 16.2 years) first underwent CE and then DBE. The most frequent positive findings at CE were vascular lesions (74 patients, 38.3 %), blood or clot in the lumen (34, 17.6 %), and tumor mass (20, 10.4 %). The most frequent findings at DBE were vascular lesions (72 patients, 37.3 %), neoplasia (30, 15.5 %) and ulcers/inflammatory lesions (12, 6.2 %). Overall, kappa coefficient was 0.46 (95 % CI: 0.38 to 0.54), with maximum concordance for vascular (0.72 [95 % CI: 0.59 to 0.84]) and inflammatory (0.78 [0.58 to 0.99]) lesions and minimum for polyps (0.46 [0.16 to 0.80]). Blood in the lumen was the only positive finding at CE in 34 cases; of these, 12 had negative DBE findings whereas 10 had vascular lesions, 6 neoplasia, 1 ulcer, and 5 diverticula. The authors concluded that CE and DBE have good agreement for vascular and inflammatory lesions but not for polyps or neoplasia. Double balloon enteroscopy provides valuable adjunctive information, particularly in patients with neoplasia or polyp at CE; and DBE clarified the origin of bleeding in two-thirds of patients with CE showing only blood in the lumen.

Bellutti et al (2009) evaluated the use of DBE for the detection of the primary tumor in patients with neuroendocrine tumors (NETs). A total of 12 consecutive patients (4 men and 8 women) with suspected carcinoid syndrome, either metastatic to the liver (n = 5), symptoms of a neuroendocrine tumor with elevated tumor markers (n = 5), or OGIB (n = 2) underwent DBE for the search of the primary tumor or the source of bleeding. All patients underwent abdominal sonography and a computed tomography (CT) scan, EGD, ileocolonoscopy, and octreotide scintigraphy prior to DBE. Capsule endoscopy was performed in 4 patients. A total of 17 DBE were performed in the 12 patients. The CT scan and sonography of the abdomen as well as EGD and ileocolonoscopy were unable to detect the primary tumor in any patient. A submucosal tumor of the ileum or the jejunum could be detected by DBE was detected in 7 patients (58 %) (anal route, n = 4; oral route, n = 3). In 4 of these
patients (33 %), this finding could be confirmed by the surgical resection of a NET. In 2 patients (17 %) with a submucosal ileum protrusion suspicious for NET, laparotomy and intra-operative endoscopy did not confirm the tumor. The authors concluded that the diagnostic yield of DBE for primary tumor search in patients with metastatic or suspected NET was 33 %. They stated that although endoscopic small bowel investigation by DBE appears to enrich the diagnostic possibilities for the diagnosis of small bowel-NET, at the present time DBE should only be performed in selected cases, possibly based on a positive previous work-up.

In a review on the diagnosis and management of GI tract diseases, Akahoshi and colleagues (2006) stated that DBE is a feasible technique that allows adequate small and large bowel examination.

In a pilot study, Gay and Delvaux (2007) examined the use of DBE after failed conventional colonoscopy. A total of 29 patients (5 men, 24 women; mean age of 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. A prototype instrument (working length 152 cm, diameter 9.4 mm) designed to incorporate the principles of DBE 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 adhesions (n = 16), or to 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 mins; a long sigmoid loop limited the examination to the left flexure in 1 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 5 patients. Fluoroscopy was used in 16 patients to monitor endoscope progression. No complications were
reported. The authors concluded that double-balloon colonoscopy enables full colonic examination in almost all patients with a previous incomplete colonoscopy. The overtube should be used in most cases. The use of fluoroscopic assessment of scope progression could be reduced further with increasing experience.

In a retrospective chart review, Pasha et al (2007) evaluated the completion rate of DBE for colon evaluation (ie, double-balloon colonoscopy) and therapeutic interventions after a prior incomplete colonoscopy by conventional colonoscope. A total of 16 patients (11 women and 5 men; mean age of 69 years) had retrograde DBE between April 20, 2005 and February 8, 2006, after a prior incomplete colonoscopy. Main outcome measures were completion rate of double-balloon colonoscopy, therapeutic success of standard procedures, as well as post-procedure complications. A completion rate of 88 % (14 patients) was achieved with 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 mins (SD, 15.2 mins). The authors concluded that double-balloon colonoscopy has a high rate of effectiveness for completion of colon evaluation in patients with incomplete conventional colonoscopy. It allows diagnostic and therapeutic interventions and can be performed with the patient under conscious sedation within a reasonable time.

Moreels et al (2010) examined if the therapeutic Fujinon double-balloon endoscope EN-4S0T5/20 is a valuable tool to intubate the cecum and to carry out all conventional endoscopic procedures after incomplete conventional colonoscopy. A total of 45 patients with prior incomplete conventional colonoscopy were prospectively enrolled. All but 3 procedures were performed under conscious sedation with the patient in the left lateral decubitus position without fluoroscopic guidance. The cecum was reached in 42 of 45 patients (93 %) and in 62 % additional therapeutic interventions were carried out. Double-balloon colonoscopy required less
conscious sedation compared to conventional colonoscopy. No external abdominal compression nor fluoroscopic control was used. The insertion depth of the double-balloon endoscope did not exceed the working length of a conventional colonoscope. The authors concluded that findings of the present study showed that the concept of DBE is a valuable alternative to reach the cecum after prior incomplete conventional colonoscopy, especially due to redundant colon and colonic loop formation. The procedure requires less conscious sedation and no fluoroscopic control, but allows all conventional endoscopic interventions.

Yano and Yamamoto (2009) stated that DBE is useful for cases of difficult colonoscopy, providing success rates of total colonoscopy between 88 to 100%. Furthermore, the Netherlands Association of Comprehensive Cancer Centres' practice guideline on hereditary colorectal cancer (2009) stated that in the case of incomplete colonoscopy, the colon should be imaged using another method (e.g., DBE, CT colonography, a double contrast barium enema).

Teshima et al (2011) performed a new meta-analysis comparing CE and DBE focused specifically on OGIB. A comprehensive literature search was performed of comparative studies using both CE and DBE in patients with OGIB. Data were extracted and analyzed to determine the weighted pooled diagnostic yields of each method and the odds ratio for the successful localization of a bleeding source. A total of 10 eligible studies were identified. The pooled diagnostic yield for CE was 62% (95% CI: 47.3 to 76.1) and for DBE was 56% (95% CI: 48.9 to 62.1), with an odds ratio for CE compared with DBE of 1.39 (95% CI: 0.88 to 2.20; p = 0.16). Subgroup analysis demonstrated the yield for DBE performed after a previously positive CE was 75.0% (95% CI: 60.1 to 90.0), with the odds ratio for successful diagnosis with DBE after a positive CE compared with DBE in all patients of 1.79 (95% CI: 1.09 to 2.96; p = 0.02). In contrast, the yield for DBE after a previously negative CE was only 27.5% (95% CI: 16.7 to 37.8). The authors concluded that CE and DBE provide similar diagnostic yields in patients with OGIB.
However, the diagnostic yield of DBE is significantly higher when performed in patients with a positive CE.

Meckel's diverticulum (MD) is one of the most common congenital GI malformations. It is difficult to make a pre-operative diagnosis of MD. To-date, few data are available describing the diagnosis of MD by DBE and CE. He and colleagues (2013) evaluated the value of DBE in the diagnosis of MD and comparatively evaluated the diagnostic yield of DBE and CE for MD. A single-center study was performed on patients with a confirmed diagnosis of MD by surgery and post-operative pathology between January 2003 and December 2011. A total of 74 patients (60 males) with a mean age of 29.0 +/- 14.3 years were analyzed; 33 (55.0 %) were between 21 and 40 years of age. Gastro-intestinal bleeding was the major finding in 86.5 % of the patients who were referred for DBE or CE examination. The mean duration of symptoms was 32.3 +/- 48.7 months. In the 74 patients, the diagnostic yield of DBE for MD before surgery was 86.5 % (64/74), and correct diagnoses were made in the majority of cases by retrograde DBE, with a few cases by antegrade DBE. In the 26 patients undergoing CE before DBE, the overall diagnostic yield of DBE was 84.6 %, significantly greater than that of CE (7.7 %, p < 0.000, McNemar's $\chi^2$ test). Poor agreement was found between the 2 modalities (kappa = 0.03). The authors concluded that for patients who are highly suspected of having MD, DBE provides a safe, effective, and reliable means of diagnosis before surgery. Moreover, these investigators noted that “A negative Meckel’s scan does not exclude the presence of MD; furthermore, a negative CE procedure also does not exclude important small bowel pathology, and additional invasive balloon-assisted enteroscopy remains mandatory if small bowel pathology is suspected even after a negative CE. Considering the relatively small sample size in this study, our findings still remain to be further confirmed”.

Also, an UpToDate review on “Meckel’s diverticulum” (Javid and Pauli, 2013) states that “Adult and pediatric patients with gastrointestinal bleeding are initially evaluated using standard
algorithms. Patients who present with gastrointestinal bleeding may undergo routine upper or lower gastrointestinal endoscopy, neither of which can demonstrate a Meckel’s diverticulum. However, Meckel’s diverticulum has been identified using advanced endoscopy techniques (double balloon enteroscopy, capsule endoscopy), but these studies are not routinely obtained”.

The American College of Radiology’s Appropriateness Criteria on “Suspected small-bowel obstruction” (Small et al, 2010) did not mention the use of DBE. Furthermore, an UpToDate reviews on “Intussusception in children” (Kitagawa and Miqdady, 2013) does not mention the use of DBE as a therapeutic option.

In a multi-center, retrospective cohort study, Zhang et al (2013) stated that little is known about the clinical impact of DBE in patients with Peutz-Jeghers syndrome (PJS). These investigators evaluated the safety and effectiveness of DBE in the management of small-bowel polyps in PJS patients. Consecutive patients diagnosed with PJS who underwent DBE for polypectomy between January 2006 and August 2012 were included in this study. In all cases, previous video capsule enteroscopy had shown at least 1 polyp greater than or equal to 10 mm in size. A total of 25 patients (13 men; median age of 36 years; 14 with prior laparotomy) underwent 46 DBE procedures (1 to 5 per patient, 44 via oral route). Polypectomy was performed in 39/46 DBEs. A total of 214 polyps were removed (median size of 30 mm), with a median number of polypectomies per procedure of 5.0 (range of 1 to 18). The estimated maximum-sizes of resected polyps significantly decreased at each session: 30.0, 25.0, 20.0, 15.0, and 17.5 mm (p = 0.02). In 7 DBEs no polypectomy was performed (4-only minor polyps detected; 3-endoscopic irresectability). Complications occurred in 3/39 of therapeutic procedures (2-minor delayed bleeding; 1-mucosal tear), all of them were dealt with conservative or endoscopic therapy. A total of 6 patients underwent elective surgery post DBE due to polyps not amenable for endoscopic resection. There were no small-bowel
polyp related complications during a median follow-up of 56.5 months. The authors concluded that DBE showed to be a safe and effective technique in the management of small-bowel polyps in PJS patients, allowing a pre-symptomatic and non-surgical approach. These preliminary findings need to be validated by well-designed studies.

Furthermore, UpToDate reviews on “Peutz-Jeghers syndrome: Epidemiology, clinical manifestations, and diagnosis” (Lembo, 2014) and “Peutz-Jeghers syndrome and juvenile polyposis: Screening and management of patients and families” (Bonis et al, 2014) do not mention the use of DBE as a management tool.

**Endoscopic Retrograde Cholangio-Pancreatography (ERCP) in Patients with Surgically Altered Gastro-Intestinal Anatomy:**

Osoegawa and colleagues (2012) examined the clinical outcome of DBE-assisted endoscopic retrograde cholangio-pancreatography (DB-ERCP) in patients with altered GI anatomy. Between September 2006 and April 2011, a total of 47 procedures of DB-ERCP were performed in 28 patients with a Roux-en-Y total gastrectomy (n = 11), Billroth II gastrectomy (n = 15), or Roux-en-Y anastomosis with hepatico-jejunostomy (HJ; n = 2). DB-ERCP was performed using a short-type DBE combined with several technical innovations such as using an endoscope attachment, marking by submucosal tattooing, selectively applying contrast medium, and CO2 insufflations. The papilla of Vater or HJ site was reached in its entirety with a 96% success rate (45/47 procedures). There were no significant differences in the success rate of reaching the blind end with a DBE among Roux-en-Y total gastrectomy (96%), Billroth II reconstruction (94%), or pancreatoduodenectomy (100%), respectively (p = 0.91). The total successful rate of cannulation and contrast enhancement of the target bile duct in patients whom the blind end was reached with a DBE was 40/45 procedures (89%). Again, there were no significant differences in the success rate of cannulation and contrast enhancement of the target bile duct with a DBE among Roux-en-Y total gastrectomy (88%), Billroth II reconstruction (89%), or
pancreatoduodenectomy (100 %), respectively (p = 0.67). Treatment was achieved in all 40 procedures (100 %) in patients whom the contrast enhancement of the bile duct was successful. Common endoscopic treatments were endoscopic biliary drainage (24 procedures) and extraction of stones (14 procedures). Biliary drainage was done by placement of plastic stents. Stones extraction was done by lithotomy with the mechanical lithotripter followed by extraction with a basket or by the balloon pull-through method. Endoscopic sphincterotomy was performed in 14 procedures with a needle precutting knife using a guide-wire. The mean total duration of the procedure was 93.6 ± 6.8 mins and the mean time required to reach the papilla was 30.5 ± 3.7 mins. The mean time required to reach the papilla tended to be shorter in Billroth II reconstruction (20.9 ± 5.8 mins) than that in Roux-en-Y total gastrectomy (37.1 ± 4.9 mins), but there was no significant difference (p = 0.09). A major complication occurred in 1 patient (3.5 %): perforation of the long limb in a patient with Billroth II anastomosis. The authors concluded that short-type DBE combined with several technical innovations enabled them to perform ERCP in most patients with altered GI anatomy.

Shah and associates (2013) noted that data on overtube-assisted enteroscopy (OAE) to facilitate ERCP in patients with surgically altered pancreaticobiliary anatomy, or long-limb surgical bypass, is limited. These researchers evaluated and compared ERCP success by using single-balloon (SBE), DBE, or rotational overtube enteroscopy. Main outcome measurements included (i) enteroscopy success: visualizing the pancreaticobiliary-enteric anastomosis or papilla; (ii) ERCP success: completing the intended pancreaticobiliary intervention; and (iii) clinical success: greater than 50 % reduction in abdominal pain or level of hepatic enzyme elevations or resolution of jaundice. From January 2008 through October 2009, a total of 129 patients had 180 enteroscopy-ERCPs. Anatomy was Roux-en-Y: gastric bypass (RYGB; n = 63), HJ (n = 45), post-gastrectomy (n = 6), Whipple procedure (n = 10), and other (n = 5). Endoscopic retrograde cholangio-pancreatography success was 81 of 129 (63 %).
Enteroscopy success: 92 of 129 (71%), of whom 81 of 92 (88%) achieved ERCP success. Reasons for ERCP failure (n = 48): afferent limb entered but pancreaticobiliary anastomosis and/or papilla not reached (n = 23), cannulation failure (n = 11), afferent limb angulation (n = 8), and jejunoojestunostomy not identified (n = 6). Select interventions: anastomotic stricturoplasty (cauterity ± dilation, n = 16), stone removal (n = 21), stent (n = 25), and direct cholangioscopy (n = 11); ERCP success rates were similar between RYGB and other long-limb surgical bypass and among SBE, DBE, and rotational overtube enteroscopy. Complications were 16 of 129 (12.4%). The authors concluded that (i) ERCP is successful in nearly 2/3 of long-limb surgical bypass patients and in 88% when the papilla or pancreaticobiliary-enteric anastomosis is reached; (ii) enteroscopy success in long-limb surgical bypass is similar among SBE, DBE, and rotational overtube enteroscopy methods, and (iii) referral of long-limb surgical bypass patients who require ERCP to high-volume institutions may be considered before more invasive percutaneous or surgical alternatives.

Shimatani and colleagues (2014) stated that endoscopic treatment for pancreatobiliary diseases is less invasive than surgery and percutaneous trans-hepatic biliary drainage is highly beneficial to patients. The endoscopic approach is indicated for an increasing number of patients, including those who have undergone previous GI surgery, although these patients face 2 major challenges. First, the endoscopic approach to the afferent loop, blind end, and the site of choledocho-jejunostomy is difficult with the use of a conventional endoscope because of the distance from the gastro-jejunal anastomosis site, unusual anatomical features of the intestine such as its winding shape, and post-operative adhesion. Second, it is difficult to reach Vater's papilla or the site of choledocho-jejunostomy and to cannulate selectively into the pancreatic and/or biliary duct. The balloon-assisted endoscope (BAE), a recently developed technology, can be useful for carrying out ERCP in patients with surgically altered anatomy. The authors concluded that ERCP using the BAE is
highly safe and effective in patients with altered GI anatomy, especially in patients with Roux-en-Y reconstruction.

Itokawa et al (2014) noted that in patients with Roux-en-Y HJ (HJ with R-Y) and Whipple resection, ERCP can be challenging. These investigators reported their experience with ERCP using BAE (BAE-ERCP) in patients with HJ with R-Y, and Whipple resection. BAE-ERCP procedures were carried out in 62 patients (HJ with R-Y:Whipple resection = 34:28). Overall, the rates of reaching the anastomosis were 85.3 % (29/34) in HJ with R-Y and 96.4 % (27/28) in Whipple resection. In terms of HJ with R-Y, insertion success rate by standard SBE was 89.3 % (25/28). Insertion success rate by short BAE, including SBE and DBE, was 50 % (3/6). There was a statistically significant difference of insertion success rate between standard long BE and short BE (p = 0.021). However, in the Whipple patients, insertion success rate by standard and short SBE was 93.8 % (15/16) and 91.7 % (11/12), respectively. Initial insertion success rate by short BAE in Whipple patients was significantly higher than in HJ with R-Y (91.7 % versus 50 %, p = 0.045). Therapeutic interventions included dilation of Anastomosis stricture, stone extraction, endoscopic mechanical lithotripsy, biliary stent placement, stent extraction, endoscopic nasobiliary drainage, direct cholangioscopy, and electrohydraulic lithotripsy. The HJ with R-Y series and Whipple series treatment success rate was 90 % (18/20) and 95.0 % (19/20), respectively. The authors concluded that BAE-ERCP enabled ERCP to be carried out in patients with HJ. It is considered safe and feasible.

Skinner et al (2014) stated that OAE techniques have increased the ability to perform ERCP in patients with altered upper GI anatomy, such as RYGB. These researchers compared the safety and effectiveness of OAE-ERCP in patients with different configurations of upper GI anatomy. They performed a systematic review following a literature search for papers published between 1966 and August 2013. The following databases were searched: MEDLINE (via PubMed), Embase, Cochrane library, and Scopus. The following end-points were analyzed: diagnostic and therapeutic success rates, cannulation
success rate, ERCP success rate, type of enteroscopy, types of intervention, complications. A total of 23 relevant reports on OAE procedures, including SBE, DBE, and spiral enteroscopy, were analyzed. Studies included a total of 945 procedures in 679 patients (age of 2 to 91 years) who had a variety of post-surgical upper GI anatomical configurations. Among patients who underwent RYGB, endoscopic success was 80% and ERCP success was 70%. In patients who had undergone a Roux-en-Y with either a pancreaticoduodenectomy, pylorus-preserving pancreaticoduodenectomy, or HJ, endoscopic success was 85% and ERCP success was 76%. In patients who had undergone a Billroth II procedure, endoscopic success was 96% and ERCP success was 90%. In patients with native papilla who underwent successful endoscopy, cannulation was successful in 90% of patients compared with 92% in patients with an anastomosis. Overall, ERCP success for all attempts was approximately 74%. Interventions included sphincterotomy, pre-cut papillotomy, anastomotic stricturoplasty, stone removal, stent insertion, stent replacement, and balloon dilation of stenotic anastomosis. There were 32 major complications among the 945 procedures (3.4%). The authors concluded that both endoscopic and ERCP success rates were highest in patients with Billroth II anatomy, followed by those with pancreaticoduodenectomy and HJ with R-Y; the lowest success rates were in patients with RYGB. Cannulation rates appeared to be equivalent in patients with both native papilla and biliary-enteric or pancreaticoenteric anastomoses. The diagnostic and therapeutic potential of balloon-assisted ERCP were high and the adverse event rate was low.

Furthermore, and UpToDate review on “Overview of deep small bowel enteroscopy” (Kita, 2015) lists “Diagnostic endoscopic retrograde cholangiopancreatography (ERCP) in patients with Roux-en-Y anatomy” as one of the diagnostic indications of deep small bowel enteroscopy.

**Evaluation of Suspected Small Bowel Malignancies:**

In a retrospective, single-center study, Robles and colleagues
(2015) evaluated the role of DBE in malignant small bowel tumors (MSBT). All consecutive patients who underwent a DBE with final diagnosis of a malignant neoplasm from 2004 to 2014 in the authors’ referral center were included. Patient demographic and clinical pathological characteristics were reviewed. Diagnosis of MSBT was achieved either by DBE directed biopsy with multiple tissue sampling, endoscopic findings or histological analysis of surgical specimen. These researchers analyzed the impact of DBE in outcome as well as clinical course of these patients. Of 627 patients, 28 (4.5 %) (mean age of 60 ± 17.3 years) underwent 30 procedures (25 anterograde, 5 retrograde) and were diagnosed of a malignant tumor. Patients presented with OGIB (n = 19, 67.9 %), occlusion syndrome (n = 7, 25 %) and diarrhea (n = 1, 3.6 %). They were diagnosed by DBE biopsy (n = 18, 64.3 %), histological analysis of surgical specimen (n = 7, 25 %) and unequivocal endoscopic findings (n = 2, 7.1 %). Gastro-intestinal stromal tumor (n = 8, 28.6 %), adenocarcinoma (n = 7, 25 %), lymphoma (n = 4, 14.3 %), neuroendocrine tumor (n = 4, 14.3 %), metastatic (n = 3, 10.7 %) and Kaposi sarcoma (n = 1, 3.6 %) were identified. Double balloon enteroscopy modified outcome in 7 cases (25 %), delaying or avoiding emergency surgery (n = 3), modifying surgery approach (n = 2) and indicating emergency SB partial resection instead of elective approach (n = 2). The authors concluded that DBE may be critical in the management of MSBT providing additional information that may be decisive in the clinical course of these patients.

Furthermore, and UpToDate review on “Overview of deep small bowel enteroscopy” (Kita, 2015) lists “Evaluation and tattooing of suspected small bowel malignancies (e.g., adenocarcinoma, lymphoma, GI stromal tumors, metastatic tumors)” as one of the diagnostic indications of deep small bowel enteroscopy.

**Removal of Entrapped Foreign Body:**

May and colleagues (2005) described the technique of push-and-pull enteroscopy using DBE made it possible to remove swallowed foreign bodies causing intestinal obstruction
deep in the small bowel without the need for surgical laparotomy. They reported 2 cases of enteroscopic removal of entrapped capsules. In 1 patient with acute recurrent intestinal bleeding and recurrent abdominal pain, Crohn's disease had been suspected on capsule endoscopy. The 2nd patient, with known Crohn's disease, was suffering from abdominal pain and underwent capsule endoscopy for investigation of the small bowel. Prior enterolysis had not revealed stenoses in either patient. An oral approach was chosen and the capsules were identified approximately 140 cm and 310 cm from the pylorus, respectively, in front of stenoses. The capsule endoscopes were removed successfully in both patients by means of push-and-pull enteroscopy using a new enteroscope device.

Van Weyenberg et al (2010) stated that capsule retention in the small bowel is a known complication of small-bowel video capsule endoscopy. Surgery is the most frequently used method of capsule retrieval. These investigators determined the incidence and causes of capsule retention and described the use of DBE as the primary technique used for capsule retrieval. A total of 904 patients who underwent small-bowel video capsule endoscopy were included in this analysis. Main outcome measurements included the number of patients in whom capsule retention occurred and the number of patients in whom an entrapped capsule could be retrieved by using DBE. Capsule retention occurred in 8 patients (incidence 0.88 %; 95 % CI: 0.41 % to 1.80 %) and caused acute small-bowel obstruction in 6 patients. All retained capsules were successfully removed during DBE. Five patients underwent elective surgery to treat the underlying cause of capsule retention. One patient required emergency surgery because of multiple small-bowel perforations. The authors concluded that in their series, the incidence of capsule retention was low; and DBE is a reliable method for removing retained capsules and might prevent unnecessary surgery. If surgery is required, pre-operative capsule retrieval allows pre-operative diagnosis, adequate staging in case of malignancy, and optimal surgical planning.
In a retrospective case-series study, Makipour et al (2014) described an endoscopic method of retrieval retained video capsules using DBE. A total of 10 patients who underwent DBE for retrieval of a retained video capsule at 2 large tertiary referral academic centers from May 2007 to June 2013 were included in this study. Mean age of patients was 64.9 ± 18.1 years (4 females, 6 males). Five patients failed to pass the capsule as a result of an ileal or jejunal stricture (1 patient with ulcerative colitis; 4 patients with Crohn's disease); 2 patients had a small bowel stricture as a result of non-steroidal anti-inflammatory drug (NSAID) enteropathy; 1 patient had intermittent partial small bowel obstruction without evidence of a stricture; 1 patient had an obstructing malignant jejunal mass and 1 patient had a small bowel stricture as a result of radiation enteritis. Endoscopic removal via DBE was successful in 8 of 10 patients (80 %). The remaining 2 patients underwent surgical removal of the retained capsule. The 2 failed cases of capsule retrieval were both patients with suspected ileal disease. The authors concluded that the most common cause of capsule retention was underlying Crohn's disease; and DBE is an effective and minimally invasive method of capsule retrieval, including those patients with ileal disease, which has not been previously described. They stated that DBE can prevent unnecessary surgery while providing endoscopic therapy of inflammatory strictures by dilation.

Chen et al (2015) stated that recent case series have shown that enteroscopy is safe and effective to remove entrapped small bowel foreign bodies. However, the optimal timing for the foreign body retrieval in terms of duration of entrapment and when to consider surgical intervention are unknown. In this case-series study, these investigators reported that antegrade and retrograde enteroscopy can be used safely to retrieve foreign bodies entrapped in the small bowel for longer than 70 days. In total, 20 patients (mean age of 48 years; 11 females) with entrapped foreign bodies in the small intestine underwent antegrade, retrograde, or combined double balloon enteroscopy for retrieval of objects. Symptoms prompted removal of entrapped, non-sharp objects in all patients and
included abdominal pain, nausea, and vomiting. The mean time of entrapment was 83 days (range of 4 to 272 days). There were 15 cases of retained video capsule endoscopy (VCE) with a mean entrapment time of 106 days (range of 7 to 272 days). Two VCEs could not be removed safely with enteroscopy. Other retained small bowel objects included in this study were nails and fish hooks. Their average entrapment time was 13 days (range of 4 to 43 days). Of the 30 enteroscopies, there was only 1 case (3 %) with a complication (perforation). The authors concluded that according to this case-series study, experienced endoscopists can safely and effectively retrieve foreign bodies in the small bowel, particularly VCE, that are retained for extended periods of time.

Furthermore, and UpToDate review on “Overview of deep small bowel enteroscopy” (Kita, 2015) lists “Foreign body retrieval (e.g., retained video capsule)” as one of the therapeutic indications of deep small bowel enteroscopy.

Peutz-Jeghers Syndrome:

Goverde and colleagues (2016) noted that small-bowel surveillance with polypectomy of polyps greater than or equal to 15 mm prevents complications in patients with Peutz-Jeghers syndrome (PJS). These investigators compared magnetic resonance enteroclysis (MRE) and DBE for diagnostic yield of these polyps and for patient preference. Patients prospectively underwent MRE followed by proximal DBE within 20 weeks. Endoscopists were blinded to the MRE results. These researchers compared number of polyps greater than or equal to 15 mm detected by MRE and DBE. Patients' perceptions of both procedures were assessed using questionnaires. A total of 15 PJS patients (67 % males, median age of 47 years) underwent both MRE and DBE. Polyps greater than or equal to 15 mm were identified by MRE and/or DBE in 12/15 (80 %) patients. There was no significant difference in the detection of polyps greater than or equal to 15 mm (38 by MRE versus 50 by DBE, p = 0.37). Sensitivity for these polyps was 62 % (38/61) for MRE and 82 % (50/61) for DBE. Patients' perceived shame and
burden did not differ significantly between MRE and DBE. Patients reported significantly more pain during preparation for MRE than for DBE (moderate versus no pain, \( p = 0.02 \)), although perceived pain during the procedures was comparable (both mild, \( p = 0.89 \)). For future small-bowel surveillance 10/13 (77\%) patients preferred DBE over MRE (\( p = 0.09 \)). The authors concluded that these findings suggested that MRE and DBE have a comparable diagnostic yield of polyps greater than or equal to 15 mm. However, DBE allowed for direct intervention and was preferred over MRE by most patients in this series. They stated that larger cohorts of PJS patients are needed to fully evaluate the diagnostic yield of DBE compared with other modalities.

American College of Gastroenterology guidelines (Syngal, et al., 2015) state that the advent of double balloon enteroscopy allows nonoperative removal of polyps in many Peutz-Jehgers syndrome cases. The European Society of Gastrointestinal Endoscopy (Pennazio, et al., 2015) recommends device-assisted enteroscopy with timely polypectomy when large polyps (>10–15 mm) are discovered by radiological examination or small-bowel capsule endoscopy in patients with Peutz-Jehgers syndrome (strong recommendation, moderate quality evidence). An UpToDate review on Peutz-Jeghers syndrome (Chung and Adar, 2016) states that "[s]uccessful small bowel polypectomy using balloon-assisted enteroscopy has been described with both single and double balloon enteroscopies. Endoscopists should be aware of possible challenges in performing double balloon enteroscopy in patients who have had previous abdominal surgery and may have peritoneal adhesions and altered anatomy. Patients with PJS may also be at increased risk for perforation with polypectomy due to serosal invagination within the polyp stalk."

Pyogenic Granuloma:

Kikuchi and associates (2014) stated that a pyogenic granuloma (PG) is a capillary hemangioma that usually occurs on the skin
or in the oral cavity; it is rarely observed in the GI tract. These investigators described a case of a 86-year old woman who presented with anemia. Esophagogastroduodenoscopy and colonoscopy did not reveal any significant bleeding focus, but capsule endoscopy revealed a bleeding focus in the small intestine. These researchers performed DBE and identified a 7-mm-diameter, reddish, sub-pedunculated, hemispheric polyp with a smooth surface in the small intestine, approximately 100 cm from the ileo-cecal valve. The polyp was surgically removed, and the histological findings were consistent with a diagnosis of PG.

An UpToDate review on “Pyogenic granuloma (Lobular capillary hemangioma)” (Lawley, 2016) does not mention DME as a diagnostic tool.

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<th>CPT Codes / HCPCS Codes / ICD-10 Codes</th>
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<td><strong>ICD-10 codes will become effective as of October 1, 2015:</strong></td>
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**ICD-10 codes not covered for indications listed in the CPB (not all-inclusive):**

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<td>Secondary malignant neoplasm of small intestine</td>
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</table>
The above policy is based on the following references:

7. Lo SK, Mehdizadeh S. Therapeutic uses of double-balloon


Available at: http://www.msac.gov.au/internet

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diagnostic yield in small-bowel disease: A meta-analysis.

enteroscopy detects small bowel mass lesions missed by

concordance between double-balloon enteroscopy and
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AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0737
Double Balloon Enteroscopy

There are no amendments for Medicaid.