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Medical Policy Manual

Topic: Percutaneous Angioplasty and Stenting of Veins

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Section: Surgery

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Percutaneous Transluminal Angioplasty (PTA) of the Veins

PTA of the veins is a procedure that has been used as an alternative to open vascular surgery in order to restore blood flow through narrowed veins. Techniques may include balloon angioplasty, laser angioplasty, and stent placement.

Intravascular Stents

Intravascular stents are used as an adjunct to angioplasty to prevent vessel wall collapse. They can be placed via transluminal catheters or placed with catheters during open vascular procedures. Drug-eluting stents are intended to prevent restenosis by reducing the growth of neointimal tissue. A number of different drugs are being evaluated for this use, including paclitaxel and sirolimus. These stents are coated with a mixture of synthetic polymers blended with the drug. A second coat of drug-free polymers is then added to serve as a diffusion barrier, thus allowing the gradual release of drug to the precise site of interest while avoiding systemic side effects.

Iliac Vein Compression Syndrome

Iliac vein compression syndrome is deep vein thrombosis (DVT) that occurs as a result of compression of the left common iliac vein between the overlying right common iliac artery and the body of the fifth

lumbar vertebra. This syndrome is relatively uncommon. If DVT occurs, it is treated with anticoagulation therapy. However, the underlying mechanical compression must be treated with surgery or stent placement. Left untreated it may result in recurrent DVT or postthrombotic syndrome (PTS) characterized by chronic swelling and pain in the affected extremity. Some patients also develop varicosities and stasis ulcers. This condition may also be referred to by other terms including but not limited to May-Thurner syndrome, nonthrombotic iliac vein lesions (NIVL), and Cockett syndrome.

Proximal Upper Extremity Venous Thrombosis

Proximal upper extremity venous thrombosis occurs as a result of mechanical compression of the subclavian vein at the thoracic outlet. The natural history of the disorder is typically one of chronic venous obstruction with development of a painful, swollen extremity. [1,2] Thrombosis may affect the brachiocephalic, subclavian, and/or axillary veins. Typical management of this condition involves thrombolysis and surgical decompression after a variable interval of oral anticoagulation. Venous stent placement may be helpful in maintaining patency of the vein following thoracic outlet decompression surgery that includes first rib resection. This condition may also be referred to by other terms including but not limited to axillary-subclavian venous thrombosis, effort thrombosis, Paget-Schroetter syndrome, or venous thoracic outlet syndrome.

Idiopathic Intracranial Hypertension

Idiopathic intracranial hypertension (IIH) is characterized by elevated intracranial pressure (ICP). The most common symptoms are headache and papilledema. Other symptoms include transient visual obscurations, pulsatile tinnitus, diplopia, and sustained visual loss. Initial evaluation of patients presenting with headache and papilledema consists of CT or MRI scan for possible hydrocephalus or tumor. Occlusion of the venous sinus, particularly the transverse sinus, is considered an uncommon cause of increased ICP. There has been some debate as to whether this occlusion is the cause or the effect of ICP. The hypothesis is that obstruction of venous return decreases venous outflow from the brain which also decreases cerebrospinal fluid (CSF) outflow with subsequent increase in intracranial CSF pressure. Medical treatment includes medications that lower CSF production and/or therapeutic lumbar puncture. Since most patients with IIH are obese, weight loss is commonly recommended. If medical treatment fails to control IIH, surgical treatments include ventriculoperitoneal shunting, optic nerve sheath fenestration (optic nerve decompression), and subtemporal decompression. Angioplasty with stenting has been proposed for maintaining venous sinus patency. IIH may also be referred to as pseudotumor cerebri or benign intracranial hypertension, though these terms are considered inadequate and IIH is the preferred term.

Chronic Cerebrospinal Venous Insufficiency in Multiple Sclerosis

Multiple sclerosis (MS) is generally considered a chronic inflammatory demyelinating disease of the central nervous system which is thought to be triggered by an autoimmune response to myelin. Vascular etiologies (i.e., chronic cerebrospinal venous insufficiency [CCSVI]) had not been actively pursued. There has been renewed interest recently due to preliminary reports suggesting that outflow obstruction of the jugular and/or azygos veins results in abnormal venous drainage from the brain. The hypothesis is that this abnormal draining may cause intracerebral flow disturbance or outflow problems. Those studying this hypothesis have promoted percutaneous transluminal angioplasty (PTA) with or without stenting to treat the CCSVI outflow problems with the goal of reducing MS symptoms by improving venous drainage of the central nervous system. This treatment may also be referred to as the “Liberation Procedure.”

Regulatory Status

While there are several types of stents that are approved by the U.S. Food and Drug Administration (FDA) for improvement of outflow for arteriovenous (A-V) access grafts in hemodialysis patients, and for the creation of intrahepatic shunt connections between the portal venous system and hepatic vein [i.e., transjugular intrahepatic portosystemic shunt (TIPS)], there are currently no stents with FDA approval for use in veins for any other indications.

In May 2012, the FDA issued an alert concerning the potential for adverse events following endovascular interventions to treat chronic cerebrospinal venous insufficiency (CCSVI).[3] Reports of adverse events obtained by the FDA included death, stroke, detachment and/or migration of stents, vein damage, thrombosis, cranial nerve damage, and abdominal bleeding. This alert included the caveat that clinical trials of this procedure require FDA approval and an investigational device exemption due to potential for harms.

Note: This policy addresses percutaneous angioplasty and stenting of **veins** only. This policy does *not* address percutaneous angioplasty and stenting of peripheral arteries, including repair of aneurysms, which are considered medically necessary. Carotid and intracranial vessels are addressed in separate policies (see Cross References below).

MEDICAL POLICY CRITERIA

I. Percutaneous transluminal angioplasty, with or without stenting, may be considered **medically necessary** for the treatment of venous vascular stenoses in the following instances:

   A. Stenotic lesions of arteriovenous dialysis fistulas and grafts, and ipsilateral venous stenosis in the outflow of a functioning dialysis fistula and graft

   B. Superior vena cava in patients with malignant superior vena cava syndrome, when standard treatments (radiation and/or chemotherapy) have failed

   C. Left iliac vein compression syndrome (May-Thurner Syndrome)

   D. As an adjunct to prior or concurrent ipsilateral first rib resection for proximal upper extremity venous thrombosis due to persistent extrinsic compression (Paget-Schroetter syndrome) documented by pre-procedure imaging (i.e., ultrasound, venography, CT, or MRI) restrict

II. The use of angioplasty and/or endoprostheses for creation of intrahepatic shunt connections between the portal venous system and hepatic vein may be considered **medically necessary**.

III. Percutaneous transluminal angioplasty, with or without stenting, is considered **investigational** for all other venous indications, including but not limited to:

   A. Deep vein thrombosis that is *not* related to upper extremity venous compression or iliac vein compression syndrome (I.C.-D.)

   B. Chronic cerebrospinal venous insufficiency in multiple sclerosis or other conditions

C. Venous sinus obstruction or occlusion in idiopathic intracranial hypertension

SCIENTIFIC EVIDENCE

The following discussion focuses on the investigational indications noted in III.A-C above. As noted above, there are currently no stents with approval from the U.S. Food and Drug Administration (FDA) for use in veins for these indications. Therefore, this use is considered an off-label use of vascular stents.

Deep Vein Thrombosis (DVT)

There are several objectives of treatment for venous thromboembolism, namely:[4,5]

- Prevention of pulmonary embolism,
- Restoration of unobstructed blood flow through the thrombosed vein,
- Preservation of venous valve function, and
- Prevention of recurrent thrombosis.

The current standard of treatment for achieving these goals is anticoagulant therapy (i.e., intravenous unfractionated heparin) to achieve a therapeutic partial thromboplastin time (PTT). After completion of an initial course of anticoagulation therapy, patients with venous thromboembolism require continuing therapy to prevent recurrence. Thus, anticoagulation therapy is the standard against which percutaneous transluminal angioplasty (PTA) with or without stenting must be compared in order to evaluate the safety, efficacy, and final health outcomes.

Literature Appraisal

The following literature appraisal is focused on the published evidence for DVT that is not related to left iliac vein compression syndrome or proximal upper extremity venous thrombosis.

Randomized Controlled Trials

There are no randomized controlled clinical trials in which PTA with or without stenting was compared to standard medical management of DVT.

Non-randomized Trials

- The bulk of the current literature investigating thrombolysis followed by angioplasty and stenting is limited to small (n<50), non-randomized, non-comparative retrospective reviews and case series of short- to medium-term duration. [5-8]
- The majority of studies are for DVT related to extrinsic compression (e.g., May-Thurner syndrome), or have heterogeneous patient populations that include both compression-related and noncompression-related DVT.

Idiopathic Intracranial Hypertension (IIH)

Studies for the diagnosis and treatment of IIH must answer the following questions:

1. Is venous sinus occlusion the cause or the effect of increased intracranial pressure (ICP)?

2. Is venous PTA with or without stenting safe and effective in reducing ICP compared with conventional treatment?

To assess the effectiveness and safety of intracranial venous stenting as a treatment of IIH, health outcomes must be compared with current standard treatments. The ideal clinical trial design is random allocation of like patients to active or sham venous angioplasty, and/or conventional medical or surgical treatments. A search of the PubMed database failed to return any randomized controlled trials (RCTs).

Cochrane Review

A 2009 updated Cochrane review found no studies that met their inclusion criteria due to the lack of a control group for comparison.[9] "...many different treatments have been proposed, as discussed above. Unfortunately, none of these treatments has yet been the subject of an adequately-controlled trial and there is currently insufficient evidence on which to base the treatment of IIH...Other procedures such as surgery to induce weight loss and endoluminal stenting of venous sinuses must be subjected to controlled studies before being considered for routine clinical use." The authors did note a multicenter randomized controlled trial currently in progress. They concluded that there "is insufficient evidence to recommend or reject any of the treatments currently available for idiopathic intracranial hypertension."

Randomized Controlled Trials

There are no randomized controlled clinical trials in which PTA with or without stenting was compared to standard medical or surgical management of IIH.

Non-randomized Trials

Current evidence is limited to clinical trial data from small retrospective reviews and uncontrolled case series.

- All but one of these trials included 18 or fewer subjects.[10-13]
- The largest study was a retrospective review of 52 patients at a single center who underwent stenting due to IIH unresponsive to maximum acceptable medical treatment.[14] The follow-up period ranged from 2 months to 9 years. All 52 patients were reported to have immediate elimination of the transverse sinus stenosis gradient and rapid improvement in IIH symptoms including resolution of papilledema. Six patients had relapse of symptoms (headache) and increased venous pressure with recurrent stenosis adjacent to the previous stent. In these patients, an additional stent was placed, with response similar to that following the first stent placement.

Chronic Cerebrospinal Venous Insufficiency (CCSVI) in Multiple Sclerosis (MS)

Studies for the diagnosis and treatment of CCSVI and MS must answer the following questions:

3. Is there a relationship between CCSVI and the development, progression, or symptoms of MS?
4. Is venous PTA with or without stenting safe and effective in reducing MS symptoms compared to conventional treatment?

Literature Appraisal

Systematic Reviews

A Cochrane review[15] and five systematic reviews[16-20] with critical analyses of the current literature concluded that there is insufficient evidence to verify a relationship between CCSVI and MS. The authors noted the high degree of heterogeneity between study outcomes, sensitivity, and specificity, and marked variability of odds ratios.

Randomized Controlled Trials

No randomized controlled clinical trials have been reported. Randomized controlled trials are in progress and will be evaluating both the diagnostic approach to and the potential treatment of CCSVI.

Non-randomized Trials

- Clinical trial data are limited to small, non-randomized preliminary case series.
    - The studies that focused on the potential relationship between CCSVI and MS reported varying and contradictory outcomes. For example, while Zamboni et al and other authors[21-24] reported a strong association between CCSVI and MS, numerous studies have reported insignificant or no difference in the prevalence of CCSVI in MS patients compared to healthy controls, or no association between CCSVI and MS occurrence or symptoms[23,25-32].
    - The studies that focused on outcomes of PTA with or without stent placement reported few adverse events, but mixed efficacy outcomes. [33-38] For example, while Zamboni et al[34] reported significant improvement in all measures for patients with relapsing-remitting MS, Kostecki and colleagues reported a significant improvement only in heat intolerance and fatigue severity 6 months post endovascular treatment.[33] No trials were found that compared PTA with concurrent control groups.
- All authors noted the need for well-designed randomized clinical trials. Many authors asserted that PTA with or without stenting in these patients should not be performed outside the clinical trial setting.

<u>Adverse Effects</u>

As noted above, the FDA issued an alert in 2012 reporting the following potential for adverse events following endovascular interventions for CCSVI:[3]

- Death
- Stroke
- Stent detachment and/or migration
- Vein damage
- Blood clots
- Cranial nerve damage
- Abdominal bleeding

The following additional adverse effects have also been reported in the published literature:[35,39,40]

- Internal jugular vein stent thrombosis
- Cerebral sinovenous thrombosis
- Cardiac arrhythmia
- Other injury associated with venous catheterization (e.g., vein dissection; groin hematoma)
- Neck pain
- Persistent headache

Clinical Practice Guidelines

Deep Vein Thrombosis

- There are no evidence-based clinical practice guidelines that recommend angioplasty with or without stenting for the treatment of deep vein thrombosis.
- Two consensus-based clinical practice guidelines provided evidence appraisals and noted a benefit in venous stenting for DVT. [41,42] However, the majority of the references listed were related to May-Thurner syndrome which is caused by extrinsic compression for which stenting is considered medically necessary. Both guidelines graded the available evidence as very limited.

Idiopathic Intracranial Hypertension

- No clinical practice guidelines were found that addressed the treatment of Idiopathic intracranial hypertension.

CCSVI in MS

- No evidence-based practice guidelines were identified which recognize a relationship between CCSVI and MS, or that recommend PTA with or without stenting as a treatment of CCSVI.
- The Society of Interventional Radiology (SIR) published a position statement on the association of CCSVI with MS and the efficacy of endovascular treatments. [43] Their recommendations included the following statements:
  - At present, SIR considers the published literature to be inconclusive on whether CCSVI is a clinically important factor in the development and/or progression of MS, and on whether balloon angioplasty and/or stent placement are clinically effective in patients with MS.
  - SIR strongly supports the urgent performance of high-quality clinical research to determine the safety and efficacy of interventional MS therapies, and is actively working to promote and expedite the completion.

Summary

The evidence related to the investigational indications listed in the policy is not sufficient to permit conclusions concerning the effects of percutaneous venous angioplasty with or without stenting on final health outcomes. Studies for these indications are limited to small case series and retrospective reviews. These studies suffer from methodologic limitations which impact the reliability of the reported results. These limitations include but are not limited to small sample size, the lack of an appropriate control group for comparison, the lack of randomized treatment allocation, the lack of long-term data, and heterogeneous patient populations. In addition, there are no clinical practice guidelines from U.S. professional societies that recommend venous angioplasty with or without stenting for these indications. Therefore, this procedure is considered investigational for all conditions that do not meet the policy medical necessary criteria. Well-designed randomized controlled trials are needed to determine whether these endovascular interventions result in improved health outcomes compared with standard therapies.

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CROSS REFERENCES

Extracranial Carotid Angioplasty/Stenting, Surgery, Policy No. 93

Endovascular Angioplasty and/or Stenting for Intracranial Arterial Disease (Atherosclerotic and Aneurysms), Medical Policy, Surgery, Policy No. 141

CODES	NUMBER	DESCRIPTION
CPT	35476	Transluminal balloon angioplasty, percutaneous; venous
	36481	Percutaneous portal vein catheterization by any method

CODES	NUMBER	DESCRIPTION
	37238	Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein
	37239	; each additional vein (List separately in addition to code for primary procedure)
	~~37205~~	~~Transcatheter placement of an intravascular stent(s) (except coronary, carotid, vertebral, iliac, and lower extremity arteries), percutaneous; initial vessel~~ (Deleted 1/1/2014)
	~~37206~~	~~; each additional vessel (List separately in addition to code for primary procedure)~~ (Deleted 1/1/2014)
	~~37207~~	~~Transcatheter placement of an intravascular stent(s) (except coronary, carotid, vertebral, iliac and lower extremity arteries), open; initial vessel~~ (Deleted 1/1/2014)
	~~37208~~	~~; each additional vessel (List separately in addition to code for primary procedure)~~ (Deleted 1/1/2014)
	~~75960~~	~~Transcatheter introduction of intravascular stent(s), (except coronary, carotid, vertebral, iliac, and lower extremity artery), percutaneous and/or open, radiological supervision and interpretation, each vessel~~ (Deleted 1/1/2014)
	75978	Transluminal balloon angioplasty, venous (eg, subclavian stenosis), radiological supervision and interpretation
HCPCS	None	