ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

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Submitted electronically to: TOTRecon@noridian.com

Re: Draft Topical Oxygen LCD DL33797 - Oxygen & Oxygen Equipment

Dear DME MAC Medical Directors,

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit the following comments in response to the Draft LCD - DL33797 - Oxygen & Oxygen Equipment for Topical Oxygen Therapy (TOT) for Wound Healing. The Alliance is a nonprofit multidisciplinary trade association of physician specialty societies, clinical and patient associations whose mission is to promote evidence-based quality care and access to products and services for people with chronic wounds including diabetic foot, venous stasis, pressure and arterial ulcers. Our clinical specialty societies and organizations not only possess expert knowledge in treating complex chronic wounds, but also in wound care research. A list of our members can be found at www.woundcarestakeholders.org.

General Comments

The Alliance appreciates that in 2017, the Coverage and Analysis Group (CAG) at CMS published a Decision Memo for Hyperbaric Oxygen (HBO) Therapy (Section C, Topical Oxygen) (CAG-00060R) [1] that revised NCD 20.29 to remove the non-coverage language addressing topical oxygen therapy (TOT), allowing the DME MACs the discretion to determine coverage moving forward. This Decision Memo included a detailed review and analysis of all the pertinent clinical evidence for TOT up until that point and also clearly articulated the position of CMS as to the level of evidence it would like to see to support positive future coverage decisions. The DME MACs later announced in 2018 that interested parties wishing to solicit LCD coverage should submit

[1] Centers for Medicare and Medicaid Services (CMS). Coverage and Analysis Group (CAG). Decision Memo for Hyperbaric Oxygen (HBO) Therapy (Section C, Topical Oxygen) (CAG-00060R). April 3, 2017. https://www.cms.gov/medicare-coveragedatabase/details/nca-details.aspx?NCAId=286&bc. Accessed November 15, 2019.

a Reconsideration request utilizing the process outlined in the Medicare Program Integrity Manual (PIM), Chapter 13 - Local Coverage Determinations, §13.7.1.[2]

Chapter 13 of the PIM was updated by CMS via Transmittal 863, dated February 12, 2019 [3] as mandated by the 21st Century Cures Act of 2016, to help; "*ensure (Medicare) beneficiary access to life saving and medically necessary products and procedure*s" by "*increasing transparency, clarity, consistency…"* in the LCD process and resultant coverage decisions. The stated intent of these changes was in part to address stakeholder concerns about the "*ineffective MAC processes for soliciting feedback…, lack of non-physician representation on Contractor Advisory Committees (CACs), and concerns that CACs are closed meetings and are not open to the public..."* etc.

The Alliance has always strongly advocated for a fair and consistent LCD process, which should be applied equally to all reconsideration requests, irrespective to the product category, or relative size of the reconsideration requestors. Therefore, we are concerned after all the regulatory changes made by CMS addressing these issues and cited above, that the LCD process for TOT was conducted very differently to that of the Tumor Treatment Field Therapy (TTFT) LCD process (DL34823), which was conducted only a few months prior, commencing on January 24, 2019.[4]

The different treatments given to each LCD are particularly apparent as it relates to the CAC meetings, where in the TTFT meeting of March 6, 2019, a) the CAC members selected clearly included multiple subject matter experts and more committee members; b) the reconsideration requestors were allowed to have their technology and the latest evidence presented to the CAC members by subject matter experts; c) a question & answer session of those experts by the CAC members followed their presentations, in total for half a day; and d) the CAC members discussing and ultimately answering the questions after being fully informed of the latest RCT evidence and understanding how to answer the questions being posed. [5] This meeting was also held at CMS offices in Baltimore, Maryland which may be more convenient to get to than San Francisco, California.

In contrast, it seems that none of these same best-practice approaches were adopted for the TOT CAC meeting of October 29, 2019, where the committee consisted of only a few members with any current clinical wound care experience and perhaps only one member who understood both wound care and evidence. Selecting the appropriate committee members with the knowledge and expertise both in evidence and the subject matter is critical in order to appropriately answer the questions. For instance, if the committee members were not practicing wound care clinicians, they might not be in the position to be informed about new wound care products and procedures in their practices. Therefore, if they are not currently practicing as a clinician in the outpatient clinics, physician offices or in the home care setting, they might have not been able to correctly answer whether TOT is generally accepted by the medical community for the treatment of chronic non-healing wounds. In addition, the committee excluded the sector who would be most knowledgeable ---podiatrists or Podiatric Surgeons (DPM) who predominately treat diabetic foot ulcers (DFUs), which was the subject of the only two new RCT studies that had been published since the 2017 CMS review. Finally, the reconsideration

[2] Joint DME MAC Article. Topical Oxygen Therapy Used for Wound Care. October 4, 2018. https://cgsmedicare.com/jb/pubs/news/2018/10/cope9459.html. Accessed February 3, 2020.
[3] CMS Transmittal 863. Local Coverage Determinations (LCDs). February 12, 2019. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R863PI.pdf. Accessed February 3, 2020.
[4] Reconsideration request to add TTFT coverage for newly diagnosed glioblastoma multiform. https://www.cgsmedicare.com/jb/pubs/news/2019/01/cope10564.html. Accessed February 3, 2020.
[5] Tumor Treatment Field Therapy Contractor Advisory Committee Meeting. March 6, 2019 https://www.cgsmedicare.com/jb/pubs/news/2019/02/cope11382.html. Accessed February 3, 2020.

requestors were not provided the opportunity to have subject matter experts present their technology and the latest RCT evidence to the CAC members, or allowed a question and answer session with the CAC members so that they could understand it relevance.

The Alliance questions whether the summary cited in the draft LCD was truly an accurate representation of the meeting, as it was clear that the committee members were not at well prepared and had not all read the background articles. This fact was painstakingly clear in relation to the latest RCT by Frykberg et al. published in *Diabetes Care* on October 16, 2019, which the CAC members had only received a few days prior to the meeting and which many acknowledged not having even read.

It is also critical for the committee members to have an understanding of the terms contained in the questions (i.e. "durability") and perhaps explain the relevance of each question.

The Alliance also believes that when combined with the inconsistencies detailed above, the extremely broad "*all topical oxygen approaches in all chronic wounds*" instructions given to the CAC members in explanation as how they were to conduct their review, resulted in them being unable to make any meaningful recommendations, or conclusive scoring, on the questions asked.

Our specific comments follow.

Specific Comments

The Analysis of the Evidence is Incomplete and thus Inaccurate

The RCT by Frykberg was only published in *Diabetes Care* on October 16, 2019, which was after the reconsideration process had started and just prior to the convening of an independent CAC meeting on October 29, 2019. The Alliance believes that the committee did not review this study completely, since it even was acknowledged by many on the committee themselves. Additionally, none of the Professional Society recommendations and guidelines, or external assessments, considered this study, as they were all conducted prior to its publication.

Furthermore, the study design utilized in the Frykberg RCT seems to have specifically addressed the earlier study limitations highlighted within the 2017 CMS CAG review, which the DMEMACs also cite as deficiencies in the summary of the existing evidence. The investigators in this study appear to have thoroughly researched a unique Intermittent TOT delivery approach in proven difficult to heal DFU, incorporating the following attributes within their protocol (summarized in the order you present), which appear to have been missed in the analysis:

- A protocol defined and controlled standard of care throughout the study in both study arms, which included a 2-week run-in of ulcers prior to being randomized;

- Appropriate sample size powering with a Group Sequential Design to avoid unnecessary patient risk;

- Strict double-blinding to remove potential biases, with control of baseline characteristics between arms;
- Only Intention to Treat (ITT) statistical analyses utilized;
- Uniform inclusion/exclusion criteria;
- A patricianly robust (for wound care) protocol design that addresses earlier study design limitations and biases;
- Assessment of both 12-week complete healing and 12-month durability of healing outcomes that showed significant outcomes at each point;
- The study utilized centralized double-blinded randomization;
- An independent Data Monitoring Committee (DMC) was used with predetermined stopping criteria;
- Functional improvements were examined and proven by a wound care quality of life assessment;
- Rarely seen 12-month reoccurrence (durability of healing) reductions were demonstrated;
- Conflicts of interest were addressed by the study protocol, blinding and use of an independent DMC;
- The mean and majority age of patients demonstrated generalizability to Medicare population.

The Summary of Evidence for TOT Supports Coverage Delineation Based on Different Chronic Wound Types

Given the variability of high-quality evidence of the efficacy of TOT across different wound types, we request that the DME MACs consider the available evidence on a per wound-type basis and make wound type specific coverage determinations. The Alliance agrees that the strongest clinical evidence for TOT coverage is related to Diabetic Foot Ulcers (DFU), followed by that for Venous Leg Ulcers (VLU). Specifically, there have only been two published TOT peer-reviewed Randomized Controlled Trials (RCT) since the 2017 CMS CAG review and both of these were in DFU. Furthermore, the most recent of these studies is a highest quality sham-controlled, double-blinded, multi-center RCT by Frykberg et al. that was only published in *Diabetes Care* on October 16, 2019, after the LCD reconsideration process had commenced and has resulted in it not being fully considered in this analysis.

There are numerous examples of national and local coverage policies that make individualized coverage determinations for specific patient populations or condition characteristics. It is curious why a similar approach was not taken for TOT coverage. Members of the CAC commented on the notable signal of TOT efficacy in DFUs that could support coverage for these wounds. It seems, however, that scoring was based on an analysis for all "chronic non-healing wounds," effectively ignoring the compelling clinical data for DFUs. We urge the DME MACs to reconsider the proposed non-coverage of TOT and, instead, adopt a wound-type specific coverage policy.

The External Assessments are Incomplete

The Alliance believes that the external assessments cited are incomplete, as they were all conducted prior to the publication of the Frykberg RCT mentioned above and as such do not include it in their assessments.

Conclusion

The Alliance of Wound Care Stakeholders appreciates the opportunity to provide our comments. We have significant concerns with the current draft of this LCD policy, especially as it relates to the inconsistencies seen in the process compared to other recent LCDs, as well as the inaccurate assessment of the device investigated in the most recent Frykberg RCT. We urge you to adopt our recommendations and reverse your draft conclusions and provide LCD coverage for Diabetic Foot Ulcers, which we believe has been demonstrated by the clinical evidence provided.

I am happy to speak with you about any of our comments.

Sincerely,

Marcia Nusgart R.Ph.

Marcia Nusgart R.Ph.
Executive Director