What parameters should be used to differentiate whether management of superficial venous disease is medically necessary?

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It is easy to look at the extremes of venous disease—such as patients with open ulceration or spider veins that are clearly asymptomatic—and determine that the former is medically necessary, and the latter is not. The difficulty arises when dealing with patients with intermediate levels of disease, as well as understanding the definition of *medically necessary*. *Medically necessary* is typically defined as treatments that are reasonable based upon evidence-based medicine, or interventions that—if not performed—could adversely affect patients' conditions.

Most experts would agree that patients who have healed or active ulcers, or those with significant stasis changes, could benefit from treatment of venous insufficiency. Traditionally, many physicians use CEAP to determine medical necessity. However, a major limitation of CEAP classification is the absence of patient symptom assessment. CEAP also does not provide a method for assessing clinical improvement other than ulcer healing.

The addition of a quality-of-life (QOL) assessment is necessary to not only determine which patients are really symptomatic and for whom intervention would be medically necessary, but also to assess the success of the interventions, whether surgical, minimally invasive, or medical, which will aid in future determination of medical necessity. Multiple QOL assessments exist; some are generic, such as the SF-36, and others are disease-specific, such as the Aberdeen Varicose Vein Questionnaire (AVVQ) or the Chronic Venous Insufficiency Questionnaire (CIVIQ). Current consensus guidelines recommend using the Venous Clinical Severity Score (VCSS) to enhance assessment of the clinical impact of venous disease and to assist in differentiating patients with medically necessary disease or disease that is appropriate for intervention, as well as to assist in the assessment of the intervention's success. A score of at least 6 on the VCSS suggests that the patient either has significant symptoms (such as lifestyle-limiting pain in addition to use of compression garments) or has more severe sequelae of chronic venous insufficiency, such as edema, stasis changes, inflammation, induration, or active ulceration.

I would also suggest that patients with lower VCSS and CEAP scores, but who have experienced other complications from venous insufficiency—such as repeated episodes of bleeding or superficial phlebitis—should be considered to have medically necessary disease and would benefit from intervention, whether it is ablation, avulsion phlebectomy, or sclerotherapy.

Clearly, the problem with treatment of superficial venous disease is the ability to differentiate patients with purely cosmetic issues from those with more advanced disease. For those choosing to be involved in the care of venous patients, it is important that we concur to define medically necessary disease to avoid the definition being thrust upon us by insurance companies, government, or other nonmedical groups. It is important for all of us to utilize and document some form of QOL assessment, in addition to appropriately classifying patients using CEAP to facilitate correct classification of medically necessary interventions, as opposed to cosmetic interventions.

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It is common knowledge that the United States spends more on health care per capita ($8,608), and more on health care as a percentage of its GDP (17.9%), than any other nation. The overuse of medical benefits is known as a moral hazard—individuals who are insured are more inclined to consume health care. The health care system tries to eliminate this problem through cost-sharing tactics.

Overutilization is multifactorial:

1. Innovation translates to high-tech, high-priced treatments because device manufacturers pass pricing through to their customer base.
2. The tort system drives defensive medicine, resulting in overuse of diagnostic testing.
3. Broader-access plans breed consumer entitlement, demand, and coverage for QOL care.
4. Hospitals overcharge third-party payers to subsidize high-tech infrastructure and administrative salaries.
5. Private insurance charges higher health insurance premiums or other cost-sharing tactics like copays and deductibles.
6. Government insurance (Medicare, Medicaid) is paid by taxpayers through higher taxes.

In my opinion, physicians treating venous disease in 2013 would be remiss if they don't begin practicing in the context of the total health care system. Consideration for billing third-party payers should be based on venous disease severity. There are several validated measuring tools for quantitating disease severity (VCSS, Venous Severity Score, etc.), but they can be cumbersome.

With respect to the question at hand, venous disease can be stratified by the simple and universally known CEAP class. The endpoint of the physician evaluation should be to determine the risk of venous ulceration. The Bonn Vein and Edinburgh epidemiologic studies have given us some insight into disease progression. In summary, patients with varicose veins (CEAP 2) have a risk of 2% to 3% per year of progressing to skin damage (CEAP 4). Therefore, CEAP class 1–3 should not be a covered insurance benefit, and these patients should pay for their treatments out of pocket. However, CEAP 4–6 disease should be a covered insurance benefit because these patients present with skin damage.

The Affordable Care Act is law- and volume-driven. Fee-for-service medicine is being challenged by value-based medicine. Adoption of the aforementioned practice policy could reduce utilization and decrease health care costs. Currently, superficial venous disease is very affordable because it is treated in a physician's office. Patients with low CEAP class (less disease severity) who insist on treatment can pay for their treatment out-of-pocket. If patients are responsible for more of the economic burden, they will then only consume health care when it is necessary. These practices should be implemented in other areas of vascular medicine as well, such as claudication with low ankle-brachial indices.

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Determining what constitutes medical necessity for superficial venous operations continues to be problematic for patients, providers, and health care systems, because medical necessity is, for the most part, currently dictated by insurance carriers in an effort to ration care. Generally, for coverage of superficial venous operations, insurance plans require some combination of symptomatic venous disease (significant pain or refractory edema interfering with daily living, bleeding associated with diseased veins, recurrent episodes of superficial phlebitis, stasis dermatitis, venous stasis ulceration); failure of conservative management measures (weight reduction, daily exercise, periodic leg elevation, graduated medical compression stockings) over a defined time period (usually several months); documentation of varicose vein size; and duplex-ultrasound–proven reflux in the great saphenous vein that correlates with symptoms. Specifically for endothermal ablation treatment, there must be a maximum vein diameter of at least 20 mm and absence of venous aneurysm, tortuosity, or thrombosis.

Although these criteria within insurance coverage plans do provide some structure to what constitutes medical necessity, the system is flawed. There are still patients who have significant medical issues related to venous disease that may not fall specifically within these categories. Furthermore, there is a wide degree of variability between insurance carriers, an approval process that can be quite onerous, requiring extra resource utilization, and—given some criteria based on subjective assessment and financial incentive for performing procedures—the potential for

misrepresentation of what is needed for documentation of medical necessity.

Rather, medical necessity should be based on sound and reproducible evidence-based criteria. Current evidence supporting efficacy of the nonoperative measures listed previously is lacking, because use of performance measures to assess quality of care for these nonoperative measures is also lacking. As our health care system shifts to quality care and measurable performance parameters, so too should assessment of medical necessity. For venous disease, these tools already exist. Use of clinical venous assessment tools (such as CEAP, VCSS, or Villalta score), QOL tests (such as SF-36, Venous Disability Score, AVVQ, CIVIQ, and Venous Insufficiency Epidemiological and Economic Study [VEINES-QOL/Sym]), and objectively derived duplex ultrasound and venous plethysmography parameters obtained in properly accredited vascular testing centers could all be adapted to better define medical necessity. Further investigation to determine natural history of nonoperative measures based on these assessment tools will further add evidence to support medical necessity. These performance measures should also extend to assessment of quality of care for those undergoing superficial venous procedures both before and after operation. Through participation in venous registries such as those offered through the Vascular Quality Initiative (VQI) of the Society of Vascular Surgery Patient Safety Organization (SVS-PSO) and the planned release of the Varicose Vein module—a cooperative effort between the SVS and American Venous Forum (AVF)—later this year, quality performance measures can be followed and documented in an effort to collectively improve both nonoperative and operative venous care. Only after comparing the effective outcomes of these nonoperative and operative measures within the spectrum of clinically significant venous disease can the line of medical necessity be better defined and applied.

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Chronic venous diseases (CVD) are among the most prevalent conditions to affect the QOL of Western populations, and their care entails a large socioeconomic burden. The manifestations of CVD are broad and range from aesthetic to those that impede patients' ability to participate as active members of their communities. Although we now have low-risk, low-cost, and highly successful procedures that can durably help patients with many forms of CVD, our resources for health care have limits. As a result, the more important question to answer is: at what disease severity does the cost of CVD treatment merit being part of the shared responsibility of society? As we debate the most fair and effective allocation of our health care resources, we need to consider important practical and ethical questions and recognize which of our efforts will have the greatest benefit for our patients and our communities.

Generic and disease-specific QOL instruments exist that can reliably quantify the level of patient-perceived disability. Most of us agree that physician-generated quantification, such as using the VCSS score, is an important adjunct to patient-reported data to accurately classify the severity of the ailment. Used in combination, or, perhaps in the future, as a hybrid metric combining patient-reported and physician-determined severity, we can create an assessment of disease severity. The use of such a scale would be able to create a continuum of disability.

The rub for all of us is that some line will have to be drawn—below which, the care for the disability is the responsibility of the patient. Where to draw this line is a medical, ethical, and economic decision that some liken to rationing. However, we all must recognize that the realities of the cost of health care mandate that we make some difficult decisions. This may mean that some forms of venous disease that are currently considered sufficiently severe for coverage may, in the future, not be covered.

Rather than scoff at these realities, we as physicians need to participate in the process to develop these standards as responsible experts. In the absence of our leadership, other groups will attempt to create solutions. In the wake of health care reform, we have seen that insurers have decided the easiest way to control venous costs is through increased deductibles and copays, lengthened duration of required conservative care, and, in some cases, completely excluding venous care. Certainly these approaches will decrease vein-related health care expenditures. However, by making the decision to undergo venous care heavily financial for patients at all levels of disease, the process is mostly discouraging those with the least resources from undergoing care, regardless of the severity of their disability.

Besides the ethical debate, the insurance industry approach may be shortsighted. Let's be mindful that the largest proportion of the economic burden of CVD relates to the care of patients with CEAP 5–6 disease. The direct cost of a venous ulcer, including diagnostic and therapeutic procedures and ongoing wound care is expensive. It has been estimated that 1% to 2% of the overall health care budget of the United States is related to the care of CEAP 5–6 CVD. In addition, the indirect cost of CEAP 5–6 disease to society in terms of the number of missed days of work

is tremendous. In one German study, these indirect costs exceeded the total cost of caring for patients with arterial disease.[1]

Clearly, health care economics dictate that our efforts for cost saving should be focused on the CEAP 4–6 patients. The holy grail of ulcer care needs to be ulcer prevention. In order to get there, we need to answer a few questions. First, can we identify patients with CEAP 1–4 CVD who are going to progress to CEAP 5–6 disease? If we can predict this, we could explore solutions that would have far-reaching social and economic benefits. We, of course, would study if treatment of high-risk patients with earlier forms of disease can prevent such progression. We could also look at other existing and yet-to-be-conceived mechanical or pharmacological means to treat or prevent early disease to determine their impact for the benefit of the patient and for society.

It is possible that the result may make the case that early intervention in certain patients with CVD is more cost effective than we think. Vein care providers in France, where early venous intervention is common, have anecdotally noted a decrease in the prevalence of CEAP 4–6 disease in the last decade. Although such comments are thought provoking, we need to recognize that such relationships at this point are purely anecdotal.

In summary, with regard to determining medical necessity, we need to tackle the question of what is the level of disability in CEAP 2–4 patients that merits the support of society for care. Even more importantly from the perspective of cost control and improving the QOL of our patients, we need to determine (1) if we can identify patients likely to progress from early to advanced disease, and if so, (2) what early interventions can prevent progression to CEAP 5–6 disease. Pooling the resources of the different stakeholders—including physicians, health care insurers, and the medical device and pharmaceutical industry—is necessary for us to accomplish these vital outcome analyses.

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Medical necessity of a therapy is a complex issue, and endovenous thermal ablation for superficial venous disease is no exception; no single set of data will determine that. It is difficult to state medical necessity of interventions for asymptomatic CEAP 2 patients with simple varicose veins, unless the superficial veins are very large or aneurysmal; these can be a source of bleeding or thrombophlebitis, with or without extension of the thrombus into the deep veins.

The CEAP classification has been very helpful because we know that patients with superficial venous insufficiency alone can have advanced CVD, including venous ulcerations. It is not difficult to justify medical necessity of interventions for patients with CEAP 5–6 disease (healed or active ulcer), and for many with CEAP 3 disease (edema) and CEAP 4 disease (acute or chronic skin inflammation), even in the absence of deep venous pathology.

It is the CEAP 2 patient with simple varicose veins who is the cause of the most controversy. Interventions in those with symptoms of bleeding or thrombophlebitis are easy to justify. Symptoms of pain, aching, heaviness of the leg, and responsiveness or unresponsiveness to medical treatment are controversial because of the subjective nature of pain; third-party payers want to delay costly interventions for at least 3 months, hoping that in the interim, patients will be discouraged to proceed with an obviously more effective but also more expensive treatment than compression stockings alone.

Recent Guidelines of the Society for Vascular Surgery and the American Venous Forum[2] suggest compression therapy for patients with symptomatic varicose veins (Grade of Recommendation: 2, weak; Level of Evidence: C, low to very low quality).

At the same time, the guidelines also recommend against compression therapy as the primary treatment if the patient is a candidate for saphenous vein ablation (Grade of Recommendation: 1, strong; Level of Evidence: B, moderate quality). This recommendation was based on a randomized controlled study by Michaels et al[3] that randomized 246 patients with simple varicose veins (CEAP 2) to conservative management or surgery, which included high ligation, stripping, and phlebectomies. In the first 2 years after treatment, there was a significant QOL benefit for surgery versus conservative management. In addition, cost-effectiveness analysis showed that surgery was significantly more cost effective than both sclerotherapy and conservative compression therapy.

Finally, appropriate data from a credentialed vascular laboratory are essential to justify medical necessity. Saphenous reflux with abnormally reversed flow of 500 msec or longer is required to justify ablation of the incompetent great or small saphenous vein. ■

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