DRAFT Medical Coverage Policy | Miscellaneous
Vascular Embolization Procedures

EFFECTIVE DATE: 10|01|2023
POLICY LAST UPDATED: 06|22|2023

OVERVIEW

Vascular embolization procedures allow blockage of blood vessels without invasive surgery. Vascular embolization can be used to stop arterial bleeding and can also be used to block blood vessels for other reasons, such as to treat tumors, shrink vascular malformations, or re-direct flow.

This policy does not address vascular embolization for the liver or uterine fibroids. Please refer to the Prior Authorization via Web-Based Tool for Procedures policy, listed in the Related Policies section.

MEDICAL CRITERIA

The following procedures are considered medically necessary for both Medicare Advantage Plans and Commercial Products:

1. Coil embolization in the treatment of arterio-venous malformations (AVMs)/aneurysm and splenic artery aneurysm
2. Coil embolization of gastric varices
3. Endovascular embolization for an extracranial AVM or fistula
4. Geniculate artery embolization for knee hemarthrosis following total knee arthroplasty if member has failed conservative therapies (e.g., ice, immobilization, compression, saline lavage, corticosteroid instillation, and selective COX-2 inhibitors); and demonstrated synovial hyper-vascularity on angiography
5. Splenic artery embolization for the treatment of hyper-splenism secondary to hepatic cirrhosis as an alternative to splenectomy
6. Transcatheter arterial embolization for non-variceal upper gastrointestinal bleeding
7. Vascular embolization for the treatment of type I/type II endovascular leak.
8. Pre-operative embolization of skull base meningiomas
9. Renal artery embolization/angioinfarction, as a pre-operative adjunct to nephrectomy, in the treatment of persons with large, hypervascular renal cell carcinomas
10. Selective arterial embolization for the treatment of giant cell tumor
11. Tumor embolization or pre-operative tumor embolization to reduce intra-operative bleeding prior to surgical resection in the treatment of hypervascular tumors or metastases from hypervascular tumors
12. TACE or TAE as therapeutic interventions for actively bleeding malignant or nonmalignant lesions.

For procedures or conditions not addressed in this policy, please refer to the Medical Necessity policy, listed in the Related Policies section.

PRIOR AUTHORIZATION

Prior authorization is recommended for Medicare Advantage Plans and is required for Commercial Products via the web-based tool for participating providers. Refer to the Related Policies section, below.

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

The following procedures are considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine the effects of the technology on outcomes:

1. Embolization for locoregional treatment of metastatic pancreatic cancer

2. Endovascular embolization in the treatment of spinal dural arteriovenous fistula
3. Genicular artery embolization for the treatment of osteoarthritis related knee pain
4. HydroPearl microspheres for the treatment of AVMs in the lower extremity
5. Bariatric arterial embolization to treat obesity
6. Middle meningeal artery embolization for chronic subdural hematoma
7. Pre-operative embolization for carotid body tumor resection
8. Pre-operative embolization of the inferior mesenteric artery to reduce the rate of type II endoleak following endovascular abdominal aortic aneurysm repair.
9. Prostatic arterial embolization for benign prostatic hyperplasia.

For procedures or conditions not addressed in this policy, please refer to the Medical Necessity policy, listed in the Related Policies section.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage

BACKGROUND

Vascular embolization procedures allow blockage of blood vessels without invasive surgery. Vascular embolization can be used to stop arterial bleeding and can also be used to block blood vessels for other reasons, such as to treat tumors, shrink vascular malformations, or re-direct flow.

Coil Embolization for the Treatment of Arterio-Venous Malformations (AVMs) / Aneurysm

Koebbe and colleagues (2006) reviewed the clinical and angiographic outcomes for 1,307 patients undergoing endovascular treatment of intracranial aneurysms. This analysis focused on posterior circulation and middle cerebral artery aneurysms, as well as cases of stent-assisted coil embolization. The authors concluded that long-term studies evaluating experience with aneurysm coil embolization during the past decade indicated that this is a safe and durable treatment method. The introduction of stent-assist techniques has improved the management of wide-neck aneurysms. Future technology developments will likely improve the durability of endovascular treatment further by delivering bioactive agents that promote aneurysm thrombosis beyond the coil mass alone. It is clear that endovascular therapy of both ruptured and un-ruptured aneurysms is becoming a mainstay of practice in this patient population. Although not replacing open surgery, the continued improvements have allowed aneurysms that previously were amenable only to open clip ligation to be treated safely with durable long term outcomes. Lanzino et al (2013) performed a meta-analysis of prospective controlled trials of clipping versus coil embolization for ruptured aneurysms. The authors concluded that on the basis of the analysis of the 3 high-quality prospective controlled trials available, there is strong evidence to indicate that endovascular coil embolization is associated with better outcomes compared with surgical clipping in patients amenable to either therapeutic strategy. The evidence is sufficient to determine the effects of the technology on health outcomes.

Gastric Variceal Embolization

Bazarbashi et al (2020) noted that gastric variceal (GV) bleeding is a feared complication of cirrhosis. Traditional endoscopic treatment with cyanoacrylate (CYA) injection can be challenging. Alternatively, endoscopic ultrasound (EUS)-guided delivery of hemostatic coils has shown high therapeutic success without the complications profile of CYA alone. These researchers compared the clinical outcomes of EUS-guided coil embolization with endoscopic CYA injection for the treatment of GV. Technical success was 100 % for EUS coil therapy versus 96.7 % for CYA injection ($p = 1.0$). Complication rates were 10 % in the EUS coil group versus 20% in the CYA group ($p = 0.65$). At 9 months, no EUS coil patient had rebled compared with 38 % of the CYA group. The authors concluded that compared with CYA, EUS-guided coil injection appeared superior for the treatment of GV and should be considered initial endoscopic treatment of choice in centers with interventional EUS expertise.

A review on the management of gastrointestinal varices (Boregowda, et al., 2019) reported that "the recent emergence of endoscopic ultrasound guided glue and coil injection in treating gastric varices has shown a lower bleeding rate, transfusion requirements, and mortality when compared to glue injection. When EUS guided coil embolization alone was compared with EUS guided glue injection, both had similar hemostasis rates, but coil embolization had fewer adverse events and required a fewer number of endoscopies [citing Romero-Castro, et al., 2013]. When these two techniques were combined (glue + coil), the mean number of coils used, mean volume of glue used, and the recurrence rate was lower compared to either of them alone [citing Bhat, et al., 2016]." The evidence is sufficient to determine the effects of the technology on health outcomes.

Endovascular embolization for an extracranial AVM or fistula
Based on the clinical evidence, endovascular embolization is an acceptable treatment modality for an extra-cranial AVM or fistula. The evidence is sufficient to determine the effects of the technology on health outcomes.

Geniculate Artery Embolization for Knee Hemarthrosis Following Total Knee Arthroplasty (TKA)
In a case-series study, Bagla and co-workers (2013) a total of 5 patients who underwent previous TKA presented with spontaneous hemarthrosis received selective arterial embolization with spherical embolic particles. The authors concluded that selective geniculate artery embolization with spherical embolic particles was an effective treatment for spontaneous recurrent hemarthrosis of the knee.

Weidner and colleagues (2015) reported the results for 13 patients with spontaneous recurrent hemarthrosis after TKA treated with arterial embolization. Geniculate arterial embolization led to resolution of hemarthrosis in 12 of 13 patients (92.3 %). The 1 clinical failure likely represented a case of misdiagnosed peri-prosthetic joint infection; 2 patients experienced transient cutaneous ischemia related to distal particulate embolization that resolved spontaneously. The authors concluded that selective geniculate arterial embolization was a safe and effective treatment for recurrent hemarthrosis after TKA.

van Baardewijk et al (2018) conducted a study and concluded that embolization of the geniculate arteries in was a safe and effective treatment of recurrent spontaneous hemarthrosis following TKA. Although these researchers had performed a substantial number of re-interventions, results of this study showed that this procedure could be safely repeated without adverse events. They stated that these findings indicated that embolization could possibly be the treatment of choice when conservative measures failed and can be repeated in the event of recurrent or persistent symptoms. The evidence is sufficient to determine the effects of the technology on health outcomes.

Splenic Artery Embolization for the Treatment of Hyper-Splenism Secondary to Hepatic Cirrhosis
Although the individual study numbers are small, the total studied over several years is significant and the evidence has demonstrated that coil embolization in the treatment of splenic artery aneurysms is safe and effective and may induce less morbidity than open surgery, in particular by preserving the spleen. Leffroy et al (2008) evaluated the outcomes of endovascular treatment of splenic artery aneurysms and pseudoaneurysms. The authors concluded that transcatheter embolization of splenic artery aneurysms/pseudoaneurysms is safe and effective and may induce less morbidity than open surgery, in particular by preserving the spleen. Yamamoto et al (2008) published the findings of a small study evaluating the clinical results and technical problems of transcatheter coil embolization for splenic artery aneurysm. According to the authors, transcatheter coil embolization should be the initial treatment of choice for splenic artery aneurysm. The evidence is sufficient to determine the effects of the technology on health outcomes.

Transcatheter Arterial Embolization for Non-Variceal Upper Gastro-Intestinal Bleeding
Tarasconi and colleagues (2019) noted that very few patients with nonvariceal upper gastro-intestinal (GI) bleeding fail endoscopic hemostasis (refractory NVUGIB). This subset of patients poses a clinical dilemma:

should they be operated on or referred to transcatheter arterial embolization (TAE)? These researchers performed a systematic review of the literature and carried out a meta-analysis of studies that directly compared TAE and surgery in patients with refractory NVUGIB. The authors concluded that the findings of this study showed that TAE was a safe and effective procedure; when compared to surgery; TAE exhibited a higher re-bleeding rate, but this tendency did not affect the clinical outcome as shown by the comparison of mortality rates (slight drift toward lower mortality for patients undergoing TAE). The present study suggested that TAE could be a viable option for the 1st-line therapy of refractory NVUGIB and set the foundation for the design of future randomized clinical trials. Another issue that needs to be addressed in the future is the best therapeutic option for refractory NVUGIB in hemodynamically unstable patients. The evidence is sufficient to determine the effects of the technology on health outcomes.

Vascular embolization for the treatment of type I/type II endovascular leak.
Clinical evidence shows that fibrin glue sac embolization to eliminate type I endoleak after endovascular aneurysm repair (EVAR) yielded excellent results, effectively and durably resolving the leaks. Balloon occlusion of the proximal aorta must be done during glue injection to block proximal flow and facilitate formation of a structured fibrin clot. Sidloff et al (2013) assessed the risk of rupture, and determined the benefits of intervention for the treatment of type II endoleak after EVAR. Translumbar embolization had a higher clinical success rate that transarterial embolization (81 versus 62.5 % respectively; p = 0.024) and fewer recurrent endoleaks were reported (19 versus 35.8%; p = 0·036), with a lower risk of complications. Transarterial embolization after EVAR had a higher rate of complications (9.2 % versus none; p = 0.043).

Khaja et al (2014) reported their experience with the use of an ethylene vinyl alcohol copolymer (Onyx) in an off-label fashion for the treatment of type II endoleak after thoracic endovascular aneurysm repair (TEVAR) and EVAR. The authors concluded that Onyx with or without coil/glue/Amplatzer plug embolization is safe and useful in the treatment of type II endoleak after thoracic endovascular aneurysm repair (TEVAR) and EVAR. However, long-term clinical and imaging follow-up is needed for early detection and management of recurrence of the primary endoleak or the development of new, secondary endoleaks or enlargement of the aneurysm sac. Eberhardt et al (2014) also concluded that transcatheter embolization of type I endoleaks using Onyx is a simple, safe, and sustainable treatment option with a high primary success rate for cases in which stent-graft extension is not possible. Moreover, they stated that the benefit of additional coil embolization remains uncertain.

Ishibashi et al (2014) evaluated the late events and mid-term results after EVAR and concluded the mid-term results of EVAR were excellent with a low rate of aneurysm-related deaths, although there were relatively high aneurysm-related event rates. Sac re-enlargement from type II endoleaks was the most common major issue at the mid-term follow-up. The evidence is insufficient to determine the effects of the technology on health outcomes.

According to Chaer (2015), Complications of Endovascular Abdominal Aortic Repair, the approach to the repair of type II endoleaks is most commonly endovascular, consisting of transarterial embolization of the feeding vessels or translumbar embolization of the aneurysm sac. In the systematic review, there were 393 interventions for 1515 type II endoleaks, of which 71.5 percent were technically successful. Among studies that reported outcomes of intervention, translumbar embolization (n = 57) had a higher initial success rate (81 versus 63 per cent) and fewer recurrent endoleaks (19 versus 36 percent) compared with transarterial embolization (n = 120)". The evidence is sufficient to determine the effects of the technology on health outcomes.

In a systematic review and meta-analysis, Zhang and colleagues (2021) examined the effect of preventive collateral arteries embolization before endovascular aneurysm repair (EVAR) to reduce type II endoleaks, aneurysm enlargement, and re-interventions. These researchers carried out a comprehensive search to identify articles related to preventive collateral arteries embolization before EVAR. A total of 12 relevant studies, including 11 retrospective studies and 1 RCT, were identified and fulfilled the specified inclusion criteria. A

total of 1,706 patients in 11 studies were involved in the meta-analysis. The authors concluded that collateral arteries embolization is a promising approach to prevent the occurrence of type II endoleaks, sac enlargement, and re-intervention. Moreover, these researchers stated that high-quality studies are needed to provide stronger evidence-based medical suggestions regarding the effectiveness of this approach. The evidence is insufficient to determine the effects of the technology on health outcomes.

Pre-Operative Embolization of Skull Base Meningiomas
Ilyas and colleagues (2019) stated that neoadjuvant endovascular pre-operative embolization for appropriately selected skull base meningiomas may facilitate surgical resection, thus, potentially decreasing operative morbidity. The authors also concluded that future comparative analyses are needed to determine the benefits of pre-operative EMB of skull base meningiomas with respect to extent of resection, operative duration, operative blood loss, and surgical morbidity. The evidence is sufficient to determine the effects of the technology on health outcomes.

Renal Artery Embolization
Based on the clinical evidence, renal artery embolization/angioinfarction, as a pre-operative adjunct to nephrectomy, is an acceptable alternative in the treatment of patients with large, hypervascular renal cell carcinomas. The evidence is sufficient to determine the effects of the technology on health outcomes.

Selective Arterial Embolization for the Treatment of Giant Cell Tumor
Guidelines on giant cell tumor of the bone from the National Comprehensive Cancer Network (2018) state that "[s]erial arterial embolizations have been shown to be effective in the management of patients with giant cell tumors of the extremities, especially for tumors with large cortical defects and joint involvement and for those with large giant cell tumors of the sacrum." The evidence is sufficient to determine the effects of the technology on health outcomes.

Tumor Embolization of Hypervascular Tumors
A hypervascular tumor is a tumor characterized by an abnormal increase in blood vessel growth in the area. These vessels feed the tumor cells, and may be characterized by abnormal connections between veins and arteries. Hypervascular tumors may be benign (meningiomas, osteoblastomas, chondromas), malignant (renal cell carcinoma, thyroid carcinoma, hepatocellular carcinoma, glomus tumor) or metastatic tumors from these primary sites (list is not all-inclusive). Tumor embolization or pre-operative tumor embolization to reduce intraoperative bleeding prior to surgical resection may be considered medically necessary in the treatment of hypervascular tumors or metastases from hypervascular tumors. The evidence is sufficient to determine the effects of the technology on health outcomes.

According to available literature, TACE may be indicated for symptomatic treatment of functional neuroendocrine cancers (i.e., carcinoid tumors and pancreatic endocrine tumors) involving the liver, in persons with adequate hepatic function (bilirubin less than 2 mg/dL, absence of ascites; no portal vein occlusion; and tumor involvement of less than 65 % of liver). For carcinoid tumors, TACE is indicated only in persons who have failed systemic therapy with octreotide to control carcinoid syndrome (e.g., debilitating flushing, wheezing and diarrhea). The safety and effectiveness of more than 4 TACE procedures is unknown.

Embolization for Locoregional Treatment of Metastatic Pancreatic Cancer
Timmer and colleagues (2021) stated that the prognosis of metastatic pancreatic ductal adenocarcinoma (mPDAC) remains universally poor, requiring new and innovative therapeutic approaches. In a subset of oligometastatic PDAC patients, locoregional therapy, in addition to systemic chemotherapy, may improve survival. In a systematic review, these researchers examined available evidence on locoregional treatments for mPDAC. They carried out a systematic literature search on locoregional techniques, including resection, ablation and embolization, for mPDAC with a focus on hepatic and pulmonary metastases. A total of 59 studies were identified, including 63,453 patients. The authors concluded that although the exact additive value of locoregional treatments for mPDAC patients could not be distillated from the results, locoregional

primary pancreatic and metastatic treatment appeared beneficial for a highly selected group of oligometastatic PDAC patients. Moreover, these researchers stated that for definite recommendations, large, prospective, well-designed RCTs with strict inclusion and exclusion criteria are needed to validate these findings; locoregional treatment for mPDAC should not be provided outside the context of an experimental trial. The evidence is insufficient to determine the effects of the technology on health outcomes.

Endovascular Embolization in the Treatment of Spinal Dural Arteriovenous Fistula
In a meta-analysis, Yuan et al (2022) compared the effectiveness of microsurgery and endovascular embolization in the treatment of spinal dural arteriovenous fistula (SDAVF). These researchers carried out a systematic review to retrieve all relevant studies regarding surgical treatment or endovascular embolization of SDAVF. A total of 46 studies involving 1,958 cases of SDAVF were included, in which 935 cases were treated by microsurgery and 1,023 cases were treated by endovascular embolization. The results of meta-analysis showed that the incidence of early surgical failure was lower than that of endovascular embolization and the long term recurrence was also lower than that of endovascular embolization. The improvement of neurological function in the surgical patients was significantly higher than that in the patients treated with endovascular embolization. There was no significant difference in the occurrence of complications between the 2 groups. In the cases of endovascular embolization, the risk of treatment failure or recurrence was higher with Onyx glue than with n-butyl 2-cyanoacrylate (NBCA), and the difference was statistically significant. The authors concluded that although the treatment of dural arteriovenous fistulas by intra-vascular embolization has been widely used, the clinical effect of microsurgery was still better than that of endovascular embolization. Moreover, these researchers stated that large scale and high-quality randomized controlled trials are needed to validate the safety and effectiveness of endovascular treatment in SDAVF patients. The evidence is insufficient to determine the effects of the technology on health outcomes.

Genicular Artery Embolization for the Treatment of Osteoarthritis Related Knee Pain
Torkian and colleagues (2021) noted that genicular artery embolization (GAE) is an innovative technique that has been examined as a supplementary therapy for chronic pain secondary to knee osteoarthritis (OA). In a systematic review and meta-analysis, researchers examined the available evidence on the safety and effectiveness of GAE for OA-related knee pain. They carried out a systematic literature search to identify studies related to knee OA treated with GAE. Therapeutic agents were categorized as embozene, imipenem/cilastatin, resorbable microspheres, and polyvinyl alcohol. Of 379 initially inspected studies, 11 (n = 225 patients; 268 knees) were included in the final review. The quality of the studies was fair in 8 and poor in 3-categorized according to the National Institutes of Health quality assessment tool. No significant difference between embolic agents was observed with regard to post-GAE pain reduction. No severe or life-threatening complications were reported. The authors concluded that this systematic review revealed that mild-to-moderate OA treated by GAE using different embolic particles could generally be considered safe, with no reported serious complications. The procedure resulted in significant and sustained pain improvement as well as better functional status in the studies reviewed. However, because of the paucity of high-quality trials, further investigation is needed to examine GAE's long-term outcomes, its comparative efficacy with other treatment modalities, and its role in the therapeutic approach.

In a systematic review, Casadaban and associates (2021) examined the available evidence on GAE for OA-related knee pain. A total of 3 single-arm studies were included from an initial search. The authors concluded that limited single-arm studies reported that GAE is promising for treating OA-related pain. Most treatments performed for mild-to-moderate OA demonstrated durable clinical responses from 6 months to 4 years; and limited data for severe OA suggested a nondurable response. These researchers stated that future studies should be standardized to facilitate comparison and control for placebo effect. The evidence is insufficient to determine the effects of the technology on health outcomes.

HydroPearl Microspheres for the Treatment of AVMs in the Lower Extremity
Stone (2022) states that "For symptomatic AVFs that fail compression-based therapy, we recommend surgical repair (Grade 1B). Endovascular repair with a covered stent or coil embolization are alternative

treatments for patients who may not tolerate trivial bleeding, have a hostile groin (e.g., prior surgery), or have a prohibitive risk for general anesthesia". Microsphere is not mentioned as a therapeutic option in this review. The evidence is insufficient to determine the effects of the technology on health outcomes.

Bariatric Arterial Embolization to Treat Obesity
Bariatric arterial embolization is proposed weight loss therapy which utilizes surgically induced metabolic changes by targeting the endocrine function of the gastric fundus, to decrease the appetite. Therapy involves injections of embolic microspheres into the gastric arteries to produce localized ischemia. While the procedure is considered less invasive than bariatric surgeries, weight loss does not appear to be as robust when compared to other therapies (Weiss, 2019). The evidence is insufficient to determine the effects of the technology on health outcomes.

Middle Meningeal Artery Embolization for Chronic Subdural Hematoma
Srivatsan and colleagues (2019) stated that chronic subdural hematoma is a very common neurosurgical condition. Although conventional surgical methods, such as burr hole irrigation, have been the mainstay of treatment, middle meningeal artery (MMA) embolization has emerged as a promising adjunctive or alternative treatment. These investigators performed a meta-analysis and systematic review of this topic. The authors concluded that MMA embolization is a promising treatment for chronic subdural hematoma; they stated that future randomized clinical trials are needed.

Ironside and colleagues (2021) noted that mMMA embolization has been proposed as a minimally invasive treatment for chronic sub-dural hematoma (cSDH). In a systematic review and meta-analysis, these researchers compared outcomes after MMA embolization versus conventional management for cSDH. They carried out a systematic review of studies reporting outcomes after MMA embolization for greater than or equal to 3 patients with cSDH were included. A metaanalysis comparing MMA embolization with conventional management was performed. The analysis comprised 20 studies with 1,416 patients, including 718 and 698 patients in the MMA embolization and conventional management cohorts, respectively. Compared with conservative management, MMA embolization was associated with lower rates of cSDH recurrence and surgical rescue. In-hospital complication rates were comparable between the 2 cohorts. The authors concluded that MMA embolization is a promising minimally invasive therapy that may reduce the need for surgical intervention in appropriately selected patients with cSDH. Moreover, these researchers stated that additional prospective studies are needed to examine the long-term durability of MMA embolization, refine eligibility criteria, and establish this endovascular approach as a viable definitive treatment for cSDH. The evidence is insufficient to determine the effects of the technology on health outcomes.

Pre-Operative Embolization for Carotid Body Tumor Resection
Abu-Ghanem and co-workers (2016) stated that there is no consensus on the impact of pre-operative embolization (EMB) on the surgical outcomes of carotid body tumor (CBT) resections. These researchers carried out a systematic review and a meta-analysis to examine the role of preoperative EMB in patients undergoing surgical removal of CBTs. A total of 15 studies with a total number of 470 patients met the inclusion criteria. The results of the meta-analysis showed that there was no significant difference in estimated blood loss (EBL), operative time, length of hospital stay (LOS), or risks of cranial nerve injury, vascular injury, and stroke between the EMB and non-EMB (NEMB) groups. The authors concluded that this systemic review and meta-analysis demonstrated that pre-operative EMB did not confer any operative or post-operative advantage in patients scheduled for CBT surgery.

Cobb and colleagues (2018) noted that CBTs are rare entities for which surgical resection remains the gold standard. Given their hypervascularity, pre-operative EMB is often used; however, controversy exists over whether a benefit is associated. Proponents of EMB argue that it minimizes blood loss and complications. Critics argue that cost and stroke out-weigh benefits. These investigators examined the impact of EMB on outcomes following CBT resection. Patients undergoing CBT resection were identified and were

divided into 2 groups: CBT resection alone (CBTR) and CBT resection with pre-operative arterial EMB (CBETR). A total of 547 patients were identified. Of these, 472 patients underwent CBTR and 75 underwent CBETR. When compared with CBTR, there were no significant differences in mortality for CBETR, cranial nerve injury, and blood loss. Following risk adjustment, CBETR increased the odds of prolonged length of stay. The authors concluded that CBT resection was a relatively rare procedure. The findings of this study demonstrated no benefit of pre-operative tumor EMB.

Texakalidis and associates (2019) stated that there is evidence suggesting that pre-operative selective EMB could reduce blood loss during surgery and decrease the risk of peri-operative complications; however, recent reports have questioned the benefits that pre-operative EMB provides. These investigators examined the impact of pre-operative EMB on CBT surgical resection utilizing Systematic Reviews and Meta-Analyses guidelines. Eligible studies were identified and a total of 25 studies comprising 1,326 patients were included. Patients who received pre-operative EMB had statistically significant lower intra-operative blood loss. Duration of the procedure was statistically significantly shorter in the pre-EMB group than the non-EMB group. There were no differences in the rates of cranial nerve (CN) injuries, stroke, transient ischemic attacks (TIAs) or length of stay between the 2 groups. The authors concluded that patients who received EMB prior to CBT resection had statistically significant lower blood loss and shorter duration of operation; the clinical significance of these differences were unclear. Furthermore, the rates of CN palsy, stroke, TIA, and LOS were similar between patients who had preoperative EMB and those who did not. The evidence is insufficient to determine the effects of the technology on health outcomes.

Prostatic Arterial Embolization for Benign Prostatic Hyperplasia

Prostatic arterial embolization (PAE) is being evaluated as a minimally invasive procedure for benign prostatic hyperplasia that may help improve urinary symptoms caused by an enlarged prostate without the risk of sexual side effects. Using x-ray guidance, interventional radiologists insert a catheter into an artery in the groin or wrist and advanced it to the arteries supplying blood to the prostate gland. Tiny round particles (microspheres) are injected into the arteries, partially blocking the blood flow to the prostate. This procedure is called embolization. Areas of the prostate which are most affected by BPH are deprived of oxygen which results in necrosis of targeted areas. Over months the body's immune system reabsorbs the dead tissue and replaces it with scar tissue which slowly contracts and results in shrinkage of the prostate which alleviates some of the symptoms associated with BPH. Given the strong association between BPH, lower urinary tract symptoms, sexual dysfunction, and the current standard of care (TURP), minimally invasive therapies, including PAE have been evaluated with the intention to increase voiding domains while minimizing adverse sexual effects in men with BPH.

In 2017, Embosphere microspheres (BioSphere Medical, S.A.) was reclassified by the U.S. Food & Drug Administration (FDA) into a Class II device. To classify the Embosphere Microspheres into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. The FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. As a result of this order, immediate marketing of the device, as described in the De Novo request - subject to the general control provisions of the FD&C Act and the special controls identified in the order, was granted.

Indications for use: Embolization of arteriovenous malformation, hypervascular tumors, including symptomatic uterine fibroids, and prostatic arteries for symptomatic benign prostatic hyperplasia (BPH). DEN160040. Product code: NOY

CODING

Medicare Advantage Plans

The following CPT codes are considered medically necessary when the medical criteria, above, are met:

37242 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (eg, congenital or acquired arterial malformations, arteriovenous

malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms) [for embolization of the inferior mesenteric artery]

37243 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction

Commercial Products

The following CPT codes are considered medically necessary when the medical criteria, above, are met:

37242 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (eg, congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms) [for embolization of the inferior mesenteric artery]

37243 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction

RELATED POLICIES

Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations
Medical Necessity
Prior Authorization via Web-Based Tool for Procedures

PUBLISHED

Provider Update, August 2023

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