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National Government Services, Inc.
P.O. Box 7108
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Via Electronic Submission to: PartBLCDComments@anthem.com

Re: **Proposed National Government Services (NGS) Local Coverage Determination (LCD): Treatment of Varicose Veins of the Lower Extremity (DL33575)**

Dear Drs. Clark and Cunningham,

On behalf of our specialty medical societies (the American College of Phlebology (ACP), *Society for Cardiovascular Angiography and Interventions* (SCAI), Society of Vascular Surgery (SVS) and the Society of Interventional Radiology (SIR)), we respectfully submit the following comments in response to the proposed Local Coverage Determination (LCD) : **Treatment of Varicose Veins of the Lower Extremity (DL33575)**.

Our organizations have a combined membership of nearly 15,000 physicians and are committed to ensuring access to safe and evidenced-based treatments for patients with venous disease. We are writing as experts in the area of venous medicine to express our consensus medical opinion.

It is our strong belief that the interests of patients are best managed when applying scientific evidence and, when available, society guidelines based on such science, in clinical decision-making. We would like to applaud NGS for making recommendations that are generally in accord with the scientific evidence. However, in the interest of advocacy for our patients and clarity of the policy, there are a few issues we wish to raise.

1. Regarding: "Patients are not expected to require endovenous ablation of the saphenous vein more than once in either leg".

   Concern: While we agree with the principle that in most patients with C2, C3 and C4a venous disease only a single saphenous vein ablation is required to achieve a clinically relevant improvement, realistically this is not true in all patients. There is a small subset of patients that will require ablation of 2 or rarely 3 saphenous (great saphenous, accessory saphenous, small saphenous) veins per limb to achieve acceptable improvement, but these should be the minority of patients.[1] In contrast, it is important to recognize that in patients with advanced venous disease (C4b, C5, or C6), ablation of a second or third vein may be necessary to prevent progression to ulceration, recurrence of ulceration, or delayed ulcer healing.[2] Unfortunately, chronic venous disease is a progressive disorder that can result in another saphenous vein developing reflux despite optimal primary therapy. In patients with recurrent symptoms and signs of significant venous disease attributable to new saphenous reflux, ablation of additional veins may be required again.[3,4] Finally, we must not forget that clinical failure rates of 3-5% with endovenous ablation have been published. If symptoms persist in patients with a clinical failure and the failure is related to saphenous veins that are refluxing, the patient may require re-intervention.

   Recommendation: *We recommend replacing the statement with: During a single episode of treatment, most patients with C2, C3 and C4a disease require no more than one ablation of one of the GSV, AAGSV, and SSV per leg and nearly all patients require no more than two of these veins to be treated in each*

lower extremity during an episode of care. Regardless of the indication, utilization of ablation of these veins will be monitored statistically and outlier practitioners may be required to submit medical records for prepayment or post-payment audit.

2. Regarding: "Sclerotherapy, injecting sclerosing solutions directly into the abnormal veins, is an alternative occasionally selected for the treatment of varicose veins without significant saphenofemoral or saphenopopliteal incompetence. However, it is not considered to be as reliable and effective as surgical ligation and stripping. Sclerotherapy is considered medically necessary for the treatment of small to medium sized vessels (less than 4 mm in diameter). Sclerotherapy is not considered medically necessary for vessels larger than 4 mm in diameter." We are also concerned about the statement, "The following interventional treatments are not considered medically reasonable or necessary and are denied as such: Sclerotherapy for vessels larger than 4 mm in diameter, and compressive sclerotherapy for large, extensive or truncal varicosities" which are found in the *limitations* section.

   Concern: Sclerotherapy (probably better described as endovenous chemical ablation) usually is not an alternative to ligation and stripping, which refers to removal of a saphenous vein. It is a procedure that is used to eliminate varicose veins that often are tributaries of a refluxing saphenous vein, recurrent or residual tributaries after prior saphenous ablation (endovenous or ligation and stripping) or dilated, elongated tributaries related to non-saphenous causes of reflux such as pelvic derived varicose veins or those associated with incompetent perforating veins.

   Microphlebectomy (also known as stab phlebectomy or ambulatory phlebectomy (CPT 37765 and 37766) is an alternative to sclerotherapy to eliminate these tributaries with the same indications.

   Sclerotherapy and microphlebectomy are recommended by all Society guidelines to treat symptomatic varicose veins of all sizes. [5,6] Most symptomatic varicose veins are larger than 4mm, not less than 4mm. Endovenous chemical ablation with foamed sclerosant usually is utilized to treat abnormal varicose veins that are large diameter or require ultrasound guidance given a deeper location. With deeper veins, ultrasound is utilized at the time of the procedure by the treating physician to identify the target and non-target veins, to identify the needle access sites, to guide placement of the access needles, to monitor the foam infusion, to direct the foam into the target veins, to limit passage of foam into the non-target veins, and for observation of immediate response of the treated veins to treatment. In the tributaries, endovenous chemical (foam) ablation allows treatment of a large number of symptomatic varices that are too numerous, too deep in the fatty tissues, or too complicated for any other technique to work. Post-procedure compression is an essential component of endovenous foam treatment. Please take note that treatment of the great saphenous vein with endovenous foam may be effective *(see a discussion about FDA approved foam ablation of the saphenous vein (Varithena) later in this letter)* for treatment of many varicose veins over 4 mm in diameter.

   Recommendation: *We recommend stating that for refluxing tributary veins 4 mm or larger in diameter in symptomatic patients, compression sclerotherapy (probably better described as endovenous chemical ablation) or microphlebectomy are appropriate therapies. This would be in concordance with the clinical practice guidelines we have previously mentioned.*

3. Regarding: "Foam sclerotherapy of the saphenous vein at its junction with the deep venous system has been proposed as an alternative to ligation or saphenectomy, but its efficacy lacks sufficient scientific evidence to consider medically reasonable and necessary. Sclerotherapy ablation of the saphenous vein at its junction with the deep system is not a covered procedure. Refer to the attached document for the details regarding a recent related reconsideration request."

   Concern: Endovenous chemical ablation with physician compounded or with proprietary foam have been shown to be effective in treating saphenous vein reflux although perhaps less so than saphenous ablation with surgery, thermal energy, mechanicochemical ablation, or surgical adhesive (cyanoacrylate). It is also effective at closing tributary veins of the saphenous system. However, when foam is used to ablate a

saphenous vein, it is not injected "at its junction" as this carries excessive risk of deep vein thrombosis. It is generally injected at a distance from the "junction" with a deep vein and the treated vein is compressed to prevent the foam from traveling into the deep vein. This is part of the Varithena procedure as described in its trials and in its FDA approved IFU. [7,8]

Recommendation: *We recommend coverage for endovenous chemical ablation with foamed sclerosant when Varithena, the FDA approved foam for saphenous ablation, is used according to its approved IFU.*

4. Regarding: "Medicare will consider interventional treatment of varicose veins (sclerotherapy, ligation with or without stripping, and endovenous ablation) medically necessary if the patient remains symptomatic after a six-week trial of conservative therapy.

   Concern: The description of procedures to eliminate saphenous veins and to eliminate tributary veins grouped as "interventional treatment of varicose veins" is unconventional and may lead to confusion by those required to review claims.

   Recommendation: *The accepted treatments for eliminating saphenous reflux are laser and RF (thermal) ablation, as well as endovenous chemical (foam) ablation with Varithena, Mechanicochemical (Clarivein), or cyanoacrylate adhesive ablation (Venaseal). The treatments for varicose veins are either compressive sclerotherapy (better called endovenous chemical ablation, often performed with ultrasound-guided foam treatment) and microphlebectomy. The treatments to eliminate the saphenous vein will be considered medically necessary if the patient remains symptomatic after a six-week trial of conservative therapy and has reflux in a saphenous vein. The treatments of the tributary veins will be considered medically necessary if saphenous reflux is not present or already successfully eliminated, the veins are > than 4 mm in diameter and if the patient remains symptomatic after a six-week trial of conservative therapy.*

5. Regarding: "Endovenous ablation therapy is covered only for treatment of the lesser or greater saphenous veins to improve symptoms attributable to saphenofemoral or saphenopopliteal reflux.

   Concern: The terms "greater or lesser" saphenous veins should no longer be used and should be referred to as "great or small" saphenous veins. These recommendations were made by consensus of a committee of internationally recognized experts in vein disease from multiple specialties (Caggiati) and are supported by the ACP Practice Guidelines for Superficial Venous Disease. This was recommended to eliminate confusion with the abbreviation LSV which could either refer to the "long" saphenous vein (great saphenous) or the "lesser" saphenous vein (small saphenous). [9] These standards have been widely accepted and are included as requirements for use by physicians seeking accreditation of their vein care practices by the Intersocietal Accreditation Commission. [5,6,10]

   In addition, reflux in the anterior accessory GSV (AA-GSV) has been demonstrated to be associated with similar symptoms to those that are found with GSV reflux and as measured by QOL tools, and result is similar morbidity. Since the AAGSV represents a congenital variation of the GSV, historically many veins treated and labeled as the GSV were likely the AA GSV Endovenous ablation of the anterior accessory GSV and the thigh extension of the small saphenous vein are recommended in symptomatic patients with reflux in these veins by the ACP Clinical Practice Guidelines and the most recent AVF/SVS Guidelines. [11,12]

   Recommendation: *To be consistent with the scientific literature, reporting standards for clinical practice and with the nomenclature used in other LCD policies regarding varicose veins, we would recommend, "Endovenous ablation therapy is covered only for treatment of the great, anterior accessory great and small saphenous veins to improve symptoms attributable to saphenofemoral or saphenopopliteal reflux."*

6. Regarding: "Surgery, endovenous ablation, or sclerotherapy are typically not performed for varicose veins that develop or worsen during pregnancy because most will spontaneously resolve or improve after delivery".

Concern: While invasive treatment of venous insufficiency during pregnancy is rarely indicated and symptoms improve after delivery, some remain very symptomatic after the pregnancy has completed requiring treatment.

Recommendation: *Since pregnancy and the immediate post-partum period is not a concern for Medicare beneficiaries we would suggest eliminating this from the policy.*

7. Regarding: The limitation of endovenous ablation "to a maximum vein diameter of 20 mm for laser ablation".

   Concern: Laser and radiofrequency ablation of saphenous veins can be routinely performed for very large veins and the old arbitrary criteria established in early clinical trials are not valid limits for vein size. [13,14,15,16] Proper tumescent anesthetic technique and catheter technique afford adequate vein wall contact with the thermal source. It is far less traumatic to the patient to treat these large saphenous veins with thermal ablation than with stripping.

   Recommendation: *Delete the maximum vein diameter limit for thermal ablation of saphenous veins.*

8. Regarding: "Non-cosmetic sclerotherapy will also be covered if performed in conjunction with surgical ligation or stripping procedures in appropriately selected patients."

   Concern: Sclerotherapy or endovenous chemical ablation may be the only treatment needed in some patients whose saphenous veins are competent or previously eliminated. [5,6]

   Recommendation: *"Sclerotherapy in patients with varicose veins > 4 mm in diameter will be covered when there are persistent venous symptoms after saphenous vein ablation, if saphenous vein ablation had been performed at a previous encounter or if the saphenous veins are demonstrated to be competent by ultrasound".*

9. Regarding: The limitation section statement "Sclerotherapy, ligation and/or stripping of varicose veins, or endovenous ablation therapy are not covered for patients with severe distal arterial occlusive disease; obliteration of deep venous system; an allergy to the sclerosant; or a hypercoagulable state."

   Concern: Severe arterial occlusive disease takes many forms and is not always a contraindication to treatment of a severe venous problem. Clinical practice guidelines describe the selection of patients with combined arterial and venous disease who may require venous treatments. [5,6,12] "Obliteration of the deep venous system" can be quite variable. Again guidelines assist physicians in selection patients with certain types of deep venous occlusion for superficial venous treatment. [5,6,12] Consequently, this provision likely will result in denial of necessary care for some patients who have certain degrees of deep venous obstruction from previous venous thrombosis who can be safely treated for severe venous insufficiency. Hypercoagulable state refers to the presence of a tendency to excessive clotting. There is a large spectrum of severity that is encompassed by this term from a relatively small risk of thrombosis to those associated with high risk of clotting.

   Clinical judgment for which patients would benefit from treatment involves a complex risk benefit assessment that is challenging for any LCD policy to attempt to address. Such decision-making is best assisted with the use of the clinical practice guidelines.

   Recommendation: *Eliminate this statement from the policy.*

10. Regarding: "Foam sclerotherapy of the saphenous vein at its junction with the deep venous system has been proposed as an alternative to ligation or saphenectomy, but its efficacy lacks sufficient scientific evidence to consider medically reasonable and necessary. Sclerotherapy ablation of the saphenous vein at its junction with the deep system is not a covered procedure. Refer to the attached document for the

details regarding a recent related reconsideration request." Also, see the statement and the link in the associated "Documents" section, "Attachments Varithena Reconsideration Response (PDF - 351 KB)

Concern: Varithena refers to an FDA approved drug that when used as per its IFU is part of an evidence-supported treatment for chemically eliminating the GSV, accessory GSV reflux and the associated varicose veins. Randomized trials have demonstrated improvements in disease specific and generic QOL that is durable to three years. Varithena has been assigned CPT codes by the CPT Editorial Committee that will be effective in January 2018. It has also been through the RUC committees and CMS recently proposed reimbursement levels for these planned CPT codes. [7,8]

Recommendation: *Coverage for treatment with Varithena for its FDA-approved indications beginning January 2018.*

11. Regarding: Venaseal (Cyanoacrylate ablation)

    Concern: Venaseal refers to an FDA approved delivery device and adhesive implant that are part of an evidence-supported treatment for eliminating the incompetent GSV. In its US pivotal trial that served as the basis for its approval, it was as effective as RF ablation in closing the GSV and resulted in identical improvements in disease specific and generic QOL that are durable to three years. [17,18] The six month and one year data are published and the three year follow up data has been presented and is in a submitted manuscript at this point. Venaseal has been assigned CPT codes by the CPT Editorial Committee that will be effective in January 2018. It has also been through the RUC committees and CMS recently proposed reimbursement levels for these planned CPT codes

    Recommendation: *Coverage for treatment with Venaseal for its FDA-approved indications beginning January 2018.*

12. Regarding: Reference to ligation and stripping of the saphenous vein as the "treatment of choice for moderate to large symptomatic varicose veins".

    Concern: Removal or ablation of an incompetent saphenous (great, accessory, or small) vein may be an appropriate choice, but it is incorrect to assume that all patients require treatment of a saphenous vein. While high ligation and stripping of the great and/or small saphenous veins and/or phlebectomy were important treatments for venous insufficiency for a century, these procedures no longer are the procedures of choice in most cases. Current peer-reviewed trials and systematic reviews with meta-analysis reveal that results are similar between surgical treatments of venous insufficiency and the minimally-invasive techniques which have been developed over the past 20 years such as thermal ablation and endovenous chemical (foam) ablation. High quality published peer-reviewed data demonstrate that endovenous thermal ablation provides equivalent long term improvement in symptoms compared to vein ligation and stripping as measured by QOL improvement and by disease specific and generic instruments, change in the Venous Clinical Severity Score, and with similar incidence of recurrent varicose veins. [19,23] The minimally invasive techniques are associated with lower cost, less periprocedural disability, and less pain than the surgical techniques. [21,20] The SVS/AVF guidelines and the Practice Guidelines for Superficial Venous Disease published by the American College of Phlebology suggest endovenous ablation over ligation and stripping as the procedure of choice for patients who require elimination of saphenous reflux. [5,6,12]

    Recommendation: *Update the language to indicate that the minimally invasive techniques of endovenous thermal, chemical, mechanochemical, and cyanoacrylate adhesive ablation produce similar results to surgical ligation and stripping with less cost, periprocedural pain, and disability. Surgical treatment using ligation and stripping remains an important option in selected cases, although it is rarely recommended before endovenous ablation.*

Final comments

As representatives of our societies, we understand the challenges encountered in developing coverage policies that provide fair access to scientifically reasonable care for Medicare beneficiaries, while ensuring that our Medicare financial resources are used appropriately and responsibly. We understand that this is a national concern and are very interested in helping develop solutions to these challenges, both with NGS and with the other MACs. Like you, we are concerned with the rapid increase in use of venous procedures by some practitioners. This has been an increasing, ongoing topic at our and other vein society meetings and vein disease related publications. It is our desire to partner with you and create realistic guidelines so that the right patient receives the right care by the right doctor for the right reason. Let us explore this cooperative effort for the best care of our patients. As a result of our obligation to patients with CVD, we would like to volunteer the services of experts in our organizations to engage with the coverage policy team within NGS to develop a coverage policy for CVD that is both in accord with recognized scientific evidence as well as being responsible and rational with regard to utilizing Medicare financial resources. We hope that our collaboration will result in a coverage policy that will also be recognized as the standard to which other MACs could look for guidance. We would be happy to provide NGS with the names and curriculum vitae of potential volunteer physician members to work with you.

We would also like to work with NGS to determine a pathway to ensure that intellectual honesty is utilized by our peer physicians when making treatment recommendations to Medicare beneficiaries. We recognize the potential for misrepresentation of the condition of a patient and their disease state by physicians and their technical staff, and have specific recommendations to help alleviate this shared concern.

The Societies appreciate the opportunity to provide NGS with these comments. Please consider Mr. Dean Bender (listed below) as the contact for our consortium of societies for your response to this correspondence.

Regards,

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