

White Paper: Varicose Vein Treatment - What is Medically Necessary and what is Cosmetic?

For Health Plans, Medical Management Organizations and TPAs

Executive Summary

Varicose Veins are one of the most common clinical manifestations of venous insufficiency, also known as venous reflux. Although varicose veins are simply a cosmetic concern for many individuals, they can cause aching pain and discomfort and may require medically necessary treatment. Although physical examination can reveal the likely sites of venous insufficiency, all patients should undergo imaging studies in order to accurately assess all of the sites of reflux.

A number of factors influence treatment selection, including the severity of the symptoms, the type of vein, the source of venous reflux, and the prior use of any other treatments. Varicose veins can initially be conservatively managed with compression stockings, weight loss, and exercise. More aggressive treatments, including surgery and noninvasive laser/light therapy, are used to treat venous reflux issues that are associated with varicose veins by removing or closing off the affected vein.

Independent medical review facilitates the evaluation of the medical necessity of the treatment of varicose veins, which requires an in-depth understanding of the clinical course, the findings of the disease and the available treatment options. In addition, the process is also the key to identifying whether the requested treatment is medically necessary or cosmetic in nature.

Introduction

Varicose veins are twisted, enlarged veins that most commonly occur in the lower extremities. Estimates indicate that treatments for varicose veins may account for up to 2% of all healthcare costs within the United States, and total about \$1 billion annually. About 30 million individuals in the United States are affected in some way by chronic venous disease, with varicose veins of the lower extremities present in about 20% of the population. As a result, healthcare companies have been facing a continuously increasing number of requests for varicose vein treatments. Although the majority of these requests falls under the category of cosmetic procedures, varicose veins represent a significant clinical problem and are not just a cosmetic issue because of their unsightly nature.

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Varicose veins actually indicate underlying chronic venous insufficiency with ensuing venous hypertension, which can lead to a range of clinical manifestations. Venous insufficiency syndromes are most commonly caused by valvular incompetence in the low-pressure superficial venous system, but they may also result from valvular incompetence in the high-pressure deep venous system. Deep venous insufficiency occurs when the valves of the deep veins are damaged as a result of deep venous thrombosis (DVT). The hydrostatic venous pressure in the lower extremity increases due to the absence of valves to prevent deep system reflux. In superficial venous insufficiency (reflux), which is the most common form of venous disease, the deep veins are normal, but venous blood escapes from the normal deep system and flows backward through dilated superficial veins, in which the valves have failed. Untreated venous insufficiency in the deep or superficial system results in a progressive syndrome that causes pain, swelling, skin changes, and eventual tissue breakdown.

Patient Evaluation

All patients should undergo a thorough history and physical examination, with careful attention paid to the symptoms of chronic venous disease in the lower extremities. These include aching pain, a sense of heaviness in the legs, and fatigue with ambulation. Additional symptoms can include bleeding or superficial thrombosis, and patients will describe symptoms that worsen throughout the course of the day, especially if they are required to stand for long periods of time.

Although many patients present with varicose vein patterns that are suggestive of a particular form of venous insufficiency, physical examination findings often overlap among the different forms of the disease. All patients with varicose veins require an ultrasound of the superficial venous system to map the pattern of venous incompetence prior to treatment selection. Duplex Doppler ultrasonography, which is a readily available imaging modality that visualizes the lower extremity venous system, is an integral part of the evaluation and management of patients with varicose veins. Ultrasound evaluation is critical for planning procedures, documenting the extent of vascular pathology, identifying the source of venous reflux, and revealing whether deep venous insufficiency is present.

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Treatment: Cosmetic or Medically Necessary?

Identifying Treatment Goals

When varicose veins are treated for the exclusive purpose of improving a patient's appearance, this is considered cosmetic surgery and will not be covered by the patient's health insurance or Medicare. If, however, the varicose veins are causing symptoms that affect the patient's ability to work or function normally, or if the underlying venous reflux disease is producing complications such as skin ulcers or blood clots, a physician can determine that treatment is required to restore or preserve the patient's health and well-being and is, therefore, considered a medical necessity. Under these circumstances, most health insurance and Medicare plans will cover the procedure.

Conservative Management

In the early stages of venous disease, all patients should receive appropriate conservative treatment. The conservative management of varicose veins may include avoiding prolonged standing and straining, elevating the affected leg, exercise, and external compression with bandages, support stockings, and/or intermittent pneumatic compression devices. Support stockings may alleviate the discomfort of varicose veins. Other noninvasive measures that may be helpful are the loosening of restrictive clothing, cardiovascular risk factor management, the treatment of peripheral edema, and weight loss, which may reduce symptoms in obese patients.

Medical Treatment

NONINVASIVE THERAPIES

The use of sclerosing agents is very effective for the treatment of small varicose veins. However, it is less successful in treating larger varicosities. Many sclerosants have been utilized, but the only sclerosant that is approved for the specific indication of varicose vein treatment in the United States is sodium tetradecyl sulfate. Traditional sclerotherapy has been unsuccessful in providing adequate closure of larger varicose veins.

Transcutaneous laser and intense-pulsed-light (IPL) therapies have been proven effective for the tiniest surface vessels, such as those found on the face, but these techniques are generally useful as primary therapy for treatment in the lower extremity.

NONINVASIVE THERAPIES

The primary goal of surgical therapy is to improve venous circulation by correcting venous insufficiency through the removal of major reflux pathways. Common surgical approaches to large-vein varicose disease include ligation of the saphenofemoral junction with vein stripping, phlebectomy that is performed through microincisions, endovenous radiofrequency thermal ablation, and endovenous laser thermal ablation. The primary surgical approach to small-vein disease is microincisional phlebectomy followed by sclerotherapy.

Historically, the most frequently recommended form of treatment for varicose veins has been a surgical procedure, particularly in patients with involvement of the greater saphenous vein. Surgical interventions include ligation, which involves tying off the enlarged vein in portions of the leg, thigh, and groin, and phlebectomy and stripping.

Common Types of Surgical Care:

Endovenous laser ablation of the saphenous vein is a newer treatment for varicose veins, in which a long, thin catheter that emits heat or another form of energy is introduced into the vein, thereby causing collapse and sclerosis. Complications may include bruising, tightness along the course of the treated vein, recanalization, and paresthesia.

Radiofrequency ablation is similar to laser ablation in that it uses an endovascularly-placed heat source to produce vascular and endothelial damage, thrombosis, and the eventual occlusion of the treated vein.

Stab avulsion of superficial varicosities, which is also known as ambulatory phlebectomy, involves making many small incisions over the varicosities and excising them using a modified crochet hook. Although it remains a staple of treatment for varicose veins, many centers are now replacing it with transilluminated powered phlebectomy.

Transilluminated powered phlebectomy was designed as an alternative to stab phlebectomy with some potential advantages. More complete excision of the varicose vein clusters is possible since the phlebectomy is performed under direct vision. In addition, the instruments require fewer incisions, which makes the procedure minimally invasive.

Selecting a Treatment Option

Because of limited outcome data that compare various treatments, there is limited evidence that supports any single treatment option. Specific patient management should be directed by symptoms, patient preference, expense, the potential risks, the availability of medical resources, insurance reimbursement, and the level of clinician expertise in various treatment options. Combinations of conservative measures and more invasive techniques may be appropriate, depending on the patient's symptoms, the extent of the vascular pathology, and the available resources.

Obtaining approval for a procedure is not always an easy task. Health plans require the thorough documentation of failed attempts at the management of varicose veins. This may include the use of compression stockings for 6 to 12 months.

The Role of External Independent Medical Review in Determining the Medical Necessity of the Treatment of Varicose Veins

Health plans require physician documentation that establishes the medical necessity of the treatment of varicose veins. This documentation must include symptoms and complications, physical exam findings, the confirmation of the diagnosis, and the failure of any conservative attempts at management.

The continuously increasing number of available therapies for the treatment of varicose veins often complicates the process of establishing evidence-based criteria for practice guidelines and reimbursement for new procedures and treatments. Independent medical review, which is normally used by healthcare payers, looks at whether or not a specific procedure is medically necessary.

The board-certified physician specialists who work with independent review organizations keep up-to-date with the latest medical research literature and with the latest standard of care. These specialists allow healthcare plans to make sure that the requested procedures fall under the medical necessity requirements before a course of treatment is approved.

Physicians who review cases for independent review organizations stay on top of treatments as they are more extensively studied and potentially accepted into clinical guidelines. The specialty match that independent review organizations provide is especially important in the interpretation of imaging studies and the determination of the best treatment approach for varicose veins. Independent medical review also avoids conflicts of interest, which can relate to economics, the lack of specialists to review cases, or having the same doctor who denied a case review an appeal.

Conclusions

Varicose veins remain a common clinical problem and range from purely cosmetic disturbances to insufficiency-related ulcers. There are a wide variety of available treatments, ranging from conventional surgical procedures to newer, minimally invasive procedures.

By providing an unbiased evaluation of medical need for the treatment of varicose veins, external independent medical review facilitates the effective treatment of the disease, which, if not treated properly, can lead to significant discomfort or more serious medical problems. Independent medical review also provides ready access to specialists, which healthcare plans may internally lack, thereby allowing for a timely determination of whether the requested treatment falls under the medical necessity guidelines.

Bibliography

Deatrick KB, Wakefield TW, Henke PK. Chronic venous insufficiency: current management of varicose vein disease. *Am Surg*. 2010;76:125-132.

Meissner MH, Gloviczki P, Bergan J, et al. Primary chronic venous disorders. *J Vasc Surg*. 2007;46:54S-67S.

van den Bos R, Arends L, Kockaert M, Neumann M, Nijsten T. Endovenous therapies of lower extremity varicosities: a meta-analysis. *J Vasc Surg*. 2009;49:230-239.