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Society of Interventional Radiology
The vision to heal

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Submitted via email to: DMEMDs@noridian.com, PCDRecon@noridian.com and medicalpolicy@noridian.com

Re: SIR supports SVM in the request for LCD Reconsideration Call of CMS' coverage of Local Coverage Determination (LCD) ID DL33829 for intermittent pneumatic compression (IPC) devices to treat chronic limb-threatening ischemia (CLTI) in the upper and lower extremities.

Dear Dr. Ballyamanda,

The Society of Interventional Radiology (SIR) is a nonprofit, professional medical society representing more than 8,000 practicing interventional radiology physicians, trainees, students, scientists, and clinical associates, dedicated to improving patient care through the limitless potential of image-guided therapies.

SIR appreciates the opportunity to comment on the proposed draft Local Coverage Determination (LCD) for Pneumatic Compression Devices ID DL33829. The Society, and its respective stakeholders, support the coverage request of arterial IPC pump devices to treat critical limb-threatening ischemia (CLTI) of the upper and lower extremities. We ask that the coverage be extended for patients who have no alternative surgical or endovascular revascularization options and are at high risk for tissue loss and/or amputation. The arterial ICP device is currently coded under HCPCS E0675 - "Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system)."

Current research supporting this procedure

According to the current LCD, "IPC has been previously shown to increase the arterial flow rate in the popliteal artery and is thought to promote the release of angiogenic growth factors and endothelial nitric oxide,….[but] human clinical studies do not confirm these hypotheses.[5]" However, Oresanya et al., in their systematic review and meta-analysis clearly stated that "results from multiple randomized

controlled trials suggest that limb compression is beneficial in improving ACD" within human trials. Most importantly, the study confirms that the arterial flow, cutaneous blood flow, growth factors, and nitric oxide are all significantly enhanced using IPC to treat CLTI.

According to M. Mark Melin, MD FACS RPVI FACCWS, and his distinguished group of ambassadors to prevent limb amputations, the draft LCD discounts physiological and anatomical studies and refuses to use them to evaluate efficacy. Even in situations wherein efficacy is proven, the LCD then dismisses the studies for having a small sample size. However, when reviewing the evidence provided to rebuttal this notion, one can see that the average sample size for the human clinical trials was at least 34 participants with a $p < 0.05$.

The LCD also repeatedly indicates that the current research and market data is insufficient to adequately designate arterial IPC as safe, effective, reasonable, and necessary to provide our patients with a viable option to amputation where no other options are available. It harbors the narrative that even if the appropriate sample size were selected for a clinical trial, there would still be an inappropriate assessment of the target population. Why? The LCD stipulates that patients studied do not represent Medicare eligibility. The most susceptible patient populations are unlikely to improve outcomes without first improving access to higher intensity quality care measures. However, as one may dig deeper into the target population, mostly African Americans; the clear concise is that these communities are far less likely to access more advanced surgical options for limb salvage. Thus, given a proper workup for CLI, providing patients with all available treatments to prevent amputation makes good sense.

Finally, the DME MACs have indicated that they respond to a collection of vascular and surgical specialties with extensive clinical and academic research experience. However, by failing to accept the recommendations made by key stakeholders such as SVM and SIR, then DME MAC medical directors are reinforcing the lower quality of life for patients and leaving them with only one option, amputation. Therefore, if there is a need to consult with experts within this clinical specialty area, then **SIR strongly supports the Society of Vascular Medicine (SVM) recommendations for the re-consideration of CMS' coverage of Local Coverage Determination (LCD) ID DL33829. In re-establishing the coverage, SIR recommends that reimbursement be provided for intermittent pneumatic compression (IPC) devices to treat chronic limb-threatening ischemia (CLTI) in the upper and lower extremities.**

Once again, SIR appreciates the opportunity to provide feedback on this policy. If any additional information is required, please contact Keith Hume, SIR Executive Director, at khume@sirweb.org.

Sincerely,

Matthew S. Johnson, MD, FSIR
President

Cc:
Keith Hume, SIR Executive Director
Parag Patel, MD, FSIR, President-elect

Society of Interventional Radiology

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CARRIER ADVOCACY LETTER

CREATED BY

CARRIER ADVOCACY WORKGROUP

SUPPORTED BY

- Economics Committee
- Government Affairs Committee
- SIR Service Line Advisory Board

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Introduction

The Society of Interventional Radiology (SIR) is a professional medical association that represents approximately 8,000 members, including most U.S. physicians practicing in the specialty of vascular and interventional radiology. Society is dedicated to improving public health through pioneering advances in minimally invasive, image-guided therapies. Therefore, the society appreciates the opportunity to comment on the proposed draft Local Coverage Determination (LCD) for Pneumatic Compression Devices ID DL33829.

SIR and SVM are requesting coverage of arterial ICP pump devices for the treatment of patients with limb-threatening ischemia (critical limb-threatening ischemia – CLTI also called critical limb ischemia – CLI) of the upper and lower extremities who have no alternative options for surgical or endovascular revascularization and are at high risk for tissue loss and/or amputation. The arterial ICP device is currently coded under HCPCS E0675 ("Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system)").

We have carefully reviewed the draft LCD, which concludes that claims for E0675 will be denied as unreasonable and necessary. Accordingly, we present our response to the statements, opinions, and conclusions reached as a result of this.

Methodology

The Carrier Advocacy Workgroup addresses urgent carrier advocacy issues by reviewing existing research and coverage caps within specific policies. The chair and staff liaison have biweekly conference calls to prioritize and distribute work to the volunteers. In addition, the committee holds monthly conference calls to review and approve workgroup output.

The primary author of this Request: M. Mark Melin, MD FACS RPVI FACCWS, may be contacted for a response, questions, or requests of additional information at University of Minnesota Physicians, M Health Fairview Wound Healing Institute, Edina, MN Office tel. 952.915.8770 Cell: 952-237-3157 Email- mmelin4@fairview.org

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Background information

The LCD indicates concern that patients studied do not represent those of Medicare eligibility is misplaced to the extent that almost all patients studied with CLI were of Medicare age 65 or over: Kavros (3) 68.7- 71.3 IQR; Labropoulos (45) range of 65 to 83 years; Sultan (59) 68 to 81 years IQR; Montori (52) 63-79 IQR; van Bemmelen (65) 76.2 mean age….the most susceptible patient populations are unlikely to realize improvement in outcomes without first improving access to higher intensity quality care measures. - This statement in the LCD draft relates to African American communities with less access to more advanced surgical options for limb salvage. Contrary to the LCD draft's opinion that improvement in

outcome is "unlikely" without access to surgery, it is reasonable and necessary to provide this option where access to existing treatments is less available. Given a proper workup for CLI, providing patients with all available treatments to prevent amputation makes good sense.

There is no data that rural, Hispanic, African American or any other identifiable population has different anatomy, physiology, or biochemistry regarding PAD, suggesting any different result from the populations studied.

The Veterans Administration's Preservation-Amputation-for-Veterans Everywhere (PAVE) Program was created in 1993 to prevent limb amputations by providing the best possible care to ensure the Veteran receives optimal and compassionate patient-centered care by implementing evidence-based prevention practices (VHA Directive 1410). According to one of the several suppliers of devices within that framework, V.A. medical centers have been using arterial IPC devices for the past 22 years for approximately 6000 patients. This demonstrates that the often-overwhelmed V.A. system sees efficacy and value in providing this treatment modality.

Services interventions: Diagnostic and therapeutic

The draft LCD states in the 7th paragraph on page 8: "IPC has been previously shown to increase the arterial flow rate in the popliteal artery and is thought to promote the release of angiogenic growth factors and endothelial nitric oxide, an intrinsic vasodilator. However, human clinical studies do not confirm these hypotheses (5)". Reference 5 reaches an opposite conclusion stating, "Results from multiple randomized controlled trials suggest that limb compression is beneficial in improving ACD." Further, numerous supplied studies have shown that arterial flow, cutaneous blood flow, growth factors, and NO are all significantly enhanced. Thus, human trials do confirm the above hypothesis.

Heterogenicity of devices- All tested devices apply close to systolic pressures to patients in the seated position, reaching pressures much more rapidly than existing IPC types, for durations of 3 to 4 seconds and with three cycles per minute. This is far more homogeneous than the existing IPC types for venous and lymphatic treatment.

Scope and clinical indications

The draft LCD states that studies were of a small sample size (<10). The meta-analysis (5) included eight RCTs, each with experimental sizes of 20 or more. There were 34 patients in the May Clinic limb salvage study (3), 62 patients with 73% amputation free survival at three years (34), 171 patients with 94% limb salvage at 3.5 years (59), Twenty limbs with CLI studied with significant increases in arterial and skin blood flow (7). Studies are considered small, or efficacy is not obtained when P values are above 0.05. All arterial IPC studies have shown P values that support the experimental (pump) group. P values account for sample size in its calculation, so the statistical significance is met when $P<0.05$. When an experimental group demonstrates a low P-value with small sample size, this means that the effect of the pump is large compared to the control group. Therefore, the effect of arterial IPC is large.

The draft LCD is discounting physiological and anatomical studies. These studies should be used in the evaluation of efficacy. Physiological studies of patency and blood flow are primary outcome measurements in evaluating endovascular devices and procedures such as angioplasty balloons, stents, and atherectomy devices. Two submitted studies show arteriographic evidence of collateral growth (63)(64), a long-term result that supports the durable results seen in both CLI and claudication studies. Collateralization is the reason for the durability of the IPC treatment seen in CLI studies (34)(59) and the claudication trials (10)(11)(12). The submitted studies measured significant increases in biochemical factors in support of collateral arterial growth, acute blood flow increases at several arterial levels, foot skin flow where most ischemic ulcers present, and in providing beneficial hematologic effects such as increased nitrites (NO), increased tissue factor pathway inhibitor, decreased PAI-1 (plasminogen activator inhibitor). Numerous studies have identified shear stress as a regulator of endothelial cell function and vascular health. The rapidly applied pressure rises of arterial pumps, compared to pumps used for DVT prophylaxis and venous/lymphatic treatment, creates endothelial shear stress

that is largely diminished in obstructed arteries. Discounting these important studies detracts significantly from the total evidence picture that supports the use of this modality, as we recommend for no-option CLI patients.

Rationale

The draft LCD states that there is a high probability for bias without sham controls and blinding- Sham controls are not considered ethical to IRBs given the lack of equipoise for critical limb ischemia and no-option limb salvage. The IRB evaluates the existing evidence for the experimental arm of a prospective trial to determine if the sham and experimental groups have balanced expectations of the outcome. We have learned that there is a lack of equipoise making a sham-controlled trial unethical. None of the study centers were financially supported by manufacturers of pump devices which reduced possible financial incentive bias. The measurements used in the submitted studies (limb salvage, TcPO2, laser Doppler skin flow, duplex ultrasound automatically calculated values, treadmill times, and distance) are quantifiable, objective, not easily altered for preferential outcomes. Sham-controlled studies were not used in evaluating the currently accepted studies as reasonable and necessary therapeutic modalities, including supervised exercise for intermittent claudication, angioplasty devices, and associated procedures.

The draft LCD stated that "…most qualified their conclusion stating a need for additional studies". These statements do not dilute previous efficacy conclusions but usually call for additional studies to provide further insight into the field of study so that further advancements can be made.

Insufficient data to determine the durability of outcome- Several submitted studies show the durability of outcome up to 3.5 years. This is at least as good as durability expected with endovascular procedures.

Data insufficiency- The submitting physicians with support from several pertinent societies are asserting that, contrary to the opinion expressed in the LCD draft, there is adequate evidence of sufficient data that arterial IPC is safe, effective, reasonable, and necessary to provide our patients with a viable option to amputation where no other options are available.

The LCD draft statement that "Though there are several peer-reviewed published clinical studies demonstrating that IPC has a positive net health outcome in patients with CLI deemed inoperable or unsuitable for revascularization, it is uncertain if this treatment is effective" is opinionated and self-contradicting. The submitting physicians and SVM, many of whom are experts and thought leaders, are clearly of the opposite opinion.

Exclusion of comorbidities- The submitted IPC studies have reasonably excluded many Medicare-eligible patients who would not be candidates for this therapy.

We appreciate the statement that "…the DME MACs are unable to make recommendations for or against IPC with any certainty". However, our responders are a collection of vascular medical and surgical specialists with extensive clinical and academic research experience. The published research alone is enough for those who treat these patients to have established efficacy for this patient population. Additionally, our experience with this modality significantly reinforces our comfort in recognizing its need for these unfortunate patients with no likely option other than amputation.

Specialty society recommendations- The specialty society recommendations in the draft LCD are dated 2016 and 2019. With the benefit of member input, more recent society recommendations now endorse arterial IPC in no-option CLI patients. In addition, the Society of Vascular Medicine now supports the LCD request with the unanimous consent of its board. Thus, SVM is best situated to evaluate this medical modality without possible conflicts of interest from surgical organizations. Letters of specialty society recommendations are attached.

In summary, we are pained to tell our lower and fixed-income patients that amputation is their only option while knowing full well that there is a very low risk, home care option with good probabilities of pain relief, wound healing, and limb salvage. This tool is needed as part of the vascular and wound care specialist's treatment armamentarium to use judiciously for those no-option CLI patients. They must otherwise rely on opioids for pain relief, extensive wound care, and morbidities amputation. We urge the DME MACS to consider the combined biographical strength of our responding group for the many years of providing research leadership, training of upcoming physicians, and dedication to patient care.

With tremendous respect, we request and support the finding of reasonable and necessary by the DME MACS that will allow us to provide the best possible cares and outcomes for the patients we are committed to serving.

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Comments

Comments regarding the coverage recommendations may be submitted to economics@sirweb.org and will be considered in the development of future revisions of the work.

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CARRIER ADVOCACY LETTER

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