
Medical Policy



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***Current Policy Effective Date: 7/1/26**
(See policy history boxes for previous effective dates)

Title: Endovascular Repair of Iliac Artery Bifurcation

Description

Endovascular repair with a bifurcated endoprosthesis has been proposed as a minimally invasive technique to treat common iliac artery aneurysms which threaten both the external and internal iliac branches. The device seals the diseased segment while simultaneously preserving blood flow to the lower limb via the external iliac artery and to the pelvis via the internal iliac artery.

Medical Policy Statement

Endovascular repair of the iliac artery using a bifurcated endoprosthesis from the common iliac artery into both the external and internal iliac arteries is experimental/investigational. There is insufficient evidence to determine that the technology results in an improvement in net health outcomes.

Inclusionary and Exclusionary Guidelines

N/A

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

N/A

Other codes (investigational, not medically necessary, etc.)

34717

34718

Background

The iliac arteries are large blood vessels that branch off distally from the aorta, the largest of the body's blood vessels. The right and left common iliac arteries originate at the bifurcation (branching) of the abdominal aorta, and each of the common iliac arteries bifurcates further into the internal and external iliac arteries. These paired vessels supply blood to the pelvis and lower extremities.

An aneurysm is a bulging and weakness in the wall of an artery. The weakened area forms a sac or small balloon that fills with blood. Iliac artery aneurysms can develop as a result of atherosclerosis (hardening of the arteries), infection, trauma or connective tissue disorders such as Marfan syndrome and Ehlers-Danlos syndrome. Involvement of the iliac arteries occurs in 10-20% of patients with abdominal aortic aneurysms (AAAs). An iliac artery aneurysm can progressively expand and spontaneously burst, resulting in life-threatening uncontrolled bleeding.

When the iliac artery is compromised vascularly as a result of a trauma, an aneurysm, or infection, immediate repair is often necessary. The standard treatment for common iliac artery aneurysms and injuries is resection of the diseased segment with open graft repair; for internal iliac artery aneurysms, ligation (tying) with or without graft placement is the standard of care. In standard repairs, the internal iliac is often sacrificed to seal the aneurysm, which frequently leads to complications like buttock claudication and erectile dysfunction. It has been proposed that endovascular repair with a bifurcated endoprosthesis avoids the morbidity of open surgery, reduces operative time, is valuable for high risk individuals, and prevents complications such as buttock claudication, erectile dysfunction and pelvic ischemia.

The purpose of the endoprosthesis, or iliac bifurcation device (IBD), is to reinforce the weakened section of the blood vessel, to prevent rupture of the aneurysm and to maintain adequate blood flow through the vessel. Additionally, the frame of the IBD expands like a spring to press securely against the wall of the artery, cutting off the blood supply to the aneurysm. The blood bypasses the aneurysm and flows through the IBD instead.

The IBD, a flexible hollow tube comprised of synthetic materials, is contained inside a tiny catheter. Using a guide wire, the catheter is introduced into the common femoral artery under fluoroscopic guidance and advanced to the area of repair within the common iliac artery. Once the IBD is in place, it is deployed within the common iliac artery at the aneurysm site, where it

expands and adheres to the artery wall. The proximal end of the stent opens to the common iliac artery and the distal end opens and extends into the external iliac artery.

The body of the main IBD contains a branched opening to which an extension IBD is connected. The extension IBD is introduced via a second catheter through the femoral artery and advanced until it reaches the inside of the stationary main IBD. Once inside the lumen of the main IBD, the catheter containing the extension device is threaded through the branched opening and downward into the internal iliac artery, where it expands and remains stationary against the vessel wall. Once connected, the main IBD and the extension IBD form an “upside-down” Y-shaped device that extends from the common iliac artery into the external and internal iliac arteries.

Summary of Evidence

The clinical literature, including small scale studies, suggests that endovascular repair of isolated iliac artery aneurysms via bifurcation technology is a safe, effective and a technically feasible alternative to open surgical repair in individuals whose anatomy is appropriate. Studies comparing outcomes for open and endovascular repair of isolated iliac artery aneurysms reveal favorable outcomes for endovascular repair. However, because isolated iliac artery aneurysms are rare, so are the availability of large scale prospective, randomized trials. Although the literature shows potential benefits of iliac artery bifurcation endovascular repair as a minimally invasive technique, larger scale prospective, randomized trials with longer-term follow-up are necessary to confirm safety, sustained durability, and detection of potential late complications. The evidence is insufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to individuals and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms. The following is a summary of the key literature to date.

Van der Veen et al (2026) looked at the five-year outcomes of the IceBERG study, an international study that took place in the Netherlands, Italy, and New Zealand. This current study was an investigator-initiated, international, real-world, postmarket, multicenter, prospective cohort study, enrolling patients with an indication for elective treatment of an (aorto)iliac aneurysm, involving the common iliac artery, using the GORE EXCLUDER Iliac Branch Endoprosthesis (IBE). Technical and clinical outcomes were collected through the 5-year follow-up, together with questionnaire data. 100 individuals were enrolled and 69 completed the 5-year follow-up. The 5-year freedom from all-cause and aneurysm-related mortality were 82.9% and 96.0%, respectively. The 5-year primary patency of the hypogastric artery was 84.0%. The median abdominal aortic aneurysm and common iliac artery diameters decreased significantly between baseline and 5-year follow-up (-8.0 mm [P = .001] and -6.8

mm [$P < .001$], respectively). One type Ib and one type Ic endoleak were detected between 2 and 5 years of follow-up and were successfully treated. Two type III endoleaks were discovered during follow-up. There were no significant differences in the occurrence nor severity of intermittent claudication between baseline and 5-year follow-up. The outcomes on the International Index of Erectile Function-5 questionnaire on erectile dysfunction showed a significant decrease between baseline (median, 12.5; interquartile range, 3.0-20.0) and 5 years follow-up (median, 4.0; interquartile range, 1.0-16.0; $P = .001$). The EuroQol Five Dimensions 3-Level and Walking Impairment Questionnaire showed no differences between baseline and the 5-year follow-up. Limitations included a 13% loss to follow-up and incomplete questionnaire data in some cases. The authors concluded that the study supports the continued use of the GORE EXCLUDER IBE for the treatment of aortoiliac aneurysms, demonstrating durable long-term outcomes in terms of vessel patency, sac remodeling, and overall clinical performance. They stated that although these findings are encouraging, long-term surveillance remains important to ensure sustained durability and to detect potential late complications.

Turchino et al (2023) assessed the safety and effectiveness of 3 different commercial iliac branch devices (IBDs): the Zenith Branch Iliac Endovascular Graft; the Gore Excluder Iliac Branch System and the E-liac Stent Graft System for the treatment of aorto-iliac or iliac aneurysms. From January 2017 to February 2020, a retrospective reviewed was conducted on a total of 96 patients. Primary endpoint was IBD instability rate at 24 months. Secondary endpoints included onset of any endoleaks, buttock claudication, IBD-related reintervention and all-death rates, postoperative acute kidney, and changes in maximum diameter from baseline of the aortic aneurysmal sac. They found that at 24 months, the branch instability rate was similar among the 3 IBDs employed [Jotec 1/24 (4.1%), Gore 1/12 (8.3%), Cook 6/47 (12.7%), P -value = 0.502]. Also, no statistical difference in terms of branch occlusion and branch-related endoleaks was observed. The Jotec group showed a significant decrease in maximum diameter from the baseline of the aortic aneurysmal sac when compared to the Gore group alone. No other differences were found relevant to the onset of any endoleaks, reinterventions, and all-death rates. At 24 months, the Kaplan–Meier estimate of survival freedom from any branch instability was 95.8%, 91.6%, and 86.8% for Jotec, Gore and Cook groups, respectively. They found the use of IBDs represents a safe method for preserving patency of the IIA during treatment of aorto-iliac or iliac aneurysms providing a low rate of IBD instability.

Attisiani et al (2023) performed a retrospective, observational cohort study looking at the clinical outcomes and performed a macro-costing evaluation of endovascular aortic repair (EVAR) for aorto-iliac aneurysms. Individuals with iliac artery involvement treated with EVAR between January 1st, 2014 and December 31st, 2021 were included. Inclusionary criteria were intact aneurysm, elective EVAR with at least 1 hypogastric artery (HA) treatment, use of bifurcated endograft (EG), and at least 6 months of follow-up. Primary outcomes were overall survival, freedom from aneurysm-related mortality (ARM), freedom from EVAR-related reintervention, and overall EVAR(procedure)-related costs. 122 individuals were included in the study with 119 (97.5%) male and 3 (2.5%) female. Median age was 76 years. Overall, 107 (87.7%) patients had both HAs preserved according to following strategy: 45 (36.9%) with flared limbs, 13 (10.6%) with bilateral branched device, and 49 (40.2%) with a combination of flared limb on 1 side and branched device on the contralateral side. Bilateral overstenting was performed in 15 (12.3) individuals. Estimated overall survival was not different between groups of EVAR (Log-rank, $P = 0.561$). There was only 1 (0.8%) ARM ascertained during the follow-up. Estimated freedom from EVAR-related reintervention was not different among groups (Log-

rank, $P = 0.464$). During the follow-up, 9 (7.4%) patients developed buttock claudication (Society for Vascular Surgery (SVS) grade 1, $n = 4$, SVS grade 2, $n = 5$), more frequently in HA overstenting (hazard ratio (HR): 3.6; 95% confidence intervals (CIs): 0.96-13.5, $P = 0.058$). When all costs were included, branched EVAR still carried the highest burden ($P = 0.001$) in comparison with the mixed subgroup, the overstenting subgroup, and the flared limbs subgroup. The authors concluded that major aortic-related outcomes and pelvic ischemic syndromes were acceptably low in all different types of EVAR techniques for aorto-iliac aneurysms, with equally excellent freedom from ARM and that costs were significantly higher in patients receiving branched device.

Cao et al (2022) performed a systematic review and meta-analysis of the clinical effectiveness and safety of unilateral versus bilateral iliac branch devices (IBD) for aortoiliac and iliac artery aneurysms. They reviewed the literature for outcomes of IBDs in aortoiliac or isolated iliac artery aneurysms between May 2006 and December 2020. Forty-five studies with a total of 2736 patients undergoing unilateral or bilateral IBDs met inclusion criteria and were included in the analysis. The pooled technical success rate of IBDs was 98.0% (confidence interval [CI]: 97.3%-98.7%). After IBD treatment, the 30-day mortality rate was 0.4% (CI: 0.07%-0.70%); 30-day patency was 98.4% (CI: 97.7%-99.0%); buttock claudication developed in 1.84% (CI: 1.26%-2.41%); and endoleak occurred in 11.9% (CI: 9.2%-14.7%) and reintervention in 7.6% (CI: 5.65%-9.58%). Furthermore, in patients with bilateral iliac artery involvement, the pooled estimate rates of buttock claudication were 0.7% in the bilateral IBD group, 7.9% in unilateral IBD with contralateral IIA embolization patients, and 33.8% in bilateral IIA embolization/coverage patients, which were statistically significant among the three groups. Sexual dysfunction was 5.0% in the bilateral IIA occlusion group, which was significantly higher than that in IBD groups. Limitations included the fact that retrospective studies were included in the review, there were variable sample sizes and follow-up periods, and data gathered was not fully complete as not all studies reported the outcomes of interest. The authors concluded that use of IBDs in the treatment of aortoiliac or isolated iliac artery aneurysms is associated with high technical success rates as well as low incidences of pelvic ischemia. The risk of postoperative buttock claudication can be further decreased with both IIA preservation if patients are anatomically suitable for bilateral IBDs.

Choi et al (2021) evaluated risk factors affecting occlusion among patients who underwent iliac limb stent-graft extension to the external iliac artery. They compared occluded limbs with patent limbs during the follow-up period of iliac limb stent grafting to the external iliac artery using variables, including anatomical values, demographics, and other factors. From 2007 to 2016, 766 iliac limbs from 383 participants who underwent endovascular abdominal aneurysm repair were initially included in their analysis. Among them, 134 iliac limbs underwent limb extension to the external iliac artery. The limb extension was a significant risk factor for occlusion (hazard ratio = 6.34, $P < 0.001$). Occlusion occurred in 10 participants who underwent iliac limb extension. The size of common iliac artery was associated with occlusion. The most significant factor was iliac bifurcation diameter (patent vs. occluded limbs, 21.6 ± 7.6 vs. 27.5 ± 9.5 mm, $P = 0.005$). Subgroup analysis revealed that the common iliac artery of the early occlusion subgroup was generally more tortuous (1.16 ± 0.33 vs. 1.47 ± 0.25 , $P = 0.091$) and longer (53 ± 24 vs. 74 ± 9 , $P = 0.01$) than those of the patent limb group. In addition, the external iliac artery diameters of the late occlusion subgroup were narrower than those of the patent limb group (10.9 ± 1.6 mm vs. 9.1 ± 0.8 mm, $P = 0.011$). Using the log-rank test, those individuals with an external iliac artery diameter narrower than 10.1 mm had a higher risk for late limb occlusion (log-rank $\chi^2 = 5.73$, $P = 0.017$) and the patients who did not take at least a single antiplatelet agent had a significantly higher chance of limb occlusion (log-rank $\chi^2 =$

11.029, $P = 0.001$). In addition, the patients who did not take a statin had a higher risk for late limb occlusion (log-rank $\chi^2 = 7.41$, $P = 0.007$). Authors concluded that among patients who underwent endovascular abdominal aneurysm repair with iliac limb extension, the common iliac artery length affected early limb occlusion and predisposed patients to vessel injury or stent-graft kinking, and there was the possibility that common iliac artery tortuosity was associated with a higher risk. The late occlusion subgroup had narrower external iliac artery than the patent limb group.

Mendes et al (2019) compared perioperative outcomes of individuals with iliac aneurysms treated by open surgery versus endovascular repair with iliac branch endoprosthesis. Treatment of common and internal iliac aneurysms is usually done by open surgery. The study was a retrospective, single-center review of individuals who were treated for aortoiliac or isolated common and/or internal iliac artery aneurysms from 2014 to 2017. Patients with connective tissue disorders, infected grafts, or thoracoabdominal aneurysms were excluded. Primary outcomes were perioperative mortality, length of hospital (LOS) and intensive care unit (ICU) stay, estimated blood loss, need for red blood cell transfusion (RBC), and perioperative reinterventions. Sixty-seven patients (96% male) were treated with OS ($n = 25$, mean age 68 ± 8 years) or IBE ($n = 42$, mean age 73 ± 8 years; $P = 0.02$) with 1 symptomatic patient in each group. Perioperative mortality occurred in 1 patient in the OS group (4%), with no mortality in the IBE group ($P = 0.37$). Total LOS and ICU stay was higher for OS compared to IBE (total stay 7.5 ± 3.4 vs. 1.7 ± 1.4 days for IBE, $P < 0.0001$ and ICU LOS 3.3 ± 2.1 vs. 0.1 ± 0.4 days, $P < 0.0001$). Estimated blood loss was higher for patients undergoing OS ($4,732 \pm 2,540$ mL) compared to patients treated with IBE (263 ± 451 mL, $P < 0.0001$), resulting in higher RBC transfusion requirements (1.5 ± 2.4 vs. 0.2 ± 0.8 units, $P = 0.001$). Five patients in the OS group had early procedure-related reinterventions, while 2 patients in the IBE group required reintervention for access site complications (20% vs. 4.7%, $P = 0.09$). The authors concluded that endovascular repair of iliac aneurysms with IBE is feasible and is associated with lower blood loss, LOS and ICU stay and had lower RBC transfusion requirements. However, cost analysis and long-term follow-up will be needed to define the value of this modality for iliac artery aneurysm repair.

Ongoing Clinical Trials

An online search of ClinicalTrials.gov identified clinical trials in progress.

Table 1. Key Clinical Trials

Clinical Trial Identifier	Purpose	Number of Participants	Completion Date
NCT02345005	A prospective, nonrandomized, multicenter single-arm study regarding the safety and efficacy of GORE EXCLUDER® iliac branch endoprosthesis in subjects with common iliac artery aneurysms or aorto-iliac aneurysms. The primary endpoints for effectiveness will be measured at 1 month, 6 months, 1 year and then yearly up to 5 years in order to collect long-term clinical data.	100	July 2025 – Completed; No posted results

NCT: National clinical trial

Regulatory Status

The FDA has approved bifurcated devices indicated for endovascular repair of abdominal aortic aneurysm repair with extension grafts to the common iliac arteries, but these devices are

not indicated for aneurysms isolated to the common iliac arteries that extend to the internal and external iliac artery branches.

The FDA (2016) approved the Gore® Excluder® Iliac Branch Endoprosthesis (IBE device). This device is indicated for use with the Gore® Excluder® AAA Endoprosthesis to isolate the common iliac artery from systemic blood flow and preserve blood flow in the external iliac and internal iliac arteries in patients with a common iliac or aortoiliac aneurysm, who have appropriate anatomy, including:

- Adequate iliac/femoral access
- Minimum common iliac diameter of 17 mm at the proximal implantation zone of the IBE
- External iliac artery treatment diameter range of 6.5 – 25 mm and seal zone length of at least 10 mm
- Internal iliac artery treatment diameter range of 6.5 – 13.5 mm and seal zone length of at least 10 mm; **AND**
- Adequate length from the lowest major renal artery to the internal iliac artery to accommodate the total endoprosthesis length, calculated by adding the minimum lengths of required components, taking into account appropriate overlaps between components.

In 2020, the FDA recalled the Gore Excluder Iliac Branch Endoprosthesis related to reports of leading end catheter component separations. Recall event ID 84533. Terminated on August 9, 2022.

The Zenith AAA Endovascular Graft and H&L-B One-Shot Introduction system Bifurcated Main System received FDA PMA approval in 2003. This device is indicated for the endovascular treatment of patients with abdominal aortic or aorto-iliac aneurysms. In March, 2026 the FDA approved changes to the materials used to manufacture the suture for the Zenith Flex AAA Endovascular System and Zenith Iliac Branch.

Product code: MIH

Government Regulations

National

Medicare has no National Coverage Determination on this topic.

Local

Non-coronary Vascular Stents (L35998) Effective 10/1/15; Revision 10/30/25

Percutaneous Transluminal Angioplasty (PTA) and stenting of vessels is covered only when all of the following conditions are met:

- The patient has undergone prior thorough medical evaluation and management of symptoms. See below under specific categories for guidelines on medical evaluation and management recommendations.
- Surgical intervention would otherwise be considered as an alternative treatment for the patient.
- A stent may be placed as a planned adjunct to PTA rather than in response to a suboptimal or failed PTA (so-called primary stent deployment). Primary stenting is justified for situations where PTA alone is not expected to provide a durable result, such as: arterial or venous occlusions that carry a high risk for distal embolization or rapid recurrence OR occlusive lesions known to be unfavorable for PTA alone, such as significantly calcified lesions, eccentric lesions, lesions related to external compression (e.g., May-Thurner

syndrome and malignant compression of the superior vena cava) or ostial renal artery stenosis.

Coverage for non-coronary vascular stents depends on the use of an FDA approved stent. Several different stents are currently used in the medical community. Each device has specific indications described by the FDA for approved market uses. Stent placement is covered by Medicare only when an FDA approved stent is:

- Used for the FDA approved indications, **OR**
- Used for the above indications when supported by peer-reviewed medical literature.

(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

N/A

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 3/25/26, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/1/11	3/17/11	3/3/11	Joint policy established
7/1/12	4/10/12	5/18/12	Routine maintenance
1/1/14	10/17/13	10/25/13	Routine maintenance
5/1/15	2/17/15	2/27/15	Routine maintenance
7/1/16	4/19/16	4/19/16	Routine maintenance
7/1/17	4/18/17	4/18/17	• Routine maintenance • Added FDA approval for Gore Excluder
7/1/18	4/17/18	4/17/18	• Routine maintenance • 0254T revised; 0255T deleted
7/1/19	4/16/19		Routine maintenance
7/1/20	4/14/20		• Routine maintenance • 0254T replaced with 34717 and 34718
7/1/21	4/20/21		Routine maintenance
7/1/22	4/19/22		Routine maintenance
7/1/23	4/18/23		Routine maintenance (slp) Vendor managed: N/A
7/1/24	4/16/24		Routine maintenance (slp) Vendor managed: N/A
7/1/25	4/15/25		Routine maintenance (slp) Vendor managed: N/A
7/1/26	4/21/26		Routine maintenance (slp/mk) Vendor managed: N/A Policy reformatted MPS updated to current language

Next Review Date: 2nd Qtr, 2027

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: ENDOVASCULAR REPAIR OF ILIAC ARTERY BIFURCATION

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinurance covered if primary Medicare covers the service.

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.