

**STRIDE<sup>sm</sup> (HMO) MEDICARE ADVANTAGE****Effective Date: January 1, 2017****Subject: Varicose Vein Treatment****Policy:**

Harvard Pilgrim Stride<sup>SM</sup> (HMO) Medicare Advantage covers medically necessary treatment of varicose veins for eligible members with symptoms of significantly diseased vessels of the lower extremities that have not resolved after an appropriate course of conservative therapy.

Covered services must be:

- Reasonable and medically necessary based on the member's condition, complexity of requested service(s), and accepted standards of clinical practice;
- An essential part of active treatment of the member's medical condition;
- Ordered under a plan of care established and reviewed regularly by the attending physician caring for the member; and
- Furnished by provider(s) with appropriate state licensure, and (if indicated) accreditation/certification from an appropriate accrediting organization.<sup>1</sup>

Harvard Pilgrim Stride<sup>SM</sup> (HMO) Medicare Advantage does not cover cosmetic treatment including treatment of spider veins/telangiectases<sup>2</sup>, interventional treatment of asymptomatic varicosities, or sclerotherapy for cosmetic purposes.

- In addition, Harvard Pilgrim Stride<sup>SM</sup> (HMO) Medicare Advantage does not typically cover interventional treatment for varicose veins that develop or worsen during pregnancy as most will spontaneously resolve or improve after delivery.

**Authorization:**

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<sup>1</sup> Appropriate accrediting organizations include the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO), or another Centers for Medicare and Medicaid Services (CMS) Approved Accrediting Organization.

<sup>2</sup> The treatment of spider veins/telangiectasis (CPT code 36468) is considered medically necessary only if there is associated hemorrhage.

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*Harvard Pilgrim Stride<sup>SM</sup> (HMO) policies are based on medical science and relevant information including current Medicare coverage (including National and Local Coverage Determinations), Harvard Pilgrim medical policies, and Harvard Pilgrim Stride<sup>SM</sup> (HMO) Medicare Advantage Plan materials. These policies are intended to provide benefit coverage information and guidelines specific to the Harvard Pilgrim Stride<sup>SM</sup> (HMO) Medicare Advantage Plan. Providers are responsible for reviewing the CMS Medicare Coverage Center guidance; in the event that there is a conflict between this document and the CMS Medicare Coverage Center guidance, the CMS Medicare Coverage Center guidance will control.*

Prior authorization from Harvard Pilgrim Stride<sup>SM</sup> (HMO) Medicare Advantage is required for the following interventional treatments for varicose veins:

- Ambulatory Phlebectomy (Stab or Hook Phlebectomy)
- Endovenous Laser Ablation (EVLA)
- Endovenous Radiofrequency Ablation [EFRA]
- Ligation and Stripping
- Sclerotherapy
- Subfascial Endoscopic Perforator Surgery (SEPS)
- Transilluminated Powered Phlebectomy (TIPP)

**General Eligibility Criteria:**

Interventional treatment for symptomatic varicose veins is authorized when medical record documentation confirms ALL the following:

1. The member has symptomatic varicose veins evidenced by ANY of the following:
  - Significant pain and/or edema that impairs mobility and interferes with activities of daily living
  - Stasis dermatitis
  - Bleeding from a varicosity associated with diseased vessels of the lower extremity or extremities
  - Non-healing stasis ulcer of the lower leg
  - Recurrent episodes of superficial phlebitis
  - Refractory dependent edema
2. Symptoms of significantly diseased vessels of the lower extremities persist after at least 6 weeks of conservative therapy including the following components (as indicated)<sup>3</sup>:
  - Weight reduction (if overweight)
  - Regular exercise
  - Periodic leg elevation
  - Use of appropriate compressive bandages or prescription generated, pressure gradient compression stockings ( $\geq$  20-30 mm Hg)
  - NSAIDs unless contraindicated or not tolerated
3. Duplex ultrasound of the deep and superficial venous system (performed while patient is standing) confirms ANY of the following:

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<sup>3</sup> The reason(s) that any component of conservative therapy is not indicated or utilized, including patient intolerance, must be documented in the medical record.

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- Reflux >1 second, and venous diameter  $\geq 3$  mm in an axial vein connected to symptomatic varicose veins, leg ulcer, or area of lipodermatosclerosis<sup>4</sup>;
- Nonaxial varicose vein(s) with diameter  $\geq 3$ mm (by physical exam or ultrasound)\*;
- “Pathologic” perforating veins (i.e., outward flow of >500 msec duration, with a diameter of >3.5mm) located beneath or associated with the ulcer bed, and no post thrombotic deep system incompetence. (Ultrasound documented competency, or confirmation of successful ablation/removal of axial veins is required.)

4. Relevant Procedure-Specific Criteria (below) are met.

#### Procedure-Specific Criteria

Procedure	Medical Record Must Confirm:
<b>Ambulatory Phlebectomy</b>	<p>ANY of the following:</p> <ul style="list-style-type: none"> <li>• AAGSV with reflux &gt;1 second and venous diameter <math>\geq 3</math> mm; OR</li> <li>• Symptomatic secondary varicosities in the same vein field, in conjunction with, or after a successful main axial superficial vein ablation/removal performed within the past year.</li> </ul>
<p><b>Endovenous Laser Ablation (EVLA)</b></p> <p><i>Not authorized for patients with obliteration of deep venous system, allergy to the sclerosant, or hypercoagulable state.</i></p>	<p>Criteria 1 AND 2 are met:</p> <ol style="list-style-type: none"> <li>1. Patient's anatomy and clinical condition is amenable to the proposed treatment, including ALL the following:               <ol style="list-style-type: none"> <li>a. Absence of aneurysm in the target segment;</li> <li>b. Maximum vein diameter of 30 mm;</li> <li>c. Absence of thrombosis or vein tortuosity which would impair catheter advancement;</li> <li>d. Absence of significant peripheral arterial diseases.</li> </ol> </li> <li>2. EITHER of the following:               <ul style="list-style-type: none"> <li>• Reflux &gt;1 second and venous diameter <math>\geq 3</math> mm in GSV, SSV, or AAGSV; OR</li> <li>• Pathologic perforator vein directly associated with a venous ulcer</li> </ul> </li> </ol>
<p><b>Endovenous Radiofrequency Ablation (RFA)</b></p> <p><i>Coverage limited to patients</i></p>	<p>Criteria 1 AND 2 are met:</p> <ol style="list-style-type: none"> <li>1. Patient's anatomy and clinical condition is amenable to the proposed treatment including ALL the following:               <ol style="list-style-type: none"> <li>a. Absence of aneurysm in the target segment;</li> </ol> </li> </ol>

<sup>4</sup> Axial veins include the Great Saphenous Vein (GSV), the Small Saphenous Vein (SSV), and the Anterior Accessory Great Saphenous Vein (AAGSV). Documentation should note venous measurements along the refluxing axial veins in scope of treatment.

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Procedure	Medical Record Must Confirm:
<i>with no significant peripheral artery disease.</i>	b. Maximum vein diameter of 20 mm; AND c. Absence of thrombosis or vein tortuosity, which would impair catheter advancement. 2. EITHER of the following: <ul style="list-style-type: none"> <li>• Reflux &gt;1 second and venous diameter <math>\geq</math> 3 mm in GSV, SSV, or AAGSV; OR</li> <li>• Pathologic perforator vein directly associated with a venous ulcer</li> </ul>
<b>Ligation and Stripping</b>  <i>Not covered for patients with severe distal arterial occlusive disease, obliteration of deep venous system, allergy to the sclerosant, or hypercoagulable state.</i>	ALL the following: <ol style="list-style-type: none"> <li>1. Reflux &gt;1 second;</li> <li>2. Venous diameter <math>\geq</math> 3 mm in GSV, SSV, or AAGSV.</li> </ol>
<b>Sclerotherapy</b>  <i>Not covered for patients with severe distal arterial occlusive disease, obliteration of deep venous system, allergy to the sclerosant, or hypercoagulable state.</i>	EITHER of the following: <ul style="list-style-type: none"> <li>• Symptomatic secondary varicosities in vessels less than 4 mm in diameter (in the same vein field), in conjunction with, or after, successful main axial superficial vein ablation/removal performed within the past year<sup>5</sup>;</li> <li>• Pathologic perforator vein directly associated with a venous ulcer. (Sclerotherapy usually performed with Duplex guidance.)</li> </ul>
<b>Subfascial Interruption or Subfascial Endoscopic Perforator Vein Surgery (SEPS)</b>	Pathologic perforator vein(s) directly associated with a venous ulcer.
<b>Transilluminated Powered Phlebectomy (TIPP)</b>	ANY of the following: <ul style="list-style-type: none"> <li>• AAGSV with reflux &gt;1 second and venous diameter <math>\geq</math> 3 mm; OR</li> <li>• Symptomatic secondary varicosities (in the same vein field) in conjunction with, or after a successful main axial superficial vein</li> </ul>

<sup>5</sup> Sclerotherapy is not covered for vessels larger than 4 mm in diameter.

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<b>Procedure</b>	<b>Medical Record Must Confirm:</b>
	ablation/removal performed within the past year. (TIPP authorized for remaining veins ≥3mm in size.)

**Exclusions:**

Harvard Pilgrim Stride<sup>SM</sup> (HMO) Medicare Advantage does not cover interventional treatment for symptomatic varicosities when criteria above are not met. This includes:

- Interventional treatment of symptomatic varicosities without documentation of a failed six week trial of conservative therapy
- Sclerotherapy for vessels larger than 4 mm in diameter
- Sclerotherapy for cosmetic purposes

In addition, Harvard Pilgrim Stride<sup>SM</sup> (HMO) Medicare Advantage does not cover:

- Experimental and/or investigational treatments
- Reinjection following recanalization or failure of vein closure without recurrent signs or symptoms.
- Sclerotherapy of the saphenous vein at its junction with the deep system.
- Noncompressive sclerotherapy.
- Compressive sclerotherapy for large, extensive or truncal varicosities.
- Sclerotherapy, ligation and/or stripping of varicose veins, or endovenous ablation therapy for patients with severe distal arterial occlusive disease; obliteration of deep venous system; an allergy to the sclerosant; or a hypercoaguable state.
- Any interventional treatment that uses equipment or sclerosants not approved for such purposes by the FDA.
- Laser ablation of veins with a diameter greater than 20 mm.
- Endovenous ablation therapy in the presence of thrombosis or venous tortuosity which would impair catheter advancement.
- Sclerotherapy of the saphenous vein at its junction with the deep system
- Non-compressive sclerotherapy (injection of a sclerosant into a vein without the application of a compressive dressing) because it is not effective in producing long-term obliteration of the incompetent veins

**Coding: Codes are listed below for informational purposes. The list may not be all-inclusive, and does not imply or guarantee coverage or provider reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Harvard Pilgrim policies apply.**

<b>CPT® Code</b>	<b>Description</b>
<b>36470</b>	Injection of sclerosing solution; single vein
<b>36471</b>	Injection of sclerosing solution; multiple veins, same leg

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<b>36475</b>	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated
<b>36476</b>	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)
<b>36478</b>	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated
<b>36479</b>	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)
<b>37500</b>	Vascular endoscopy, surgical, with ligation of perforator veins, subfascial (SEPS)
<b>37700</b>	Ligation and division of long saphenous vein at saphenofemoral junction, or distal interruptions
<b>37718</b>	Ligation, division, and stripping, short saphenous vein
<b>37722</b>	Ligation, division, and stripping, long (greater) saphenous veins from saphenofemoral junction to knee or below
<b>37735</b>	Ligation and division and complete stripping of long or short saphenous veins with radical excision of ulcer and skin graft and/or interruption of communicating veins of lower leg, with excision of deep fascia
<b>37760</b>	Ligation of perforator veins, subfascial, radical (Linton type), including skin graft, when performed, open, 1 leg
<b>37761</b>	Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg
<b>37765</b>	Stab phlebectomy of varicose veins, 1 extremity; 10-20 stab incisions
<b>37766</b>	Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions
<b>37780</b>	Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure)
<b>37785</b>	Ligation, division, and/or excision of varicose vein cluster(s), 1 leg
<b>37799</b>	Unlisted procedure, vascular surgery

**Approved by UMCPD: 7/27/16**

### **Implementation/Revision History**

<b>Date</b>	<b>Update</b>
<b>7/27/16</b>	New policy, effective 1/1/17.

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## References:

1. Code of Federal Regulations: Title 42 - Public Health Chapter IV - CENTERS FOR MEDICARE & MEDICAID SERVICES- DEPARTMENT OF HEALTH AND HUMAN SERVICES, Subchapter B - MEDICARE PROGRAM, Part 410 SUPPLEMENTARY MEDICAL INSURANCE (SMI) Benefits, Subpart C - Home Health Services Under SMI
2. CMS Local Coverage Determination (LCD): Treatment of Varicose Veins of the Lower Extremity (L33575)
3. CMS LCD: Treatment of Varicose Veins of the Lower Extremities (L34536)
4. Barwell JR, Davies CE, Deacon J, et al. Comparison of surgery and compression with compression alone in chronic venous ulceration (ESCHAR study): randomised controlled trial. *Lancet*.2004; 363(9424):1854-1859
5. Bergan JJ, Schmid-Schonbein GW, Coleridge Smith PD, et al. Chronic venous disease. *N Engl J Med*.2006;355:488-498
6. Bianchi C, Ballard JL, Abou-Zamzam A, et al. Subfascial endoscopic perforator vein surgery combined with saphenous vein ablation: results and critical analysis. *J Vasc Surg*.2003;38(1):67-71
7. Blaise S, Bosson JL, Diamand JM. Ultrasound-guided sclerotherapy of the great saphenous vein with 1% vs 3% polidocanol foam: a multicentre double-blind randomised trial with 3-year follow-up. *Eur J Vasc Endovasc Surg*. 2010;39(6):779-786
8. Blomgren L, Johansson G, Dahlberg-Akerman A, et al. Changes in superficial and perforating vein reflux after varicose vein surgery. *J Vasc Surg*.2005;42(2):315-320
9. Chetter IC, Mylankal KJ, Hughes H, Fitridge R. Randomized clinical trial comparing multiple stab incision phlebectomy and transilluminated powered phlebectomy for varicose veins. *Br J Surg*. 2006;93(2):169-174
10. Christenson JT, Gueddi S, Gemayel G, et al. Prospective randomized trial comparing endovenous laser ablation and surgery for treatment of primary great saphenous varicose veins with a 2-year follow-up. *J Vasc Surg*. 2010;52(5):1234-1241
11. Coleridge Smith P. Sclerotherapy and foam sclerotherapy for varicose veins. *Phlebology*. 2009;24(6):260-269
12. Elias S, Khilnani N. Treating the small saphenous vein. *Endovasc Today*.2008;7(8):60-64
13. Frullini A, Avezzi A. Sclerosing foam in the treatment of varicose veins and telangiectases: history and analysis of safety and complications. *Dermatol Surg*.2002;28(1):11-15
14. Gloviczki P, Camerota AJ, Dalsing MC, et al. The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. *J Vasc Surg*. 2011;53(5 Suppl):2S-48S
15. Gohel MS, Barwell JR, Taylor M et al. Long term results of compression therapy alone versus compression plus surgery in chronic venous ulceration (ESCHAR): randomised controlled trial. *BMJ*. 2007;335(7610):83

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16. Greenberg DL, Scovell S. Liquid, foam, and glue sclerotherapy techniques for the treatment of lower extremity veins.[Up to Date Web site]. 06/02/2015. Available at: <http://www.uptodate.com> [via subscription only]. Accessed June 30, 2016
17. Hamel-Desnos C, Allaert FA. Liquid versus foam sclerotherapy. *Phlebology*. 2009; 24(6):240-246
18. Hirsch SA, Dillavou E. Options in the management of varicose veins, 2008. *J Cardiovasc Surg (Torino)*. 2008;49(1):19-26
19. Hoggan BL, Cameron AL, Maddern GJ. Systematic review of endovenous laser therapy versus surgery for the treatment of saphenous varicose veins. *Ann Vasc Surg*. 2009; 23(2):277-287
20. Howard DP, Howard A, Kothari A, et al. The role of superficial venous surgery in the management of venous ulcers: a systematic review. *Eur J Vasc Endovasc Surg*. 2008;36(4):458-465
21. Jia X, Mowatt G, Burr J. Systematic review of foam sclerotherapy for varicose veins. *Br J Surg*. 2007;94(8):925-936
22. Kalra M, Gloviczki P, Noel AA, et al. Subfascial endoscopic perforator vein surgery in patients with post-thrombotic venous insufficiency – is it justified? *Vasc Endovascular Sur*.2002;36(1):41-50
23. Khilnani N, Grassi C, Kundu S, et al. Multi-society consensus quality improvement guidelines for the treatment of lower extremity superficial venous insufficiency with endovenous thermal ablation from the Society of Interventional Radiology, Cardiovascular Interventional Radiology Society of Europe, American College of Phlebology, and Canadian Interventional Radiology Society. *J Vasc Interv Radiol*.2010;21(1):14-31
24. Klem TM, Schnater JM, Schutte PR, et al. A randomized trial of cryo stripping versus conventional stripping of the great saphenous vein. *J Vasc Surg*. 2009;49(2):403-409
25. Kundu S, Lurie F, Millward SF, et al. Recommended reporting standards for endovenous ablation for the treatment of venous insufficiency: joint statement of the American Venous Forum and the Society of Interventional Radiology. *J Vasc Interv Radiol*. 2007;18(9):1073-1080
26. Laredo J, Lee BB, Neville RF. Endovenous thermal ablation of the anterior accessory great saphenous vein. *Endovasc Today*.2010;9(3):36-39
27. Leopardi D, Hoggan B, Fitridge R, et al. Systematic review of treatments for varicose veins. *Ann Vasc Surg*.2009;23(2):264-276
28. Luebke T, Brunkwall J. Meta-analysis of subfascial endoscopic perforator vein surgery (SEPS) for chronic venous insufficiency. *Phlebology*.2009;24(1): 8-16
29. Luebke T, Brunkwall J. Meta-analysis of transilluminated powered phlebectomy for superficial varicosities. *J Cardiovasc Surg (Torino)*. 2008;49(6):757-764
30. Luebke T, Brunkwall J. Systematic review and meta-analysis of endovenous radiofrequency obliteration, endovenous laser therapy, and foam sclerotherapy for primary varicosis. *J Cardiovasc Surg (Torino)*. 2008;49(2):213-233.
31. Luebke T, Gawenda M, Heckencamp J, et al. Meta-analysis of endovenous radiofrequency obliteration of the great saphenous vein in primary varicosis. *J Endovasc Ther*. 2008;15(2):213-223
32. Meissner MH, Gloviczki P, Bergan, et al. Primary chronic venous disorders. *J Vasc Surg*.2007;46 Suppl S:54S-67S

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33. Merchant RF, Pichot O. Long-term outcomes of endovenous radiofrequency obliteration of saphenous reflux as a treatment for superficial venous insufficiency. *J Vasc Surg.* 2005; 42(3):502-509
34. Michaels JA, Campbell WB, Brazier JE, et al. Randomised clinical trial, observational study and assessment of cost-effectiveness of the treatment of varicose veins (REACTIV trial). *Health Technol Assess.* 2006;10(13):1-196,iii-iv
35. Morrison N, Gibson K, McEnroe S, et al. Randomized trial comparing cyanoacrylate embolization and radiofrequency ablation for incompetent great saphenous veins (VeClose). *J Vasc Surg.* Apr 2015;61(4):985-994
36. Myers KA, Jolley D. Factors affecting the risk of deep venous occlusion after ultrasound-guided sclerotherapy for varicose veins. *Eur J Vasc Endovasc Surg.* 2008; 36(5):602-605
37. National Institute for Health and Clinical Excellence (NICE). Ultrasound-guided foam sclerotherapy for varicose veins; IPG 314. [NICE Web site]. August 2009. Available at: <https://www.nice.org.uk/guidance/ipg440>. (Accessed June 30, 2016)
38. National Institute for Health and Clinical Excellence (NICE). Endovenous laser treatment of the long saphenous vein. Interventional procedure guidance IPG52. [NICE Web site]. March 2004. Available at: <https://www.nice.org.uk/guidance/ipg52> (Accessed June 30, 2016)
39. National Institute for Health and Clinical Excellence (NICE). Radiofrequency ablation of varicose veins. Interventional procedure guidance IPG8. [NICE Web site]. September 2003. <https://www.nice.org.uk/guidance/ipg8>. (Accessed June 30, 2016)
40. Nelzén O, Fransson I. True long-term healing and recurrence of venous leg ulcers following SEPS combined with superficial venous surgery: a prospective study. *Eur J Vasc Endovasc Surg.* 2007;34(5):605-12
41. Nicolaides A, Allegra C, Bergan J, et al. Management of chronic venous disorders of the lower limbs. Guidelines according to scientific evidence. *Int Angiol.* 2008;27(1):1-59
42. O'Donnell TF, Jr. The present status of surgery of the superficial venous system in the management of venous ulcer and the evidence for the role of perforator interruption. *J Vasc Surg.* 2008;48(4):1044-1052
43. Ouvry P, Allaert FA, Desnos P, et al. Efficacy of polidocanol foam versus liquid in sclerotherapy of the great saphenous vein: a multicentre randomised controlled trial with a 2- year follow-up. *Eur J Vasc Endovasc Surg.* 2008;36(3):366-370
44. Palm MD, Guiha IC, Goldman MP. Foam sclerotherapy for reticular veins and nontruncal varicose veins of the legs: a retrospective review of outcomes and adverse effects. *Dermatol Surg.* 2010;36:1026-1033
45. Nelzén O. Prospective study of safety, patient satisfaction and leg ulcer healing following saphenous and subfascial endoscopic perforator surgery. *Br J Surg.* 2000;87(1):86-91
46. Pierik EG, van Urk H, Hop WC, et al. Endoscopic versus open subfascial division of incompetent perforating veins in the treatment of venous leg ulceration: a randomized trial. *J Vasc Surg.* 1997;26(6):1049-1054

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47. Rabe E, Otto J, Schliephake D, et al. Efficacy and safety of great saphenous vein sclerotherapy using standardized polidocanol foam (ESAF): a randomised controlled multicentre clinical trial. *Eur J Vasc Endovasc Surg.* 2008;35(2):238-245
  48. Raju S, Neglen P. Clinical practice. Chronic venous insufficiency and varicose veins. *N Engl J Med.* 2009;360(22):2319-2327
  49. Rasmussen LH, Bjoern L, Lawaetz M, et al. Randomised clinical trial comparing endovenous laser ablation with stripping of the great saphenous vein: clinical outcome and recurrence after 2 years. *Eur J Endovasc Surg.* 2010;39(5):630-635
  50. Rutgers PH, Kitslaar PJ. Randomized trial of stripping versus high ligation combined with sclerotherapy in the treatment of the incompetent greater saphenous vein. *Am J Surg.* 1994;168(4):311-315
  51. Sato DT, Goff CD, Gregory RT, et al. Subfascial perforator vein ablation: comparison of open versus endoscopic techniques. *J Endovasc Surg.* 1999;6(2):147-154
  52. Society of Interventional Radiology (SIR). Position statement on endovenous ablation. [SIR Web site]. December 2003. Available at: [http://www.sirweb.org/clinical/cpg/SIR\\_venous\\_ablation\\_statement\\_Final2015.pdf](http://www.sirweb.org/clinical/cpg/SIR_venous_ablation_statement_Final2015.pdf) (Accessed June 30, 2016)
  53. Sparks SR, Ballard JL, Bergan JJ, et al. Early benefits of subfascial endoscopic perforator surgery (SEPS) in healing venous ulcers. *Ann Vasc Surg.* 1997;11(4):367-373
  54. Stuart WP, Adam DJ, Allan PL, et al. Saphenous surgery does not correct perforator incompetence in the presence of deep venous reflux. *J Vasc Surg.* 1998;28(5):834-838
  55. Stucker M, Kobus S, Altmeyer P, Reich-Schupke S. Review of published information on foam sclerotherapy. *Dermatol Surg.* 2010;36:983-992
  56. Tenbrook JA, Iafrati MD, O'Donnell TF et al. Systematic review of outcomes after surgical management of venous disease incorporating subfascial endoscopic perforator surgery. *J Vasc Surg.* 2004;39(3):583-589
  57. Theivacumar NS, Darwood R, Gough MJ. Neovascularisation and recurrence 2 years after varicose vein treatment for sapheno-femoral and great saphenous vein reflux: a comparison of surgery and endovenous laser ablation. *Eur J Vasc Endovasc Surg.* 2009; 38(2):203-207
  58. Tisi PV, Beverley C, Rees A. Injection sclerotherapy for varicose veins. *Cochrane Database Syst Rev.* 2006;(4):CD001732
  59. Van Gent WB, Hop WC, van Praag MC, et al. Conservative versus surgical treatment of venous leg ulcers: a prospective, randomized, multicenter trial. *J Vasc Surg.* 2006;44(3):563-71
  60. Van der Velden SK, Biemans AA, De Maeseneer MG, et al. Five-year results of a randomized clinical trial of conventional surgery, endovenous laser ablation and ultrasound-guided foam sclerotherapy in patients with great saphenous varicose veins. *Br J Surg.* Jul 1 2015
  61. Zierau U. Sealing Veins with the VenaSeal Saphenon Closure System: Results for 795 Treated Truncal Veins after 1000 Days. *Vasomed.* 2015;27:124-127
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## Medical Review Criteria

### Varicose Vein Treatment

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