ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

July 9, 2015

Ms. Jackie Dunn
Novitas Solutions
Medical Policy Department
Union Trust Building
Suite 600
501 Grant Street
Pittsburgh, PA 15219

Submitted electronically to: jackie.dunn@novitassolutions.com

RE: DRAFT Local Coverage Determination (LCD) for Hyperbaric Oxygen (HBO) Therapy (DL35021)

Dear Ms. Dunn:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit the following comments in response to the draft local coverage determination for Hyperbaric Oxygen Therapy (HBOT) (DL35021). The Alliance is a nonprofit multidisciplinary trade association of physician medical specialty societies and clinical associations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. These comments were written with the advice of the Alliance clinical specialty societies and organizations who not only possess expert knowledge in complex chronic wounds, but also in wound care research. Many of our members utilize HBOT in their practices as an adjunctive therapy when treating a patient with a chronic non-healing wound and especially when treating patients with diabetic foot ulcers. As such, we have a vested interest in this policy. A list of our members can be found at www.woundcarestakeholders.org.

GENERAL COMMENTS

HBOT is a valuable treatment option for improving wound healing in patients with diabetes, radiation complications, compromised flaps and grafts, and complex non-healing wounds. HBOT has contributed to a decrease in the national amputation rate, as more patients have received advanced wound care, including HBOT, from a multidisciplinary team of providers. The Alliance supports the need for a LCD to ensure the safe and effective use of HBOT but also one that minimizes administrative burdens while still easy to implement and enforce.

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However, Novitas' draft policy contains confusing, inconsistent and incorrect information. For example, there are several areas in the draft policy in which Novitas provides specific dose and frequency parameters which are contrary to current standards of practice. In addition, some of the evidence that Novitas has used to substantiate the provisions in this policy is outdated, contradicts existing evidence and is not relied upon by those physicians that perform HBOT for the treatment of covered HBOT indications. As a result, we highly recommend that Novitas revisit this draft LCD and clear up any inconsistencies, confusing language, inaccurate information, and outdated evidence prior to issuing this policy in final.

While this policy is more general in nature, due to the Alliance's emphasis on wound care, our comments will focus solely on the wound care aspects of HBOT. Our specific comments, listed below, are not based in the order of importance, but rather in the order the issue appears within the draft LCD.

SPECIFIC COMMENTS

Coverage Indications, Limitations and/or Medical Necessity

Specific Conditions: Skin Grafts and Flaps

Language in the policy: This indication is not for primary management of wounds or split thickness skin grafting for open or slowly healing surgical wounds.
AND
The number of sessions provided to enhance graft survival is not expected to exceed 12.

Concern: The Alliance disagrees with the language contained in this draft. HBOT is appropriate for the management of skin grafts and flaps that are at risk as well as those that are placed over poorly healing surgical wounds as a means of secondary closure. The decision as to the treatments depths, time and frequency should be made by the treating physician and based, not on a predetermined number of treatments, but on how well the patient is responding to them. It is quite possible that patients will require additional sessions based on their progression and how they are responding to HBOT.

Recommendations: The Alliance recommends that Novitas not limit treatments to 12 sessions. Instead, the Alliance recommends that a review of the patients' progress be done after 12-15 treatments and if the patient is responding to HBOT, that the sessions continue and allow for the clinician to appropriately determine the number of sessions their individual patient requires.

Specific Conditions: Diabetic Wounds

Language in the policy: Adjunctive treatment of an ulcer of the lower extremity deemed to be secondary to the neuropathic effects of diabetes will be allowed no more than 30 treatments (60-90 minutes daily) without documentation of improvement.

Concern: The adjunctive treatment of the diabetic foot ulcer (DFU) is not solely based on the neuropathic effects of diabetes, but also the vascular effects of diabetes. The dysvascular foot is the basis for the Wagner scoring system**.** The accepted number of treatments identified in this draft policy is insufficient. The standards of practice as well as the evidence suggests it is more appropriate for there to be 40 treatments, not the 30 identified in this draft LCD. Furthermore, oxygen breathing times are not total treatment times. Most clinicians include a 10 minute pressurization time, a 10 minute depressurization time, and 2 5-minute air breaks in the treatment protocol. This results in a total treatment time of 120 – 150 minutes, of which 90 - 120 minutes is breathing 100% oxygen. As such the treatment time identified in the policy, 60-90 minutes daily, is insufficient.

Recommendation: The Alliance recommends deleting the language and instead allow for the clinician to appropriately determine the amount of treatment time their individual patient requires.

Language in the policy: NOTE: Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days. Indications of effective therapy include:

- Decrease in margin or depth (surface area or volume deficit) of wound
- Lack of exuberant granulation, mounds or polyps of granulation consistent with foreign body (osteomyelitis), pale or necrotic wound base.
- Epithelial growth or advanced skin margins across wound surface

Concern: Failure to respond to standard wound care does not always manifest itself by a LACK of any healing, but by slow or delayed wound healing. The industry standard is to use a 4 week healing percentage to predict which wound will heal with standard care in 12 weeks, and which will not. If the wound area is not reduced by 50% in 4 weeks, there is a 91% probability the wound will not be healed in 12 weeks and therefore, more advanced care such as HBOT would be appropriate. [1] The Alliance would like to point out that lack of exuberant granulation would be an indication of possible *ineffective* therapy. Additionally, the absolute lack of any evidence of improvement, such as reduction in necrotic tissue, some advancement of an epithelial border, or evidence of some granulation tissue is unreasonable, as some improvement is to be expected, although, a lack of significant improvement should be a trigger to the clinician to employ advanced modalities in these patients.

The inconsistency is highlighted by this analysis:

> If the patient does not have osteomyelitis, they must have a Wagner 3 or greater ulcer. That means that they are likely to have necrotic or gangrenous tissue. According to the LCD, gangrenous tissue must be debrided. The definition of "no measureable sign of healing" includes that there has NOT been a reduction in necrotic tissue. This means that debridement of gangrenous tissue would constitute a measureable improvement and that HBOT is not indicated. However, because necrotic tissue must be debrided, if a clinician does not do that, then the patient is not a candidate for HBOT. Therefore, according to the LCD, a patient must

[1] *Sheehan P, Jones P, Caselli A, Giurini JM, Veves A. "Percent change in wound area of diabetic foot ulcers over a 4-week period is a robust predictor of complete healing in a 12-week prospective trial". Diabetes Care 2003; 26:1879-1882*

have gangrenous tissue but must undergo debridement after which they no longer meet the requirement for HBOT.

Similarly, according to the draft LCD, there must be documentation of "maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings." However, patients with gangrene or active osteomyelitis, do not, by definition, HAVE granulation tissue because if they did, then the patient would not meet the definition of a Wagner 3, 4 or 5 DFU. Yet, if they do NOT have granulation tissue they are not a candidate for HBOT. If they develop granulation tissue this would be a measurable sign of healing which would mean HBOT is not needed. Therefore, they must both NOT have granulation tissue and must HAVE granulation tissue to justify HBOT.

Recommendation: The Alliance recommends replacing the language with

"Note: Failure to respond to standard wound care occurs when the wound area has not reduced by 50% or greater over 4 weeks of standard care."

The Alliance further recommends that Novitas delete the language that "there must be documentation of a "moist bed of granulation tissue" as well as that "a reduction in necrotic tissue would constitute a "measurable sign of healing."

Language in the policy: Wound volume or surface is expected to diminish by at least 50% over a 30 day period to justify continued therapy.

Concerns: The Alliance questions this requirement and would like to know the basis for this provision. We are not aware of any literature or evidence to support this requirement. The data states that the percent change in wound area of a diabetic foot ulcer over a 4-week period is a robust predictor of whether the wound will heal using standard care[2]. Therefore the statement above misconstrues the clinical data in the evidence and is inappropriate. Additionally, the paper cited only addresses Wagner 1 and Wagner 2 ulcers without the use of hyperbaric oxygen or other advanced modalities. By virtue of the fact that only Wagner 3 or greater ulcers are candidates for hyperbaric oxygen therapy, this study cannot be used as a criteria for continued therapy.

There are other clinical findings such as amount of granulation, decreased discharge, less odor, presence of epithelialization which are all important markers of healing that could be utilized**.**

Recommendation: The Alliance recommends deleting "wound volume or surface is expected to diminish by at least 50% over a 30 day period to justify continued therapy" as there is no evidence to support this statement. Instead, the Alliance recommends stating, "Measurable signs of healing <u>are</u> best defined as specific, documented, clinical signs of healing. Physician statements should be descriptive and complete in order to describe the wound and its progression".

Language in the policy: NOTE: Failure of transcutaneous oxygen measurements to demonstrate adequate local blood flow with which to effect improvement, when treating diabetic wounds of the lower extremities, will result in the HBO treatments to be considered not medically necessary. An

[2] *Ibid*

ankle brachial index of not less than .6 is considered the standard required for healing of a lesion on a diabetic's foot. Alternative measurements of toe pressures, plethysmography or similar demonstration of small vessel perfusion may be considered

Concerns: Guidelines published by the Wound Healing Society (WHS) state that all patients with lower extremity ulcers should be assessed for arterial disease. Thus, the Alliance agrees that vascular screening of patients with Diabetic Foot Ulcers (DFU) is imperative in order to identify patients who are candidates for revascularization. However, Transcutaneous oxygen measurements (TcOMs) have absolutely no predictive value when assessing whether a patient will respond to HBOT or not. Its only value is in evaluating whether the patient is responding to HBOT. The purpose of non-invasive vascular screening is to identify patients who may require arterial revascularization, NOT to identify patients who require hyperbaric oxygen therapy. HBOT should NOT be used as a substitute for revascularization. If patients have undergone revascularization and their transcutaneous oxygen values have increased to normal levels, they do not require HBOT because they are likely to heal spontaneously.[3]

Furthermore, the wording of this LCD does not follow the recommended use of TcOM. Transcutaneous oximetry measures the oxygen partial pressure in the skin (TcPO2). Fifteen studies (1137 patients) have demonstrated that TcPO2 provides better overall predictive capability than Doppler studies or ABI at predicting whether a DFU will heal spontaneously. If TcPO2 values are below approximately 40 mmHg, invasive vascular assessment is recommended. Once revascularization has been performed, if TcPO2 increases by at least 30 mmHg, spontaneous healing is likely and HBOT is not needed.[4]

HBOT is reserved for patients whose vasculature has been optimized and whose baseline TcPO2 is still below 40 mmHg. Among those patients, the best way to predict who will benefit from HBOT is to perform a TcPO2 during the first hyperbaric oxygen therapy treatment. During HBOT, if the TcPO2 is >200 mmHg, HBOT is likely to be of benefit. If TcPO2 is <50 mmHg, HBOT is NOT likely to be of benefit.[5]

Recommendation: The Alliance recommends that a vascular evaluation on all non healing wounds should be part of the clinical algorithm and if possible, compromised blood supply to the area should be corrected prior to starting HBOT. However, TcOMs should not be utilized to predict whether patients will or will not respond to HBOT.

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[3] Hanna GP, Fujise K, Kjellgren O, Field S, Fife CE, Schroth G, Clanton T, Anderson V, Smalling RW. Infrapopliteal Transcatheter Interventions for Limb Salvage in Diabetic Patients: Importance of Aggressive Interventional Approach and Role of Transcutaneous Oximetry. J Am Cardiol. 30:664-9, 1997.

[4] Fife CE, Smart DR, Sheffield PJ, Hopf HW, Hawkins G, Clarke D. Transcutaneous Oximetry in Clinical Practice: Consensus Statements from an Expert Panel Based on Evidence. Undersea Hyperbaric Med. 36(1):43-53, 2009

[5] Fife CE, Buyukcakir C, Otto GH, Sheffield PJ, Warriner RA, Love TL, Mader J. The Predictive Value of Transcutaneous Oxygen Tension Measurement in Diabetic Lower Extremity Ulcers Treated with Hyperbaric Oxygen Therapy; a Retrospective Analysis of 1144 Patients. Wound Rep Regen. 10:198-207, 2002

Provider Qualifications /Certification

Language in the policy – the Scope of Practice for a physician supervising HBOT must include neurologic, cardiothoracic, critical care and internal medicine components necessary to evaluate the potential HBOT recipient to insure that there is no relative contraindication to treatment. The physician supervising HBOT should be both cognizant of the potential hazards of the therapy and have the capability of immediate and appropriate treatment of the complication should it arise. The physician's Scope of Practice shall include the ability to insert a chest tube, endotracheal intubation, treatment of seizures, recognition of sudden eardrum rupture, signs of oxygen toxicity and hypoxia as well as to differentiate these problems from anxiety or claustrophobia. All potential treatment of medical and surgical emergencies arising in the patient receiving HBOT must be within the scope of practice of the supervising physician who is immediately available throughout the HBOT session

AND
Limited licensed providers performing hyperbaric medicine services must have an unlimited licensed physician who is also credentialed in hyperbaric medicine readily available to render assistance if needed

Concerns: 42 C.F.R. § 410.27(a)(1)(iv), expressly allows *non-physician practitioners* to supervise services that they may personally furnish in accordance with state laws and other requirements. CMS defines a "non-physician practitioner" to include, in pertinent part, physician assistants, nurse practitioners and clinical nurse specialists. Accordingly, under CMS regulations, non-physician practitioners, such as physician assistants, nurse practitioners and clinical nurse specialists, are permitted to supervise HBOT services in clinics, provided such services are within the non-physician practitioner's scope of practice as defined in applicable state and other requirements.

Furthermore, podiatrists would be categorized as limited licensed physicians under this draft policy. We do not agree that these physicians need to have an unlimited licensed physician available in order to perform HBOT. Podiatrists currently supervise HBOT safely. The two certifying boards in podiatry, the American Board of Podiatric Medicine (ABPM) and the American Board of Foot and Ankle Surgery (ABFAS), include items on their board exams to evaluate a podiatrist's knowledge on the indications of HBOT and emergency management, including complications of HBOT. Based on their training and their state practice act, podiatrists should be permitted to supervise HBOT services.

Recommendation: The Alliance recommends the following language be added to the draft LCD: Podiatrists as well as nurse practitioners, physician assistants and clinical nurse specialists may administer and/or supervise HBOT provided such services are within the purview of their state practice act as defined in state law.

Coverage Guidance

Language in the policy: The following conditions are conditions that are presumed to be provided in the inpatients only setting: gas gangrene, Acute Peripheral Ischemia (including arterial embolism and thrombosis, reimplantation and/or crush injuries of the extremities)

necrotizing fasciitis and air embolisms. Therefore, HBOT for these services in an outpatient setting would be considered not reasonable and necessary

Concerns: Many of the conditions covered only in the inpatient setting fall within a spectrum of severity--from mild to moderate to severe --where the initial medical, surgical, or interventional therapy is appropriate to the inpatient setting. Other conditions require inpatient care for the entire course of HBOT. However, it is not uncommon for many of these conditions to be treated entirely in the outpatient setting if the patient is clinically stable. Additionally, cases requiring initial inpatient HBOT can often be completed in an outpatient setting. The need for hospitalization is properly made after the initial intervention and assessment of the patient's status and should be at the attending physician's discretion. Although the extremes of these cases would merit admission, the trending towards early discharge and outpatient management has made that delineation arbitrary.

It is unreasonable to put the restriction of inpatient only on the indications listed above. As the practice of medicine evolves to a more outpatient setting, previously rigid admission standards are being changed. Ten years ago, no one could have imagined being discharged 12 hours after appendectomy. Financial pressures on hospitals are encouraging decreasing lengths of stay with more coordinated outpatient care. This is evidenced clearly in a paper authored by Kalra in 2010 reviewing the average length of stay in Philadelphia; this was reported as 5.6 days, a statistically significant decrease from previous. (Amit D. Kalra, MD, Robert S Fisher, MD, Peter Axelrod MD, *Decreased Length of Stay and Cumulative Hospitalized Days Despite Increased Patient Admissions and Readmissions in an Area of Urban Poverty*, **Society of General Internal Medicine** published online April 29, 2010) Likewise, to impose these conditions on the provision of hyperbaric services to these patients would limit access to care. The decision as to who to treat, when to treat, and where to treat should be left firmly under the auspices of the physician caring for the patient.

The Alliance agrees that while a few indications may be treated in an inpatient setting, most conditions listed depend on the multidimensional nature of clinical decision making and are appropriate to treat in an outpatient setting.

Recommendation: The Alliance recommends that Novitas look to the specialty societies/associations for their guidance to determine which conditions are appropriate for treatment in the inpatient versus outpatient setting.

Language in the policy: Hyperbaric oxygen therapy is not considered medically necessary or appropriate treatment of osteomyelitis of small or non-weight-bearing bones of the forefoot and fingers (metatarsal bones, phalanges) which are more effectively treated with debridement.

Concerns: The Alliance is concerned that the above description is not anatomically or functionally correct. All of the bones of the toes and metatarsals are weight bearing and none of the bones in the fingers are weight bearing. The Alliance can not find a single reference that states that HBOT is less effective for the phalanges or metatarsals. These bones are necessary for the foot to function as a single unit. The LCD seems to "sacrifice" some bones deemed less important by Novitas, but not by any evidence. Osteomyelitis of any bone should be treated aggressively and HBOT is an adjunctive

treatment, meaning that pharmaceuticals and surgical methods should be employed in addition to HBOT.

Recommendation: The Alliance recommends deleting the statement outlining which bones should or should not receive HBOT for osteomyelitis and instead state that "HBOT is an adjunctive treatment for osteomyelitis, which is a complex disease that requires a medical and/or surgical approach."

Documentation Requirements - Legible signatures and notes?

Novitas expects that in order for a physician to meet the documentation requirements in this policy, the medical record documentation must be legible and the physician's signature needs to be legible. This seems to be a rather subjective standard which physicians will be held accountable. The Alliance questions how will the determination be made as to whether a signature or medical record note is legible? One reviewer may be able to read and comprehend the information while another may not. This seems to be a requirement which could arguably never be met – yet again, clinicians will be held accountable and their payment can depend on it.

The Alliance does not believe, that a policy which requires much documentation already should contain language that is subjective at best. We urge you to delete this requirement.

Documentation Requirements – Diabetic Wounds

Language in the policy: For diabetic wounds of the lower extremity, the Wagner classification of the wound and the failure of an adequate course (at least 30 days) of standard wound therapy must be documented at the initiation of therapy. Documentation must demonstrate an ulcer with bone involvement (osteomyelitis), localized gangrene or gangrene of the whole foot.

Concerns: The language in the policy is not reflective of the correct definition to the Wagner Grading System[6]. There are 5 grades to the Wagner Grading scale for diabetic foot ulcers. As defined by CMS, they are as follows:

Grade 0 = no open lesion;

Grade 1 = superficial ulcer without penetration to deeper layers;

Grade 2 = ulcer penetrates to tendon, bone, or joint;

Grade 3 = lesion has penetrated deeper than grade 2 and there is abscess, osteomyelitis, pyarthrosis, plantar space abscess, or infection of the tendon and tendon sheaths;

Grade 4 = wet or dry gangrene in the toes or forefoot;

[6] Wagner FW Jr. The dysvascular foot: a system for diagnosis and treatment. Foot Ankle. 1981;2:64-122.

Grade 5 = gangrene involves the whole foot or such a percentage that no local procedures are possible and amputation (at least at the below the knee level) is indicated

Furthermore, this section is contradictory. Novitas states that there be more documentation of maintenance of a clean moist bed of granulation tissue with appropriate moist dressings. However, patients with gangrene or active osteomyelitis do not have granulation tissue. If these patients did have granulation tissue then they would not meet the definition of a Wagner diabetic foot ulcer. However, if these same patients do not have granulation tissue, then they are not eligible for HBOT.

Recommendation: We request the statement, "Documentation must demonstrate an ulcer with bone involvement (osteomyelitis), localized gangrene or gangrene of the whole foot." be changed to reflect the correct Wagner III definition. The language should read, "lesion has penetrated deeper than grade 2 and there is abscess, osteomyelitis, pyarthrosis, plantar space abscess, or infection of the tendon and tendon sheaths, which defines Wagner III."

Utilization Guidelines

Language in the policy: Notice: This LCD imposes utilization guideline limitations. Despite Medicare's allowing up to these maximums, each patient's condition and response to treatment must medically warrant the number of services reported for payment. Medicare requires the medical necessity for each service reported to be clearly demonstrated in the patient's medical record. Medicare expects that patients will not routinely require the maximum allowable number of services.

Concern: The Alliance would like to point out that there are no utilization parameters/guidelines identified in this LCD. It is unclear what Novitas is referencing with the notice that was provided in the draft policy. This language is causing confusion for clinicians. As such, removing any reference to imposing utilization parameters would eliminate this confusion.

Recommendation: The Alliance recommends removing the Notice referring to utilization guidelines.

Conclusion

On behalf of the Alliance of Wound Care Stakeholders, we appreciate the opportunity to submit these comments. If you have any questions or would like further information, please do not hesitate to contact me.

Sincerely,

Marcia Nusgart R.Ph.

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Executive Director