ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

August 7, 2018

Glenn Hamilton, MD, FAAFP
Vice President, Corporate Clinical Policy
AmeriHealth Caritas Family of Companies
200 Stevens Drive, Bldg. 200
Philadelphia, PA

RE: AmeriHealth Caritas Clinical Policy: Full-body Hyperbaric Oxygen Therapy (HBO_2), Clinical Policy Number: 18.02.01

Dear Dr. Hamilton;

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit the following comments in response to AmeriHealth Caritas Clinical Policy: Full-body Hyperbaric Oxygen Therapy (HBO_2).

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 (diabetic foot ulcers, venous stasis ulcers, pressure ulcers and arterial ulcers) 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_2 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 on our website: http://www.woundcarestakeholders.org/about/members.

GENERAL COMMENTS

The Alliance appreciates that AmeriHealth has drafted a clinical policy for HBO_2. HBO_2 is a valuable treatment option for improving wound healing in patients with diabetes, radiation complications, compromised flaps and grafts, and complex non-healing wounds. The use of HBO_2 has contributed to a decrease in the national amputation rate, as more patients have received advanced wound care, including HBO_2, from a multidisciplinary team of providers. We support the need for safe and effective HBO_2 and the need for policies that minimize administrative burdens while still being easy to implement and enforce. However, in reading this policy, we have identified clinically inaccurate or unsubstantiated information which we are addressing in our specific comments listed below and would urge you to adopt our recommendations. We would welcome the opportunity to

serve as resource to you and your staff to answer questions or provide additional clinical information to you on this issue.

SPECIFIC COMMENTS

Diabetic Wound of the Lower Extremity

Within the section "Medically necessary indication for HBO_2: Diabetic wounds of the lower extremities, when all of the following criteria are met", the policy contains the following language:

Language in the Policy:

The wound has failed to respond to negative pressure wound therapy, a vacuum dressing to promote healing in acute or chronic wounds, and enhance healing of 2nd and 3rd degree burns.

Concern #1: The Alliance disagrees with the requirement that a failed response to negative pressure wound therapy must be required prior to the use of HBO_2. HBO_2 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 (Although not appropriate for well-vascularized skin grafts and flaps, since those that appear mottled or at risk should be treated as soon as the problem is recognized). For your review, there is an excellent overview of the science of hyperbaric oxygen for flaps and grafts and its treatment rationale, authored by Lisa Gould, MD, PhD who is a plastic surgeon and past president of the Wound Healing Society.[1]

There is no literature which supports the requirement that NPWT must be utilized prior to the use of HBO_2 therapy nor is there evidence to support that the rate of healing when NPWT is used prior to HBO_2 therapy is of any benefit. In fact, both NPWT and HBO_2 are appropriate adjunctive therapies to treat chronic wounds and independently have evidence to support their use and efficacy in treating patients with chronic wounds. The indication for Hyperbaric Oxygen in the diabetic wound is based on the hypoxic wound, i.e. the wound does not have inherent oxygen sufficient for the wound healing process. This includes inability for leukocytes to kill off bacteria, and minimal collagen production by fibroblasts, therefore no collagen matrix for angiogenesis. The wound does not have the capacity to heal. In such an environment, NPWT will debride dead tissue without wound enhancement often times deepening the wound with exposure to tendons and bone.

Recommendation: As such, we recommend that the requirement of the failed use of NPWT prior the use of HBO_2 therapy must be removed from the policy.

Concern #2: Moreover, the Alliance is a bit confused why AmeriHealth believes that diabetic wounds of the lower extremity are 2nd or 3rd degree wounds. Diabetic wounds of the lower extremity are not 2nd or 3rd degree burns nor are 2nd or 3rd degree burns classified as diabetic wounds of the lower extremity.

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[1] Gould LJ, May T. The Science of Hyperbaric Oxygen for Flaps and Grafts. Surg Technol Int. 2016 Apr;28: 65-72.

The notion that there is a relationship between diabetic foot ulcers and 2nd or 3rd degree wounds is completely inaccurate scientifically and clinically. Hyperbaric oxygen IS independently and indication for 2nd and 3rd degree burn wounds and are routinely treated at the Institute for Surgical Research Burn Center, collocated at Brooke Army Medical Center, Ft. Sam Houston, TX. Many of these patients are diabetic.

Recommendations:

In order for this policy to be accurate, we recommend that AmeriHealth remove this language from the policy. However, if AmeriHealth decides not to do this, we highly recommend replacing the current AmeriHealth Caritas DWLE language with the following language in order to make it clinically and scientifically accurate:

Medically necessary indication for HBO_2 Diabetic wounds of the lower extremities, when all of the following criteria are met:

- The individual has type I or type II diabetes and has a lower extremity wound that is due to diabetes;

- The individual has a wound classified as Wagner grade III or higher; and the individual has failed an adequate course of standard wound therapy;

- The individual meets the criteria for initiation or continuation of full body HBO_2:

  Initiation of full-body HBO_2 therapy to treat diabetic wounds of the lower extremities is considered medically necessary and, therefore, covered as adjunctive therapy when at least 30 consecutive days of standard wound therapy alone has produced no measurable signs of healing. Full-body HBO_2 therapy must be used in addition to standard diabetic wound care measures such as: assessment of vascular status; correction of vascular problems in the affected limb if possible;

- Optimization of nutritional status; optimization of glucose control; debridement by any means to remove devitalized tissue; maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings; appropriate off-loading; and necessary treatment to resolve any infection that might be present; OR

- Continued treatment of diabetic wounds with full-body HBO_2 therapy is considered medically necessary and, therefore, covered if measurable signs of wound healing are evident after a 30-day period of treatment with both full-body HBO_2 therapy and standard wound therapy. Wounds must be evaluated at least every 30 days during administration of HBO_2 therapy. If no measurable signs of wound healing (defined as specific, documented, clinical signs of healing) are evident after any 30-day period, continued treatment with full-body HBO_2 therapy is considered not medically necessary and, therefore, not covered.

In summary, the AmeriHealth policy as written is clinically and scientifically inaccurate. There is no scientific literature to support the language in the policy. As such, the Alliance recommends that either AmeriHealth eliminate the troublesome and inaccurate information or utilize the above recommended language provided by the Alliance.

Specialty Boards

In addition to the troublesome language in the policy identified above, the Alliance is extremely concerned about a requirement included in the Technical Criteria section of the policy. Specifically:

Language in the policy: In order for HBO_2 to be provided by a physician the following criteria below are met:

"...This physician must be appropriately educated in hyperbaric medicine and board-certified in undersea and hyperbaric medicine by any of these organizations:

- *American Board of Emergency Medicine (ABEM)*
- *American Board of Preventative Medicine (ABPM)*
- *American Board of Medical Specialties (ABMS)"*

Concerns: While the Alliance agrees and supports that clinicians receive appropriate training, we have the following concerns regarding information provided in this policy:

1. First, the American Board of Medical Specialties is not a Board in and of itself. It is an organization of all the recognized Boards and therefore does not provide any Board Certification on its own.
2. Second, in a 2002 Program Memorandum, CMS concluded that special supervision and credentialing requirements should not be imposed on physicians who perform HBO_2 therapy. Conditions for HBO_2 supervision that do not include a requirement for Board Certification specific to UHM were defined. Contractors cannot impose a higher level of training for supervision than what is already accepted by CMS, who encourages physicians that supervise HBO_2 therapy to obtain adequate training in the use of HBO_2 and in advanced cardiac life support.
3. Finally, the Alliance is concerned that the imposition of this requirement would significantly impact patient access to HBO_2 therapy. There are very few practicing HBO_2 therapy Board certified physicians nationwide. The imposition of this requirement would mean that physicians who are not currently Board certified would no longer be able to treat their patients – causing a disruption in their care. Obtaining Board certification takes over a year. Having clinicians give up their practice and their current patient load in order to obtain this certification is not reasonable.

Recommendations: As stated above, the Alliance is supportive of the requirement to obtain adequate training in the use of HBO_2 therapy; but we believe the mandatory requirement of obtaining Board

Certification is not permissible nor advisable since it also would be disruptive to patient care. However, the Alliance would be supportive of a requirement that physicians should receive appropriate training and education to safely supervise HBO_2.

As such, the Alliance recommends that AmeriHealth modify its policy to read as follows:

All physicians who administer or supervise HBO_2 Therapy must complete a minimum of 40 hours of either an in person or a web based training program approved by a University or a professional organization. This physician may undergo advanced education in hyperbaric medicine and eventual board-certification in undersea and hyperbaric medicine by any of these organizations the American College of Hyperbaric Medicine (ACHM) or the Undersea and Hyperbaric Medical Society (UHMS) prior to supervising HBO_2 Therapy.

Conclusion

On behalf of the Alliance of Wound Care Stakeholders, we appreciate the opportunity to submit these comments. As mentioned previously in these comments, we would be pleased to serve as a resource to you and your staff to answer any questions or to provide additional clinical information on this important topic.

Sincerely,

Marcia Nusgart R.Ph.

Marcia Nusgart R.Ph.
Executive Director