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Primum Non Nocere and the 5 Rights

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ABSTRACT

Overutilization of hyperbaric oxygen therapy (HBOT) is commonplace and primarily associated with outpatient wound care. While the number of hospitals providing HBOT is at an all-time high, the number of those willing to treat patients in immediate need is at an all-time low. Huge areas of the country, including major population areas, are now completely devoid of 24/7 HBOT availability and inpatient access. Purchasers of healthcare, including the Centers for Medicare and Medicaid Services, have become increasingly concerned to the point that several strategies have been introduced to constructively deal with this issue. This commentary serves as a counterpoint to concerns that one such approach, prior authorization of elective indications, adversely delays medically necessary care. The historical evolution of HBOT practice will be described to underscore how this problem has become so widespread and, to date, largely unchecked. It will also address the paradoxical national crisis of access for emergencies.

INTRODUCTION

The value of hyperbaric oxygen therapy (HBOT) in the appropriate setting is unquestioned. However, overutilization is common in the outpatient wound setting, and healthcare payers, including the Centers for Medicare and Medicaid Services (CMS), have become increasingly aware of and concerned about this problem. This commentary is a counterpoint to recently expressed concerns by some that preauthorization for treatment causes a delay in care. The authors examine the historical background of HBOT and its evolution. They also review HBOT's current application in the context of overutilization and loss of 24/7 access and discuss their insights relative to the preauthorization process.

For the first time in its 5-decade history, Medicare has introduced a clinical prior-authorization mandate. This CMS process is in response to perceived overutilization of HBOT.[1] It took effect in 2015 as a 3-year demonstration project involving New Jersey, Illinois, and Michigan. Clinicians in these 3 states wishing to treat hyperbaric medicine's elective indications must now seek prior authorization. Hyperbaric prior authorization has long been required for commercial insurance plans (with the exception of immediate life-threatening issues that are most appropriate for emergency care), but this clinical practice prior authorization is unique within CMS. Should a patient truly present with an emergency that does not allow time for an immediate preauthorization, such as severe carbon monoxide poisoning, symptomatic air or gas embolism, or acute limb-threatening arterial occlusions, HBOT can be provided on an emergent basis pending preauthorization for payment purposes. In these cases, providers can seek retroactive authorization.

Early results of this initiative have confirmed to Medicare's leadership that a great deal of overutilization exists. What has become equally apparent is that overutilization takes the form of medically unnecessary courses of HBOT and inappropriate/nonapproved indications for HBOT in all outpatient treatment venues (privately owned, hospital owned, and/or investor owned). The experience of CMS appears to mirror the experience of commercial payers, which has prompted a redesign of HBOT oversight.

In response to this change in oversight and the CMS preauthorization rule, the Undersea and Hyperbaric Medical Society (UHMS) asked its members in affected states to complete a survey called the ''CMS Prior Authorization Innovation Project'' regarding this initiative. The UHMS was to meet with CMS on September 23, 2016, to discuss the particulars of this program ''and some of the issues practitioners and patients are experiencing with delayed care'' (quote from e-mail from John Peters, UHMS Executive, September 2016). The complete survey is available at www.surveymonkey.com/r/PreAuth16.

Apparently, some HBOT physicians and the UHMS claim that the preauthorization requirement is causing injurious delays in care. This article serves as a counterpoint to the apparent concern that this HBOT preauthorization process delays medical care. It will also examine what lies behind the loss of availability for a majority of the US FDA–approved

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and UHMS-recommended indications, those from which patients arguably have the most to gain. Long recognized for its lifesaving, central nervous system–sparing, infection-fighting, and tissue-salvaging attributes, HBOT has been called into question by a broad cross section of healthcare delivery system stakeholders.[1–5]

BACKGROUND

Because the aforementioned issues are so complex, in order to fully appreciate them, one needs to understand the historical evolution of the use of HBOT for various conditions. Throughout the first half of the last century, hyperbaric (recompression) chambers did not exist within the traditional healthcare delivery system. Rather, they were located at compressed air tunneling and bridge caisson work sites, within select military facilities, and in support of various underwater operations. In these medically remote settings, chambers were used to both decompress individuals from elevated pressures and treat any resulting decompression sickness. It was not until the 1960s that chambers were first introduced into hospitals and therefore to mainstream medicine.

This was the period in which several therapeutic mechanisms associated with exposure to hyperbaric doses of oxygen were identified and the term ''hyperbaric oxygen therapy'' was introduced. These mechanisms included the transportation of high levels of oxygen within plasma to support acutely ischemic tissues, an antimicrobial-like action on certain anaerobic and aerobic bacteria, enhanced elimination of carbon monoxide, vasoconstriction (without component hypoxia) to augment management of acute ischemia, and stimulation of repair in deficient wound healing secondary to local hypoxia. Therefore, the FDA eventually accepted the recommendations of the Undersea (now Undersea and Hyperbaric) Medical Society on approved uses of HBOT. These same uses were adopted by government and commercial purchasers of healthcare for beneficiary reimbursement policy purposes.

OVERUTILIZATION

Given that many of the approved indications are acute or emergent in nature, for the benefits of HBOT to be fully realized, it is imperative that patients are promptly evaluated and treated for these acute conditions. However, in elective and chronic cases, the same urgency does not exist. Consequently, treatment protocols and guidelines exist for each approved indication, whether it is acute or chronic. However, over the years, it has become apparent that the very nature of hyperbaric reimbursement (where payment is provided for each individual procedure) presents the incentive to provide additional treatments beyond those considered medically necessary and to recommend treatment for conditions that do not meet stringent evidence-based medical necessity criteria, creating the risk of overutilization and putting patients unnecessarily at risk.

The potential for overutilization is not helped by the fact that precise dosing protocols have never been adequately validated for a majority of the HBOT indications. Specifically, no well-defined end points exist, although the UHMS has identified indication-specific treatment thresholds that, if reached, should prompt utilization review. When to stop HBOT is often also a somewhat inexact decision. This issue is most commonly encountered in the outpatient wound care setting, and healthcare payers, including CMS, have become increasingly aware of and concerned about this problem.

Not infrequently, clinicians adopt the UHMS utilization review threshold as their initial number of ordered treatments, when in fact this number should represent only outlier cases, according to the UHMS.[6] Others provide or request to provide HBOT for conditions that are either nonexistent or are upgraded from a condition that does not meet medical necessity criteria; examples include HBOT treatment for diabetic foot ulcers and treating wounds to complete epithelialization and closure. As reasonable as this may sound as a treatment goal, it is medically unnecessary and leads to high rates of overutilization, because HBOT is used in the setting of locally hypoxic wounds to stimulate healing responses by a variety of mechanisms (the most important being induction of angiogenesis sufficient to normalize an otherwise deficient reparative process). Once unaided spontaneous healing has begun, wounds should be expected to move along anticipated timelines with standard care alone. This therapeutic end point is identified to a large extent by tissue oximetry testing, clinical assessment, and/or a short ''medical holiday.''

The use of HBOT in this manner requires considerably fewer treatments; uses them in a medically necessary, evidence-based manner; and greatly improves cost-effectiveness, in addition to minimizing exposure of patients to potential adverse events. Utilization review indicates that overutilizers of HBOT generally do not follow this approach. For example, it is not uncommon to learn of patients enduring 80 to 100 treatments or more, with estimated provider charges of $250,000 to $300,000. While HBOT is generally a safe treatment modality, treatment is not without risk, particularly in patients with significant comorbidities; these rates of utilization are well above even the UHMS upper thresholds and have no basis in peer-reviewed published medical literature.

EVIDENCE-BASED TREATMENT WITHOUT DELAY

Based on the extensive peer-reviewed literature, there are 14 approved indications for HBOT.[6] Although many are acute conditions, in the authors' experience, the majority of HBOT requests referred for preauthorization are for chronic conditions, and therefore, there is no delay in care arising from the

need for preauthorization. The preauthorization process is not only swift and efficient, but it also serves an important second purpose: to ascertain that every patient is being managed with the right treatment at the right time for the right indication and right length of time, based on evidence in the literature and generally accepted treatment guidelines (the 5 rights).

Based on these treatment guidelines and the available literature, Humana has undertaken an extensive program review of the HBOT authorization review process, including education for their nurse and physician reviewers and revision of pre-and post-HBOT authorization procedures. On the commercial payer side, Humana has strengthened its evidence-based decision making, which relies heavily on UHMS's 13th edition textbook; up-to-date, available, evidence-based literature[7–12]; and frequent consultations with nationally recognized subject matter experts. As a consequence of this enhanced review process, they can better support evidence-based clinical decisions made by responsible clinicians, which allow HBOT to be rendered to the right patient at the right time for the right indication and right length of time. Not only does this promote utilization of HBOT for appropriate clinical indications, but it also ensures that patients are not exposed to potentially harmful adverse events (eg, barotrauma, seizures, pulmonary edema) unnecessarily.

It is incorrect to assume that the preauthorization process in and of itself is in place to delay or deny necessary care; rather, it ensures that patients in need of HBOT receive medically sound and responsible care in an efficient, safe, and evidence-based manner. Surely, clinicians who overutilize HBOT in conflict with recommended treatment guidelines will be affected by the preauthorization process. However, those practicing evidence-based medicine should not be adversely affected by prudent review procedures.

It would be exceedingly unlikely that any payer would deny a legitimate and urgent request for HBOT if documentation shows that a true emergency existed. In addition, it is incumbent upon the treating physician to protect his/her patients in urgent/emergent situations. Coverage decisions should never prevent a physician from doing what he/she feels is in the best interest of his/her patients when they are truly at risk of immediate injury. In contrast, when a physician has a patient who suffers from a chronic, nonurgent condition, he/she can afford to wait for preauthorization for treatment to ensure coverage of his/her services. Therefore, Humana aims to assist the physician in providing safe, efficient, medically efficacious, and cost-effective care to those patients with evidence-based indications for HBOT in a partnership/cooperative care model.

Along those lines, everyday experience with HBOT prior-authorization requests has shown that the majority of requests for HBOT are inappropriate and inconsistent with evidence-based medical principles. These cases are usually conditions that have existed for weeks, months, or even years. There is no evidence that the requirement of prior authorization for these chronic conditions is deleterious to these patients. The questions then arise: What are the driving factors for this trend toward overutilization, these requests for unapproved indications, and what motivates the desire to halt efforts of preauthorization?

THE WOUND MANAGEMENT BUSINESS MODEL

The authors are of the opinion that what has changed is the introduction of a wound management business model, with its genesis in the mid-1990s. In the wound management business model, companies would propose to hospitals the introduction of wound care centers that included hyperbaric chambers, which the company would then operationally and administratively oversee. The company's compensation would be structured as a fixed monthly management fee and a share of the hospital's health insurance payments generated from services rendered within the center. In order to maximize net revenues, the model was structured to be used during normal business hours and based in the outpatient setting. This is where problem/chronic wound patients can expect to be seen. No less importantly, it is where reimbursement is its most robust.

This model is a significant departure from the 24/7 hyperbaric medicine availability required to treat acute HBOT-responsive emergencies. Traditional hospital-owned and managed hyperbaric medicine programs rely heavily on outpatient-generated revenue to underwrite the not inconsiderable costs associated with the provision of 24/7 care. Such costs include the acquisition of specialized hyperbaric-specific biomedical technologies and related ancillary equipment; more highly qualified (more expensive) clinical and technical staff; and on-call compensation for nursing, technical, and physician teams. Lower reimbursement prospects associated with inpatient care caused most wound management companies to shy away from making hyperbaric services available to those patients who arguably need it the most.

As the wound management business model blossomed, it increasingly competed head-to-head with existing 24/7 programs for outpatient market share. All too commonly, hospital-owned programs providing evidence-based 24/7 care suffer as a result. Many have found it necessary to reexamine their financial and clinical commitments to 24/7 access and provision of inpatient care. Perhaps not surprisingly, many of these institutions have elected to convert to outpatient services only or close their service altogether. It is conceivable that some may have elected to do so independent of the above market forces, but they certainly would have been a distinct minority.

The consequence of all of this is that today huge swaths of the country, including major population centers, are now

completely devoid of critical 24/7 hyperbaric access. This point is illustrated by letters received from conscientious physicians who find themselves practicing in this relatively new model. The aforementioned UHMS survey has prompted some HBOT clinicians to contact the leadership at National Baromedical Services. The following are excerpts of anonymized letters received from concerned clinicians:

''Interestingly, they have another hospital close by that is managed by the wound care management company that manages the program where I am employed as a physician. I have done my best to provide the best services for my patients, inform administrators of my concern, and maintain my integrity regarding patient work-ups and HBOT. Unfortunately, I have failed despite my best efforts. For those who have been invested in hyperbaric medicine for many years, the current growth of low-acuity, high-volume practices may be like watching a metastasizing cancer. A well-managed basic hyperbaric course has provided great benefit to many by expanding the availability of HBOT. Unfortunately, many clinicians have utilized this model to find and train healthcare clinicians who participate in a high-volume, profit-driven practice causing great damage to the hyperbaric medicine profession. Potential hyperbaric patients are routed to 'more aggressive hyperbaric physicians,' avoiding those of us who practice HBOT conscientiously.''

''An example of the advantages of available inpatient hyperbaric treatment is a patient we had here. He had suffered 3 previous heart attacks. I wrote in my note that his condition would indicate HBOT but that it would pose a significant risk with his severe cardiac impairment. He was transferred to another physician, and orders were written for HBOT after his internal defibrillator was cleared for pressure. He had another heart attack and died before the first treatment. Hyperbaric therapy may have benefited him, but it would have been foolish to attempt this at an outpatient wound care clinic across town from our hospital without Advanced Cardiovascular Life Support capability. Unfortunately, the high-volume, low-acuity model favors those arguably least likely to benefit from HBOT. Those with complicated medical conditions who may benefit the most from therapy are excluded. My idea of an aggressive physician is someone who is willing to take complicated cases and do the difficult work of measuring risks and benefits for complicated patients, not to increase the volume of low-acuity patients who can be placed in a chamber and then receive payment when the condition could heal with conservative therapy.''

These letters from physicians who treat patients everyday are disturbing, albeit not surprising. They describe what has become commonplace in the world of hyperbaric medicine. Access to the most vulnerable is lost, training and formal HBOT exposure are inconsistent, and HBOT requests often do not follow evidence-based guidelines. Payers are rightfully concerned, and the issues are much bigger than overutilization and lack of 24/7 access. The aim is to protect the right of the patient, avoid patient exposure to potentially harmful therapy, and provide care that is evidence driven and guideline based.

The following section reviews representative samples of HBOT requests, which abound in commercial plans. There is no reason to believe that Medicare requests would be any different, on the basis of which CMS has already taken corrective action with the preauthorization demonstration project. The case examples listed here serve to demonstrate the importance of preauthorization in order to minimize inappropriate use of HBOT and to maximize the provision of the right care for the right patient at the right time for the right indication and for the right amount of time.

CASE EXAMPLES

1. A request was received for 40 HBOT treatments. The purported indication for treatment was a Wagner 3 diabetic foot ulcer. The documentation by the HBOT physician stated that treatment was needed because the patient's limb was at risk of loss, the wound was large, tendon was exposed, and he debrided the wound during the last visit. No further documentation was provided regarding the provision of standard wound care. The wound care center was contacted proactively to obtain the necessary information for approval. The wound care nurse attending to the patient reported that the wound was $0.1 \times 0.1 \times 0.1$ cm (the size of a pencil tip). The request for HBOT was not authorized because the wound was not consistent with the purported diagnosis.
2. An authorization request was received for HBOT for a wound on the basis of a ''compromised surgical flap,'' a recognized indication for HBOT. The patient had previously undergone surgery for a calcaneal fracture, and he developed wound dehiscence. This resulted in an L-shaped wound on the medial hind foot. Photographs of the wound showed no surgical flap. However, the operative note referred to a periosteal flap, which meant that the periosteum had been elevated off the bone. This was entirely unrelated to a skin flap, and the request for HBOT was not authorized. The nonapproval decision was appealed, and the independent external reviewer upheld the decision and agreed that no flap failure was present. The external reviewer documented, ''The attempt to justify HBOT on the basis of the term 'flap' in this context in the operative note is disingenuous.''

3. A patient self-referred to a hyperbaric center in Texas. She claimed that she had experienced a traumatic brain injury in childhood, and she was requesting treatment with HBOT to help her brain function better. The HBOT physician agreed that she was a candidate for HBOT and prescribed 40 treatments. The prescribing physician's preauthorization request stated that the patient had brain malaise and that the provision of HBOT would help her ''nonhealed brain injury'' heal. The request was denied because this was not an evidence-based indication.
4. A primary care physician made a referral to the wound care center for his 42-year-old patient. The referral stated: ''Evaluation and treatment of wounds to include debridement and compression wraps, if needed ×20 visits.'' The HBOT physician instead submitted a preauthorization request for HBOT. The wound care doctor self-referred for HBOT. The patient had a venous stasis ulcer of many months' duration in the setting of chronic leg swelling and varicose veins. However, venous stasis ulcers are not an evidence-based indication for HBOT, and the preauthorization request was not approved.
5. An authorization request was received for a 21-year-old woman with a history of recurrent pancreatitis. She had recently undergone a sphincterotomy with stent placement. She had long-standing anemia with iron deficiency and a recent blood transfusion. The HBOT physician recommended 40 treatments because of anemia. Her hemoglobin was 8 and stable. The requested treatment was not authorized because this was not an evidence-based indication for HBOT. The denial of coverage was appealed and went for external review, and the decision not to authorize coverage was upheld.

CONCLUSIONS

In closing, the authors of this commentary are of the opinion that a nationwide expansion of HBOT prior authorization, including but not limited to CMS's prior authorization of HBOT, is needed in order to maximize positive clinical outcomes through the provision of the right care at the right time for the right patient for the right indication and right length of time (the 5 rights). Furthermore, the authors implore wound care/HBOT centers to employ properly trained clinicians who understand the evidence-based indications for HBOT and are motivated by the desire to provide excellent, ethical, cost-effective, and evidence-based treatments for their patients. ●

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