

## **Consensus statement and petition for use of pneumatic compression devices for PAD**

To: [MedCACpresentations@cms.hhs.gov](mailto:MedCACpresentations@cms.hhs.gov)

Or by post: Maria Ellis, Executive Secretary for MEDCAC, Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, Coverage and Analysis Group, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244

### Statement

Studies published in peer reviewed journals including randomized control trials have demonstrated the efficacy of arterial pneumatic compression devices (APCDs) in treating patients with peripheral arterial disease (PAD); for intermittent claudication and critical limb ischemia. My personal experience in vascular patients strongly supports its use.

APCDs should therefore be covered as reasonable and necessary with consistent, nation-wide coverage as follows.

For intermittent claudication, APCDs should be available to prescribing physicians when the patient is unwilling or unable to undergo a supervised exercise program or if the supervised exercise program was unable to provide satisfactory results.

For patients with critical limb ischemia, APCDs should be available to prescribing physicians:

1. As a first line therapy for limbs not in immediate need for surgical revascularization or,
2. For limbs that are not candidates for surgical revascularization or,
3. For limbs that have had failed revascularization.

Prescriptions should require an initial treatment for at least three months to allow for collateral artery formation.

APCDs need a separate policy from venous / lymphatic types of pneumatic compression devices since they apply very different modes of compression (short duration pulses at high pressure) for completely different medical indications.

The timing and pressures associated with venous / lymphatic types of pneumatic compression are contraindicated for PAD.

Gianni Belcaro, Circulation, Sciences, Vascular Surgery, Angiology, MD, PhD  
Director Irvine3 labs  
Chieti University  
[cardres@abol.it](mailto:cardres@abol.it)

<http://www.irvine3.com/>

## References

1. Effect of Intermittent Pneumatic Compression of Foot and Calf on Walking Distance, Hemodynamics, and Quality of Life in Patients with Arterial Claudication, A Prospective Randomized Controlled Study with 1-Year Follow-up. Konstantinos Delis and Andrew N. Nicolaides. *Annals of Surgery* March 2005; Volume 241, Number 3:431-4.
2. Rapid Foot and Calf Compression Increases Walking Distance in Patients with Intermittent Claudication: Results of Randomized Study. Ramaswami, G.; D'Alaya, M.; Hollier, L.; Deutsch, R.; McElhinney, A.J. Houston, Tex; Brooklyn and Bronx, NY; New Orleans, LA; and San Diego, CA. *J Vasc Surg*, May 2005; Volume 41, Number 5:794-801.
3. Improvement of the Walking Ability in Intermittent Claudication due to Superficial Femoral Artery Occlusion with Supervised Exercise and Pneumatic Foot and Calf Compression: A Randomized Controlled Trial. Kakkos, S.K.; Geroulakos, G.; Nicolaides, A.N. Imperial College of Science, Technology and Medicine, London U.K. *Eur J Vasc Endovasc Surg*. August 2005; Volume 30: 164-175.
4. Using intermittent pneumatic compression therapy to improve quality of life for symptomatic patients with infrapopliteal diffuse peripheral obstructive disease. Chang ST, Hsu JT, Chu CM, Pan KL, Jang SJ, Lin PC, Hsu HC, Huang KC. *Circ J*. 2012;76(4):971-6. Epub 2012 Feb 4. Division of Orthopedic Surgery, Chia-Yi Chang Gung Memorial Hospital, 6 Sec. West Chai-Pu Road, Pu-TZ City, Chai-Yi Hsien, Taiwan. cst1234567@yahoo.com.tw
5. Randomized study on the effects of different strategies of intermittent pneumatic compression for lower limb claudication. A. Berni; L. Tromba; L. Falvo; F. Tartaglia; M. Sgueglia; S. Blasi; P. Polichetti. "Sapienza" University of Rome, Italy, Department of Surgical Sciences. *G Chir Vol*. 30 - n. 6/7 - pp. 269-273. Giugno-Luglio 2009.
6. Intermittent Compression Pump for Nonhealing Wounds in Patients with Limb Ischemia. The Mayo Clinic Experience (1998-2000). Montori, V.M.; Kavros S.J.; Walsh E.E.; and Rooke T.W. Mayo Clinic, Rochester, MN, USA. *Int Angiol* 2002;21:360-6.
7. Improving limb salvage in critical ischemia with intermittent pneumatic compression: a controlled study with 18-month follow-up. Kavros, S.J., et al., *J Vasc Surg*, 2008. 47(3): p. 543-9.
8. Sequential Compression Biomechanical Device in Patients with Critical Limb Ischemia and Nonreconstructible Peripheral Vascular Disease. Sultan, S.; Hamada, N.; Soylu, E.; Fahy, A.; Hynes, N.; and Tawfik, W. Dept. Vasc. And Endovasc. Surg., Western Vascular Institute, and Dept. Vasc. And Endovasc. Surg. Galway Clinic, Galway, Ireland. Presented at the 2010 Vascular Annual Meeting of Society for Vascular Surgery, Boston, Mass., June 14, 2010. *J Vasc Surg* 2011;54:440-7.
9. The ArtAssist<sup>®</sup> Device in chronic lower limb ischemia. A pilot study. Louridas, G.; Saadi, R.; Spelay, J.; et al. Section of Vascular Surgery, the Department of Surgery and the Department of Rehabilitation Medicine, University of Manitoba, St. Boniface Hospital and Health Sciences Centre, Winnipeg, Manitoba, Canada. *Int Angiol* 2002;21:28-35.
10. Limb Salvage Using High-Pressure Intermittent Compression Arterial Assist Device in Cases Unsuitable for Surgical Revascularization. van Bemmelen, P.; Gitlitz, D.B.; Faruqi, R.M.; Weiss-Olmanni, J.; Brunetti, V.A.; Giron, F.; Ricotta, J.J. Dept of Vascular Surgery and Podiatry, VA Medical Center, Northport, NY; and the Division of Vascular Surgery, State University of New York at Stony Brook. *Arch Surg*. 2001;136:1280-1285.
11. Critical Limb Ischemia Successfully Treated by Intermittent Pneumatic Compression. Yoram Moses, MD and Boris Yoffe, MD, FACS. Department of General and Vascular Surgery, Marailai Medical Center, Ashkelon, Israel. *IMAJ* ;Vol 4, Issue 9: September 2002.
12. Hemodynamic effects of intermittent pneumatic compression in patients with critical limb ischemia. Labropoulos, Nicos; Leon, Luis R; Bhatti, Ahmad; Melton, Steven; Kang, Steven S.; Mansour, Ashraf M.; Borge, Marc. The Department of Surgery, Loyola University Medical Center, Maywood Ill. *Journal of Vascular Surgery*. October 2005; Volume 42, Number 4: 710-716.
13. Intermittent pneumatic compression therapy for chronically ischemic legs. Ishabushi, H.; Ohta, T.; Hosaka, M.; Sugimoto, I.; Nehei, T.; Kawanishi, J., Dept. of Vascular Surgery, Aichi Medical University, Japanese Society for Limb Salvage Research, Breakthrough in the treatment for critical limb ischemia in Japan 2004; 65-71.