ALLIANCE OF WOUND CARE STAKEHOLDERS

Meeting at CMS to Discuss Issues Regarding Final Pneumatic Compression LCD
November 16, 2015

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POWER THROUGH COLLECTIVE ADVOCACY

ALLIANCE ATTENDEES

In Person:

- Fedor Lurie, M.D. (American Venous Forum)
- Marcia Nusgart R.Ph.(Alliance of Wound Care Stakeholders)
- Maggie Thompson, Jerry Mattys (Tactile Medical)
- Joe Carberry (LymphaPress/ Patriot Medical)
- Helaine Fingold, JD; Leslie Yeung, JD Epstein, Becker and Green

Via Conference Call:

- Stanley Rockson, M.D. (Stanford)
- Alan Hirsch, M.D. (Society for Vascular Medicine)
- Michael J. Cornelison, DPM (American College of Foot and Ankle Surgeons)
- Stephen Daugherty, M.D. (American College of Phlebology)
- Kara Couch, NP(American Association of Nurse Practitioners)
- Thomas F. O'Donnell Jr. M.D.(Tufts Medical Center)
- Cathy Ormerod (Living Beyond Breast Cancer)
- Jonathan Ross (Bio Compression)
- Karen Ravitz (Alliance of Wound Care Stakeholders)

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ALLIANCE OF WOUND CARE STAKEHOLDERS

- Who is the Alliance?
  - *A non-profit interprofessional trade association of health care clinical and patient organizations*
  - *Serves as an "umbrella" association for clinical organizations whose members treat patients with wounds*
- Mission of the Alliance:
  - *To promote quality care and access to wound care products and services for people with wounds.*
  - *Focus on compelling issues of commonality to the organizations in the reimbursement, government and public affairs affecting wound care.*

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Current Members – Clinical Associations

- American Venous Forum
- Society for Vascular Medicine
- Society for Vascular Surgery
- American College of Phlebology
- American College of Foot & Ankle Surgeons
- American Podiatric Medical Association
- Undersea & Hyperbaric Medical Society
- American Physical Therapy Association

Current Members – Clinical Associations

- Association for the Advancement of Wound Care
- American Professional Wound Care Association
- Visiting Nurses Association of America
- American College of Wound Healing and Tissue Repair
- Academy of Nutrition and Dietetics
- National Association for Home Care and Hospice
- American College of Hyperbaric Medicine

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FOUNDATIONS OF ALLIANCE WORKPLAN

- Wound Care Quality Measures
- Wound Care Research
- Reimbursement Issues- Coverage, Coding and Payment
  - Submit Comments to Federal Agencies and their Contractors
    - Agency for Healthcare Research and Quality (AHRQ)
    - Centers for Medicare and Medicaid Services (CMS)
    - CMS Contractors-DMEMACs, A/B MACs

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Alliance History on Addressing Lymphedema Issues

- Nov 2009- Alliance members (American Venous Forum, Society for Vascular Medicine) present at MedCAC Meeting on Secondary Lymphedema (Dr. Caroline Fife, Dr, Steven Dean)
- Aug/Sept 2011- Alliance presented at DMEMAC Public Meeting Regarding Draft Local Coverage Determination for Pneumatic Compression Devices (DL11492) and submit comments
- Fall 2014- New Final DMEMAC LCD released- Alliance sends letter to both CMS and DMEMACs; Alliance clinical associations (American Venous Forum, Society for Vascular Medicine, American Physical Therapy Association, College of Foot and Ankle Surgeons) convene conference call with DMEMACs; LCD does not go into effect
- Fall 2015- New Final DMEMAC LCD released- Alliance sends letter to both CMS and DMEMACs; Alliance meets with CMS

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Alliance's Request

- Alliance seeks to:
  - Have the future Pneumatic Compression Device LCDs published on October 15, 2015 withdrawn
  - Maintain LCDs that appropriately mirror the NCD

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Alliance Concern with Future LCD: the LCD is More Restrictive than the NCD

- Legal Reasons
  - Section 13.5 of the Program Integrity Manual expressly states that a LCD cannot "restrict or conflict with NCDs or coverage provisions in interpretive manuals."
  - The LCDs do restrict and conflict with Section 280.6 of the NCD Manual by adding substantive burdens and requirements that are not apparent from a fair reading of the NCD.
- In the DME MACs "Response to Comments to Accompany LCD for Pneumatic Compression Devices" published on October 15, 2015, in response to assertions by stakeholders that the new LCD was more restrictive than the NCD, the DME MACs responded "The revised LCD broadens the allowed indications and thereby specifically addresses any concern in this area. There is no conflict with the revised LCD and the NCD."

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Example #1-the LCD is More Restrictive than the NCD

- NCD Position:
  - NCD allows for coverage of PCDs for the diagnosis of lymphedema without restriction on level of severity.
- LCD Position:
  - The new LCDs restrict coverage to:
    - **the most severe lymphedema presenting with end stage extreme clinical manifestations** (e.g., marked hyperkeratosis with hyperplasia and hyperpigmentation;
    - papillomatosis cutis lymphostatica;
    - deformity of elephantiasis;
    - skin breakdown with persisting lymphorrhea;
    - detailed measurements over time confirming the persistence of the lymphedema with a history evidencing a likely etiology).
- The NCD in place since 2002 has allowed coverage for patients who have not progressed to this severe state. The new LCDs will remove coverage levels that have been available for over a decade, affecting significant populations of patients.

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Example #2-the LCD is More Restrictive than the NCD

➢ NCD Position:

- The NCD allows for coverage of PCDs after a 4-week trial of conservative therapy when the treating physician determines that the patient has had "no **significant improvement or significant symptoms still remain**"

➢ LCD Position:

- The NCD allows the physician to make a determination about when the medical necessity is appropriate at the end of a four week trial for a PCD. The new LCD inappropriate restricts that physician's decision-making ability and requires failure of any conservative treatment over a 4-week period.
- At the end of the 4-week trial, "if there has been improvement then reimbursement for a PCD is not justified" **even if the improvement is not "significant" or if significant symptoms still remain.**
- Extend the 4-week trial timeline indefinitely while the patient goes through repeated weekly evaluations until "no further improvement has occurred in the most recent four weeks."
- Some incremental measurement that could be deemed "improvement" may not be clinically meaningful. The NCD's position that a PCD is covered when "significant symptoms still remain" is an appropriate criterion.

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Example #3-the LCD is More Restrictive than the NCD

- NCD Position:
  - The NCD covers chronic venous stasis ulcers when one or more ulcers have **failed to heal** after a 6-month trial of conservative therapy.
- LCD Position:
  - The new LCDs will deny coverage of a PCD if there has been **improvement** in the ulcer during the 6 month trial of conservative therapy.
  - The LCDs further require the trial to extend beyond 6 months with repeated evaluations. PCDs will not be covered unless "no further improvement in the ulcer has occurred for a continuous period of 6 months."

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Example #4-the LCD is More Restrictive than the NCD

- NCD Position:
  - The NCD allows for coverage of PCDs coded E0652 for diagnoses of lymphedema and chronic venous ulcers when the patient presents with unique characteristics that prevent satisfactory treatment with a basic PCD (coded E0650/E0651).

- LCD Position:
  - The new LCDs state that "a PCD coded E0652 is not covered for the treatment of the extremities alone."
  - The LCDs restrict coverage of E0652 PCDs to only patients who have lymphedema that extends into the trunk/chest/abdomen.
  - The new LCDs recognize no unique characteristic other than chest/trunk/abdominal swelling.

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CONCLUSIONS/NEXT STEPS

- Practical effect of the new LCDs is to restrict the coverage for PCDs that exists today under the NCD, negatively impacting populations of patients for whom PCD treatment is necessary to manage their conditions.
- The reconsideration process is not an appropriate avenue for addressing these concerns.
- The DME MACs are not procedurally permitted to add these substantive burdens and requirements to the coverage of PCDs.
- The future LCDs should not be allowed to go into effect on Dec. 1, 2015 in light of these egregious procedural and clinical flaws.
- Next steps

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