I have no conflicts with this talk

Consultant to

Angiodynamics,

BTG, Amsel, Veniti, Vascular Insights

Treatment Of C2 Varicose Veins- Should Never Be Reimbursed

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Is C2 Treatment Medical Necessary?

Or

Is it Mostly a Cosmetic Problem?

My Insurance Company Denied Me Coverage Doctor?!

Emotionally Charged

Difficult for MDs

Preventive care

Loss of revenue

Difficult for Patients

Out of pocket $

Expectations

Difficulty for Insurance

insurance cost

Over 20 million patients with GSV reflux

SO WHAT IS/ARE THE DEFINITION(S) OF MEDICAL NECESSITY?

Medical necessity is a United States legal doctrine, related to activities which may be justified as reasonable, necessary, and/or appropriate, based on evidence-based clinical standards of care.

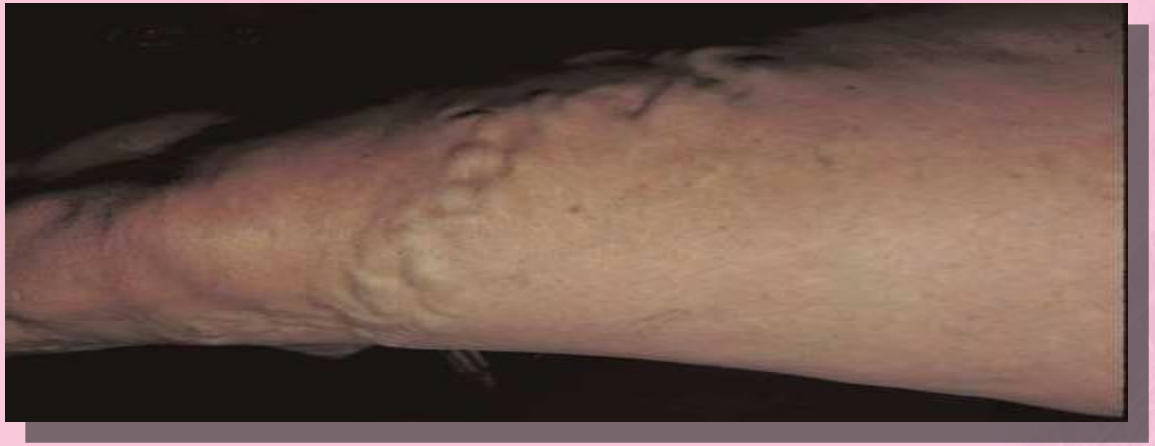
- **The definition of the term *medical necessity* varies:**

- **Providers point of view**
  - *Medical necessity* is used by managed care plans as a rationing tool to deny access to necessary care, especially to those patients with special health care needs.

- **The definition of the term *medical necessity* varies:**

- **Federal government's point of view**
  - Medicare and Medicaid statutes authorize payment only for *medically necessary* care and impose criminal and civil liability for filing claims that are "medically unnecessary"

SO IS THERE MEDICAL RATIONALE TO TREAT C2 DISEASE?



C0	no visible or palpable signs of venous disease
C1	telangiectasias or reticular veins
C2	varicose veins
C3	edema
C4	skin changes C4a: pigmentation and/or eczema C4b: lipodermatosclerosis and/or atrophie blanche
C5	healed venous ulcer
C6	active venous ulcer
S	symptoms including ache, pain, tightness, skin irritation, heaviness, muscle cramps, as well as other complaints attributable to venous dysfunction
A	asymptomatic

Clinical Classifications with examples

C_1 - telangiectasias or reticular veins

C_2 - varicose veins

C_3 - edema & corona

C_4 - lipodermato-sclerosis and eczema

C_5 - ulcer scar

C_6 - active ulcer

Distribution and prevalence of reflux in the superficial and deep venous system in the general population – results from the Bonn Vein Study, Germany

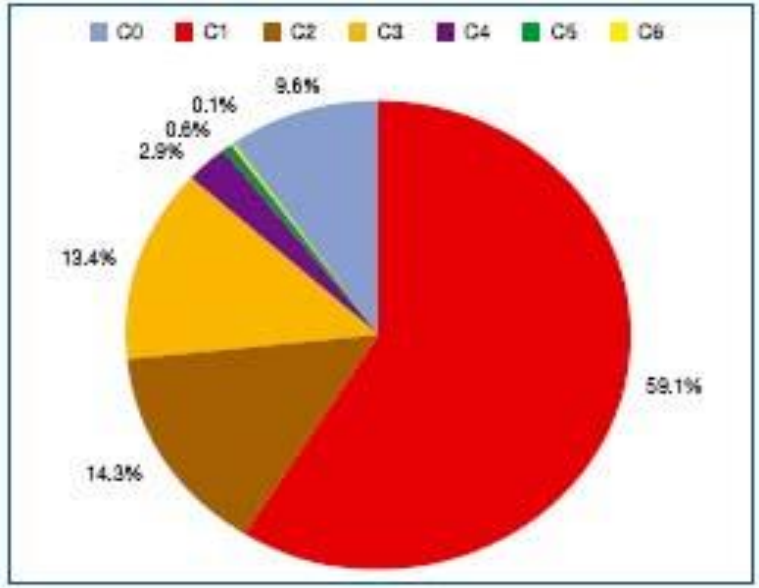


Table I. Description of the study population (N = 3016) included in prevalence analyses

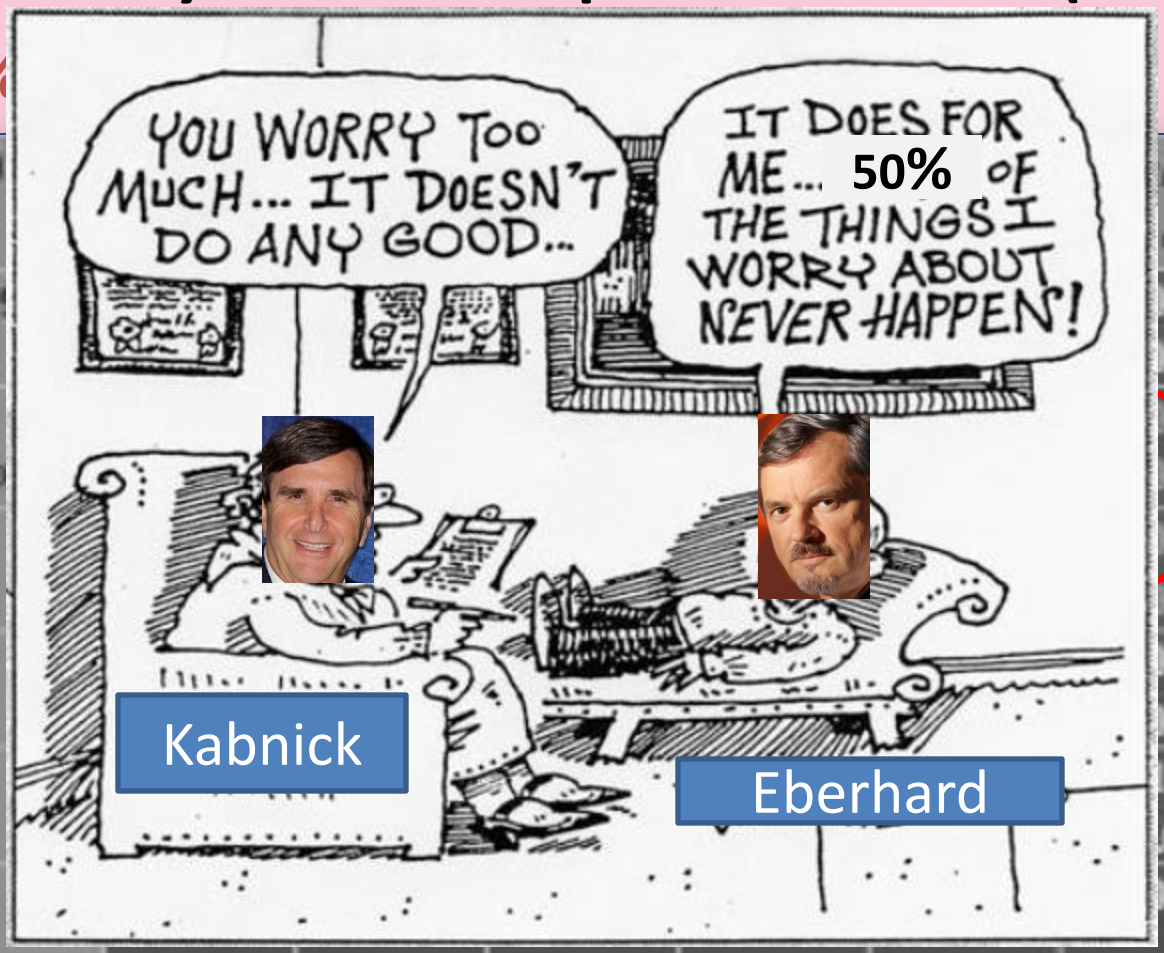
	N	%
Gender		
Female	1694	56.2
Male	1322	43.8
Age		
18-39 y	1013	33.6
40-59 y	1128	37.4
60-79 y	875	29.0
Body mass index (kg/m^2)		
<20	43	1.4
20-24.9	1278	42.5
25-29.9	1153	38.3
30-34.9	508	16.9
≥35	26	0.9
missing	8	
C stages of the CEAP classification		
C0	290	9.6
C1	1777	59.0
C2	432	14.3
C3	407	13.5
C4	86	2.9
C5-C6	22	0.7
missing	2	

Prevention of Disease

Progression

Bonn Vein II Study

- 31.8% in 6 years with saphenous reflux (4.8%/y)
- 19.8% (3 %/y)



Rabe E, Pannier F, Ko A, et al. Incidence of Varicose Veins, Chronic Venous Insufficiency, and Progression of Disease in the Bonn vein Study II.

Chronic venous disease progression and modification of predisposing factors

73 patients were prospectively evaluated using physical, DUS and classified by CEAP. After 5 years of follow-up, development of new sites of reflux among the contralateral asymptomatic limbs

3% progressed from C2 to C4 disease

C_0	5	...	2[a]	5[a]	5[a]	6[a]	...	...
C_1	...	6	3[a]	...	...	...	...	...
C_2	...	...	...	...	...	...	2	2[a]

The Edinburgh Vein Study

47.4% of patients with C2 disease showed clinical deterioration over a 13-year period.

Rate of disease progression was 3.54% per annum

Robertson L, Boghossian S, Evans C, et al. Incidence and Risk Factors for Development of Varicose Veins in the General Population: Edinburgh Vein Study. Abstract presented at: American Venous Forum, 23rd annual meeting; 2011; San Diego, CA

Annals of the Royal College of Surgeons of England (1991) *vol.* 73, 223–226

The varicose vein waiting list: results of a validation exercise

S F Brewster BSc MB BS
Senior House Officer
S Nicholson MD FRCS
Lecturer in Surgery

One of the earliest longitudinal studies documenting the details of

Since initial presentation, 68 patients (22%) had developed skin changes and 12 patients (3.9%) developed venous ulcerations

- Patients with uncomplicated varicose veins, disease progression to higher C stages is likely to be somewhere between **3.5% and 7% per annum**

- **Skin changes and deep venous incompetence** are associated with a significantly higher risk of venous ulceration.

Meissner Phlebology 2012;27 Suppl 1:27–33

- The rate of progression from skin changes to venous ulceration is unknown, but based on the available evidence, it is estimated to be in the in the region of **1% to 2%** per annum.

Meissner Phlebology 2012;27 Suppl 1:27–33

Societal costs of chronic venous disease in CEAP C4, C5, C6 disease

E Rabe* and F Pannier†
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European countries and the USA

Hundreds of millions of Euros each year for the treatment of superficial reflux, the treatment of venous ulcers, and the cost of days lost from work due to venous disorders

In the USA, venous ulcers caused the loss of 2 million work days per year in 2002

Am J Surg 2002;183:132–7

J Vasc Surg. 2010 Nov;52(5 Suppl):39S-44S.

Fifty percent reduction in venous ulcer prevalence is achievable - Swedish experience.

Nelzén O.

Cohorts	Estimated target population in Sweden (*in England*)	Number needed to treat = NNT
All with varicose veins (VV)	2 000 000 (*11 000 000*)	400
All with symptomatic VV	500 000 (*2 800 000*)	100
All with VV + edema	400 000 (*2 000 000*)	80
All with skin changes	80 000 (*400 000*)	8

C2 DISEASE AND QUALITY OF LIFE

- Varicose Veins symptoms--- non- specific?
  - Prevalence symptoms increase with age

Thus, the treatment of symptomatic varicose veins based upon quality-of-life concerns has merit

- (S

Bradbury A, et al. BMJ 1999;318:353–6
Biland L, Acta Chir Scand Suppl 1988;544:9–11
Weddell JM., 1966. Br J Prev
mith JJ, J Vasc Surg 1999;30:710–9)

Role of Compression In C2 Disease

- Compression is a standard therapy for the management of symptomatic varicose veins

  Role of compression in advanced venous disease is well supported by the evidence

  – **Clinical benefit of compression in C2 disease is substantially less clear**

  – **Reactive study --- 30% of patients with varicose veins will get some symptomatic relief**

HealthTechnolAssess 2006;10:1–196, iii–iv

What is the Evidence supporting value of surgery in Improving quality of life with C2 Disease?

Health Technol Assess. 2006 Apr;10(13):1-196, iii-iv.

Randomised clinical trial, observational study and assessment of cost-effectiveness of the treatment of varicose veins (REACTIV trial).

Michaels JA, Campbell WB, Brazier JE, Macintyre JB, Palfreyman SJ, Ratcliffe J, Rigby K.

Academic Vascular Unit, University of Sheffield, UK.

- Randomized patients with varicose veins to conservative management versus surgery
- Significantly greater improvement in symptoms and quality of life in the surgical group.
- 31% of patients did have some improvement with compression hosiery alone
- 51.6% of patients assigned to conservative management crossed over to surgical treatment by the third year of follow-up
- **Surgery was more expensive**

C2 DISEASE WITH PHLEBITIS OR BLEEDING

Annals of the Royal College of Surgeons of England (1991) *vol.* 73, 223–226

The varicose vein waiting list: results of a validation exercise

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- During four years of follow-up on the surgical waiting list
  - **Thrombophlebitis 5.2%**
  - **Haemorrhage** or bruising developed in only **3.2%** of patients

Acute complications of varicose veins are an accepted indication for intervention

- These complications are relatively uncommon

What is the medical rationale for the treatment of varicose veins?

M H Meissner
Department of Surgery, University of Washington School of Medicine, Seattle, WA, USA

Table 1 Indications for the treatment of varicose veins in C2 d

C

Li

Th

Bleeding

Prevention of disease progression

"the progression of isolated C2 disease to advanced chronic venous insufficiency occurs infrequently and the role of treatment to prevent such progression remains undefined at present"

Phlebology 2012;27 Suppl 1:27–33

Conclusions

- Is It Cost effective to do Routine surgical treatment for C2 Disease to prevent progression?

- Likely Less Cost Effective than strategies to identify C2 patients at high risk of disease progression

Conclusions

- **Less Cost Effective than strategies to identify C2 patients at high risk of disease progression**

CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE
CONTROVERSIES & UPDATES IN VASCULAR SURGERY
JANUARY 23-25 2014
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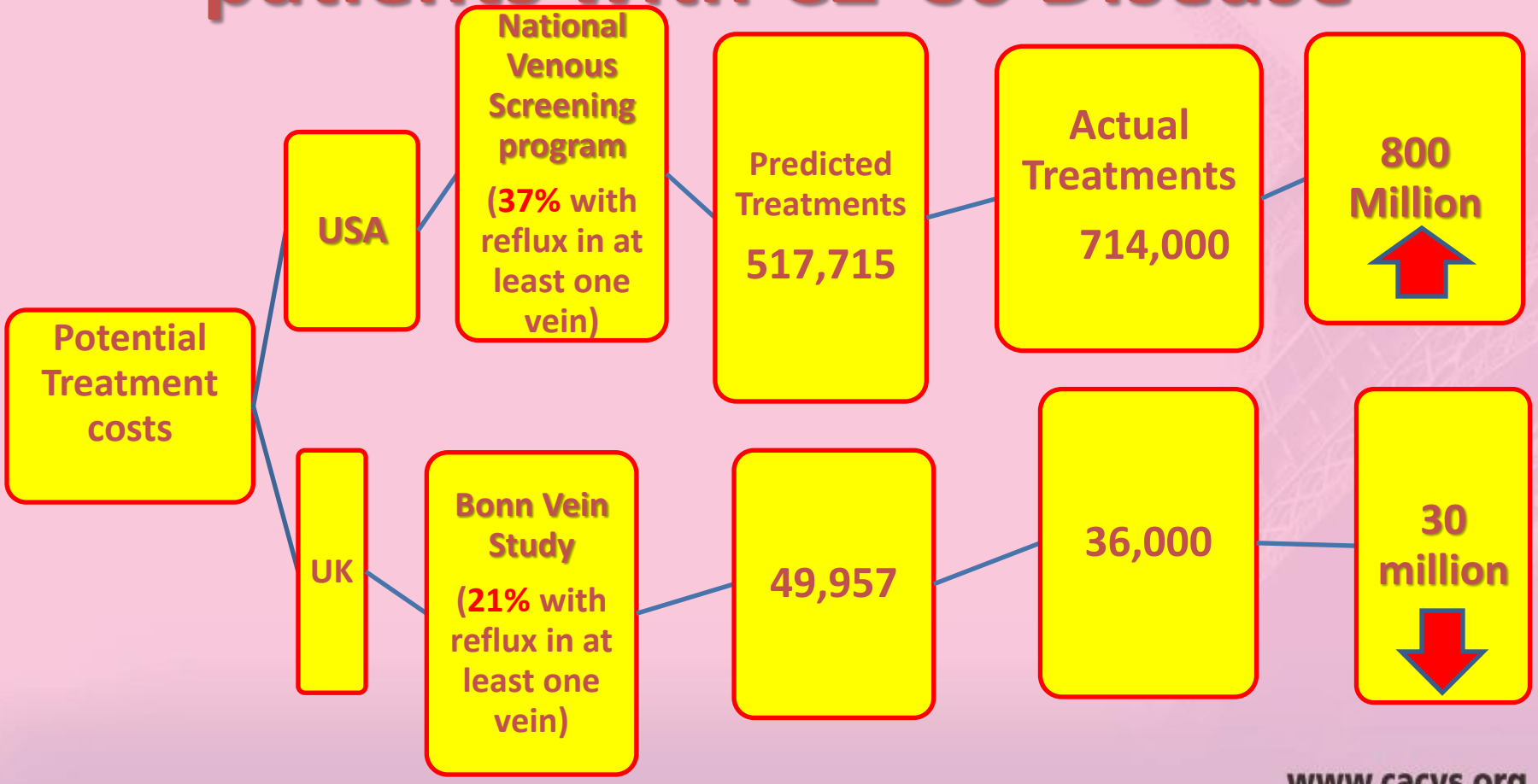
H M Moore, AH Davies
Phlebology 2012;27:307-326

Disparity in health-care provision in patients with C2-C6 Disease



INSURANCE COMPANIES AND MEDICALLY NECESSARY SUPERFICIAL VENOUS DISEASE

SVS/AVF Guidelines

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

Peter Gloviczki, MD,[a] Anthony J. Comerota, MD,[b] Michael C. Dalsing, MD,[c] Bo G. Eklof, MD,[d]

Weakly (Grade 2C) recommend moderate compression for patients with symptomatic varicose veins

Compression is not recommended as primary treatment in patients who are candidates for saphenous ablation (Grade 1B).