ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

March 6, 2014

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

Submitted electronically to: donna.mandella@novitas-solutions.com

RE: DRAFT Local Coverage Determination (LCD) for Hyperbaric Oxygen (HBO) Therapy (DL34794)

Dear Ms. Mandella:

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 (HBO) therapy (DL34794). The Alliance is a nonprofit multidisciplinary trade association of health care professional and patient organizations 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 Alliance clinical specialty societies and organizations that not only possess expert knowledge in complex chronic wounds, but also in wound care research. Many of our members utilize HBO therapy in their practices when treating a patient with a wound. As such, we have a vested interest in this policy. A list of our members can be found at www.woundcarestakeholders.org.

General Comments

There is a significant difference in oversight and payment structure between hospital affiliated outpatient centers and independent or non-hospital affiliated centers. While provider based, hospital affiliated centers are surveyed by the Joint Commission as part of the hospital evaluation, those centers that are distant from the home campus function much like non-affiliated hyperbaric centers, and with this in mind, there should be no difference in the quality of care that is rendered based on location or affiliation. Physician and staff credentialing and certification should be consistent across all sites of service. This extends to both physician qualifications as well as facility accreditation.

We recommend that Novitas require that the Undersea and Hyperbaric Medical Society (UMHS) accredit all non-hospital affiliated hyperbaric facilities. Although other organizations have proposed accreditation, the UHMS has surveyed and validated enough centers to have achieved the status of a complementary accrediting body with the Joint Commission, and should be held as the standard against

5225 Pooks Hill Rd | Suite 627S | Bethesda, MD 20814
T 301.530.7846 | **C** 301.802.1410 | **F** 301.530.7946
marcia@woundcarestakeholders.org

which other programs might be judged. The UHMS is the authoritative source of scientific information for diving and hyperbaric medicine physiology worldwide and the accrediting body for clinical hyperbaric facilities.

As the number of hyperbaric facilities continues to increase in the United States, it is also increasingly important to address the need for consistent, safe, and appropriate hyperbaric oxygen therapy across all sites of service. Although hyperbaric oxygen therapy is a relatively safe therapy, it does have defined and significant risks, all of which should be handled with patient safety and quality outcomes in mind. Specifically, the Documentation Requirements states: "No payment will be allowed for HBO without documentation that a trained emergency response team is available and that the setting provides the required availability of ICU services that could be needed to ensure the patient's safety if a complication occurred" and the Licensed Professional Training and Competency Requirements states: "All physicians (MD, DO, DPM) who administer and/or supervise HBOT must maintain current Advanced Cardiac Life Support certification by the American Heart Association".

We do not think it unreasonable for Novitas to require all facilities to have a written policy which could be audited and inspected, outlining the management of emergent events and procedures to transfer a patient to a facility capable of providing emergent clinical support for the treatment of any complication arising from HBOT. This should include the activation of the 911 local response, to support initial life saving measures initiated by a trained physician and support staff, with transfer to a facility with appropriate ICU services. Because many hospital-affiliated centers are not within the hospital building, this policy would encompass all situations and would represent best practices in hyperbaric patient care.

Our specific comments are listed below.

Specific Comments

Evaluation and Management (E/M) of HBO Therapy

Issue: The Alliance would like to point out that the restriction on billing an Evaluation and Management code with HBO supervision code 99183 is in conflict with the AMA CPT committee recommendation which specifically exclude wound care services from the supervision and attendance of a hyperbaric oxygen therapy.

Language in the policy: Medicare does not expect to see E/M services billed routinely on the same day as HBO treatment. Medical necessity and work of a separately identifiable significant concurrent E/M service must be documented when reported for Medicare payment. Generally, the contractor will expect to find the E/M service reported only in the case of medically necessary E/M work related to a separate issue (unrelated to the wound) or a complication of HBO or the underlying medical condition for which HBO is required. Routine wound assessment, wound monitoring, and redressing of the wound, in addition to an assessment of the patient, cardiopulmonary stability and general clinical condition prior to the initiation of the therapy is an integral part of the HBO treatment and all are included in payment for physician supervision of HBO services (99183).

The Alliance has two main concerns with this language:

Concern #1: Physician billing of an E/M on the same day as HBO treatment. In the CPT code book descriptor of 99183, it is described as "Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy per session" and depending upon the publication source the following language is added:

From the Optum CPT wording for 99183 (2013/2014)

- EXCLUDES: Evaluation and management services when performed
- EXCLUDES: Other procedures such as wound debridement, when performed

From the AMA CPT wording for 99183 (2013/2104)

- (Evaluation and Management services and/or procedures (e.g. wound debridement) provided in a hyperbaric oxygen treatment facility in conjunction with a hyperbaric oxygen therapy session SHOULD be reported separately).

The CPT committee specifically excluded wound care services from the supervision and attendance of a HBO therapy. Therefore, the Novitas draft LCD, as currently worded, is in direct conflict with the accepted code description. The wording is specific, as the work product of 99183 is limited to the actual hyperbaric encounter and not any other service.

Concern #2: Facility billing of an E/M on the same day as HBO treatment. Our concern is that it is implied that the facility can not bill an E/M on the same day that an HBO treatment was performed and that the physician will not be permitted to bill for wound related cognitive services.

Issue: Wound care treatments typically occur weekly while the wound heals. HBO treatments, which are an adjunctive wound care therapy, are administered five days per week for approximately 4-6 weeks. While not specifically noted in the LCD, we be believe the facility billing of an Evaluation and Management code with C1300 *Hyperbaric Oxygen under pressure, full body chamber, per 30 minute interval* represents separate and distinct uses of hospital facilities resources and therefore both may be billed on the same day. If the patient comes into the facility for HBO therapy and has a debridement performed by the physician, the facility can bill the procedure as well as the HBO treatment for the same day/visit. When a debridement is not performed yet the physician performs cognitive services and the patient receives their HBO treatment, the facility should be able to bill the E/M code and the HBO therapy and the physician should be able to bill their cognitive services. However, Novitas says the physician time to assess the patients wound is included in the HBO supervision – which it is not. The AMA CPT says that the fee is simply for the supervision of the HBO therapy and NOT for wound care.

Recommendation: The Alliance recommends that Novitas remove the section titled Evaluation and Management (E/M) services, as we believe that it does not conform to the AMA CPT instructions.

Coverage Guidance

Language in the policy: Under the Coverage Guidance section, the Coverage Indications state:
"The following conditions meet coverage indications per National Coverage Determination (NCD) 20.29: Covered Conditions
Note: Conditions marked with ** are covered only when provided in the inpatient setting.

- **Acute carbon monoxide intoxication (ICD-9-CM diagnosis code 986)
- **Decompression illness (ICD-9-CM diagnosis codes 993.2 and 993.3):
- **Gas embolism (ICD-9-CM diagnosis codes 958.0 and 999.1
- **Gas gangrene (ICD-9-CM diagnosis code 040.0):
- **Acute Traumatic Peripheral Ischemia (ATPI) (ICD-9-CM diagnosis codes 902.53, 903.1, 903.01 904.0 and 904.41):
- **Crush injuries and suturing of severed limbs (ICD-9-CM diagnosis codes 927.00–927.03, 927.09–927.11, 927.20–927.21, 927.8–927.9, 928.00–928.01, 928.10–928.11, 928.20–928.21, 928.3, 928.8–928.9,929.0, 929.9, and 996.90–996.96, 996.99):
- **Progressive necrotizing infections (necrotizing fasciitis) (ICD-9-CM diagnosis code 728.86):
- **Acute Peripheral Arterial Insufficiency (ICD-9-CM diagnosis codes 444.21, 444.22 and 444.81):
- **Cyanide poisoning (ICD-9-CM diagnosis code 987.7 and 989.0"

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 HBO therapy 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 physicians 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. 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 many indications should be treated in an inpatient setting, there are other conditions listed that depend on the multidimensional nature of clinical decision making and could be appropriate to treat in an outpatient setting.

Recommendation: The Alliance recommends that Novitas look to the specialty societies/associations to determine which conditions are appropriate for treatment in the inpatient versus out patient setting. The Alliance further recommends the language in the draft LCD be changed to read: "The following conditions meet coverage indications per National Coverage Determination (NCD) 20.29: Covered Conditions Note: Conditions marked with ** are covered only when provided in the inpatient setting.
- **Gas embolism (ICD-9-CM diagnosis codes 958.0 and 999.1
- **Gas gangrene (ICD-9-CM diagnosis code 040.0):
- **Cyanide poisoning (ICD-9-CM diagnosis code 987.7 and 989.0"

• **Progressive necrotizing infections (necrotizing fasciitis) (ICD-9-CM diagnosis code 728.86):

State Practice Act

Language in the policy: Podiatrists can perform HBOT based on their state practice act. The LCD is silent on NPs and PAs supervising HBOT.

Concerns: We agree that podiatrist can perform HBOT based on their state practice acts. However, we note that 42 C.F.R. § 410.27(a)(1)(iv), expressly allows *nonphysician practitioners* to supervise services that they may personally furnish in accordance with state laws and other requirements. CMS defines a "nonphysician practitioner" to include, in pertinent part, physician assistants, nurse practitioners and clinical nurse specialists. Accordingly, under CMS regulations, nonphysician 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 nonphysician practitioner's scope of practice as defined in applicable state and other requirements.

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

Documentation Requirements

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 System. There are 5 grades to the Wagner Grading scale for diabetic foot ulcers. The Wagner Grading System[1] is as follows:

A. Grade 1: Superficial Diabetic Ulcer
B. Grade 2: Ulcer extension
    a. Involves ligament, tendon, joint capsule or fascia
    b. No abscess or Osteomyelitis
C. Grade 3: Full thickness ulcer with abscess or osteomyelitis or tendonitis
D. Grade 4: Gangrene to portion of forefoot
E. Grade 5: Extensive gangrene of foot

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

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

the correct Wagner III definition. The language should read, "Documentation must demonstrate an ulcer with abscess or osteomyelitis, or tendonitis 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.
Executive Director