Washington State Health Care Authority

Health Technology Clinical Committee
Draft Findings and Decision

Topic: Selected treatments for varicose veins
Meeting date: May 19, 2017
Final adoption:

Meeting materials and transcript are available on the HTA website:
www.hca.wa.gov/about-hca/health-technology-assessment/meetings-and-materials

Number and coverage topic:

20170519A - Selected treatments for varicose veins

HTCC coverage determination:

Treatment for varicose veins is **a covered benefit with conditions**.

HTCC reimbursement determination:

Limitations of coverage:

The following treatments for varicose veins are cover with conditions when indications/conditions are present:

- Endovenous Laser Ablation (EVLA)
- Radiofrequency Ablation (RFA)
- Sclerotherapy
- Phlebectomy

Indications (all required to be present):

- Tributary varicose veins >= 3 mm AND
- Demonstrated reflux in the affected vein AND
- Minimum of 3 months of symptoms of pain and/or swelling sufficient to interfere with instrumental ADLs, or presence of complications (e.g. ulceration, bleeding, recurrent thrombophlebitis).

Non-covered indicators:

Exclusions: pregnancy, active infection, peripheral arterial disease, deep vein thrombosis (DVT).

Agency contact information:

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

HTCC coverage vote and formal action:

Committee decision

Based on the deliberations of key health outcomes the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee decided that the current evidence on selected treatments of varicose veins is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for treatment of varicose veins compared to the more invasive surgical intervention vein stripping. The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to cover varicose veins with conditions.

	Not covered	Covered under certain conditions	Covered unconditionally
Selected treatments for varicose veins	0	9	0

Discussion

The committee reviewed and discussed the available studies of treatment of varicose veins. Details of study design, inclusion criteria, outcomes and other factors affecting study quality were discussed. A majority of committee members found the evidence sufficient to determine that select treatment for varicose veins were equivalent for safety and equivalent for effectiveness compared to alternatives for some conditions. A majority of the committee voted to cover with conditions, selected treatment for varicose veins.

Limitations

Exclusions include pregnancy, active infection, peripheral arterial disease, and deep vein thrombosis (DVT).

Action

The committee checked for availability of a Medicare national coverage decision (NCD). Medicare does have a NCD for treatment of varicose veins.

The committee discussed clinical guidelines identified for varicose vein treatment from the following organizations:

- Society for Vascular Surgery (SVS) and the American Venous Forum (AVF): the care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines, 2011.
- Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery (SVS) and the American Venous Forum (AVF), 2014.
- Diagnosis and management of varicose veins in the legs: National Institute for Health and Care, 2013. (NICE)
- Management of chronic venous disease: clinical practice guidelines of the European Society for Vascular Surgery (ESVS). 2015.

The committee's determination is consistent with these guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on selected treatment of varicose veins for public comment; followed by consideration for final approval at the next public meeting.

Health Technology Clinical Committee Authority:

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.

Washington State Health Care Authority

Selected treatments for varicose veins

Draft findings and decision
Timeline, overview and comments

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on **Selected treatments for varicose veins**.

Timeline

Phase	Date	Public Comment Days
Technology recommendations published	February 26, 2016	
Public comments	February 26, to March 10, 2016	**14**
Selected technologies published	April 18, 2016	
Public comments	April 19, to May 18, 2016	**30**
Draft key questions published	October 21, 2016	
Public comments	October 22, to November 4, 2016	**14**
Final key questions published	December 20, 2016	
Draft report published	February 28, 2017	
Public comments	March 1, to 30, 2017	**30**
Final report published	April 20, 2017	
Public meeting	May 19, 2017	
Draft findings & decision published	June 1, 2017	
Public comments	June 2, to 16, 2017	**15**

Overview

Category	**Comment Period** June 2, to June 16, 2017	**Cited Evidence**
Patient, relative, and citizen	0	0
Legislator and public official	0	0
Health care professional	1	0
Industry & manufacturer	1	0
Professional society & advocacy organization	0	0
Total	**2**	**0**

Comments

	Respondents	Representing	Cited Evidence
☐ 1.	Brian Ferris	Lake Washington Vascular Surgeons	No
☐ 2.	Joni Holtz	Senior Program Manager, Medtronic Health Economics, Policy & Payment EndoVascular	
	Alex C. Au-Yueng	Senior Director Health Economics, Policy & Payment Coronary/ APV, Medtronic	No

From:	Brian Ferris
To:	HCA ST Health Tech Assessment Prog
Subject:	Email regarding information on your website.
Date:	Tuesday, June 13, 2017 5:06:23 PM

To Whom it May Concern,

I am writing you in response to the proposed draft:
https://www.hca.wa.gov/assets/program/varicose-veins-draft-findings-decision-20170519.pdf
Your posting pertains to **Selected treatments for varicose veins, Meeting date: May 19, 2017**

I suggest a critical clarification regarding treatment of varicose veins. First, you suggest varicose branches or tributaries >3mm. I suggest you specifically mention truncal saphenous veins as it pertains to thermal ablation (radio frequency or laser). I also suggest you specifically include the Varithena product/procedure as it is an indicated therapy for symptomatic truncal reflux. This is critical in cases where truncal veins cannot be cannulated and traversed with a catheter.

thanks,
Dr. Brian Ferris
Lake Washington Vascular Surgeons
Bellevue, Kirkland, Issaquah, and Seattle, Washington
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June 16, 2017

Washington State Health Care Authority
Health Technology Assessment Program
P.O. Box 45502
Olympia, WA 98504-5502
Attn: Josh Morse, HTA Program Director

Subject: Health Technology Assessment Topic Selection - Varicose Veins

Dear Mr. Morse,

Medtronic is pleased to provide this response to the public comment on the varicose veins draft findings and coverage decision.

Overall, we support the draft coverage decision. We request, however, that the language be made more precise in describing the limitations of coverage and non-covered indicators to ensure patients benefiting from the therapies are not excluded from coverage.

More specifically, in the "Limitations of Coverage" section, we encourage you to explicitly note that patients do not have to go through a 3-month conservative treatment requirement with the use of compression stockings be eligible for coverage. At the May 19th meeting, citing the lack of evidence, the panel agreed to remove the 3-month conservative treatment requirement with the use of compression stockings. We support this decision and just ask that language be added to ensure that providers and beneficiaries are informed that failure on compression stockings is not a condition of coverage.

Second, in the "Non-Covered Inidcators" section, we request additional language be added to three of the indicators. Currently the draft policy lists the non-covered indicators as follows: pregnancy, active infection, peripheral arterial disease, deep vein thrombosis (DVT).

Our proposed language refinement is as follows (noted in red):

- **Active infection with the exception of venous stasis ulcer**:
  Ulcers are not typically called infections, but could be "infected" – classical surgical theory is to not operate on anyone with an infection, but in this situation, the infection is due to the ulcer. The underlying problem is the venous insufficiency and thus treatment should not be delayed until after the infection clears. Based on the following 2 quotes:
  "axial reflux in the superficial veins is poorly tolerated by the skin and subcutaneous tissues of the lower extremities and deserves surgical correction" Lurie et al "Invasive treatment of deep venous disease; a UIP consensus, Int Angiol 2010;29:199-204, further in the AVF/SVS guidelines (guideline 6.1) "To decrease recurrence of venous ulcers, we recommend ablation of the incompetent superficial veins in addition to compression therapy, grade 1A.

- **Significant peripheral arterial disease**:
  We would like to draw your attention to the Hayes evidence review, Noridian LCD referenced on page 79 and Group Health's policy referenced on page 80, both state "significant peripheral arterial disease" as the non-covered indication.

- **Acute deep vein thrombosis (DVT)**
  Acute DVT is a life-threatening pathology that could lead to pulmonary embolism and sudden death and therefore requires immediate intervention (above venous disease). Chronic DVT however is by definition, chronic and should not limit access to superficial interventions.

Next year, we encourage the agency to conduct a targeted update to this review to include therapies like VenaSeal™ that have or will be introduced to the endovenous space to ensure the review and the associated coverage policy aligns with care practices.

Medtronic's VenaSeal™ system is an innovative, non-thermal, non-tumescent, non-scleroscant therapy option for varicose veins and chronic venous insufficiency, representing the next generation in endovascular technology. This device was approved by the FDA through a PMA submission with level 1 evidence in February 2015. Please reference
Medtronic appreciates the opportunity to continue to support the HCA in its review of the topics and appreciates the ongoing transparency this agency has undertaken that allows for public comments.
If you have any questions regarding this, please feel free to contact me at (707) 591-2246 or via email at alex.c.au-yeung@medtronic.com or Joni Holtz at (763)591-3547) or via email at joni.k.holtz@medtronic.com.

Sincerely,

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[redacted]
Alex C. Au-Yeung
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Coronary / APV
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VenaSeal Clinical Studies

Study Title	No. of Subjects	Published vs Presented	Primary Effectiveness Endpoint	Primary Effectiveness Results
Feasibility	38	Published	Vein closure at 6 months, no discrete segment of patency > 5cm), assessed by Investigator	94.70%
Feasibility	38	Published	Vein closure at 36 months, no discrete segment of patency > 5cm), assessed by Investigator	94.70%
eSCOPE	70	Published	Vein closure at 6 months, no discrete segment of patency > 5cm), assessed by Investigator	94.30%
eSCOPE	70	Published	Vein closure at 12 months, no discrete segment of patency > 5cm), assessed by Investigator	90.00%
eSCOPE	70	Presented	Vein closure at 36 months, no discrete segment of patency > 5cm), assessed by Investigator	88.50%
VeClose Pivotal Study Randomized Control Trial	242	Published	Vein closure at 3 months (no discrete segment of patency > 5 cm), assessed by independent vascular ultrasound core laboratory (LOCF)	99.10%
VeClose Pivotal Study Randomized Control Trial	242	Published	Vein closure at 12 months (no discrete segment of patency > 5 cm), assessed by independent vascular ultrasound core laboratory (LOCF)	97.20%
VeClose Pivotal Study Randomized Control Trial	242	Presented	Vein closure at 24 months (no discrete segment of patency > 5 cm), assessed by independent vascular ultrasound core laboratory (LOCF)	95.30%
VeClose Pivotal Study Randomized Control Trial	242	Presented	Vein closure at 36 months (no discrete segment of patency > 5 cm), assessed by independent vascular ultrasound core laboratory (LOCF)	94.40%
WAVES	50	Published	Vein closure at 1month, no discrete segments of patency > 5 cm, assessed by Investigator	100.00%
WAVES	50	Presented	Vein closure at 1month, 3 month, and 12 month, no discrete segments of patency > 5 cm, assessed by Investigator	98%