

STATE OF MICHIGAN
DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES
Before the Director of Insurance and Financial Services

In the matter of:

████████████████████

Petitioner

v

File No. 154606-001

Humana Medical Plan of Michigan, Inc.

Respondent

Issued and entered
this 22nd day of August 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On July 18, 2016, ██████████, authorized representative of ██████████ (Petitioner), filed a request with the Director of Insurance and Financial Services for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives health care benefits through an individual medical policy issued by Humana Medical Plan of Michigan, Inc. (Humana), a health maintenance organization. The benefits are defined in Humana's *Individual HMO Medical Policy*.

The Director notified Humana of the external review request and asked for the information used to make its final adverse determination. Humana provided its response on July 20, 2016. After a preliminary review of the material submitted, the Director accepted the request on July 25, 2016.

The case involves a medical issue so it was assigned to an independent review organization which submitted its recommendation to the Director on August 10, 2016.

II. FACTUAL BACKGROUND

The Petitioner is 50 years old and has type 2 insulin-dependent diabetes, end stage renal disease, and severe peripheral vascular insufficiency of his lower extremities. His left foot was partially amputated May 4, 2016 but it failed to heal. His physician recommended hyperbaric oxygen therapy (HBOT) and requested that

Humana authorize coverage for this treatment.

Humana denied coverage for the HBOT, indicating it was not medically necessary. The Petitioner appealed the denial through Humana's internal grievance process. At the conclusion of that process, on July 8, 2016, Humana issued a final adverse determination affirming its denial. The Petitioner now seeks the Director's review of that adverse determination.

III. ISSUE

Is HBOT medically necessary for treatment of the Petitioner's condition?

IV. ANALYSIS

Humana's Argument

In its final adverse determination, Humana stated that it had the Petitioner's appeal reviewed by a doctor (described as a "private review agent") who is board certified in vascular surgery and general surgery with special training and expertise in hyperbaric medicine, wound care, and critical care. Humana wrote:

We were unable to approve your appeal because a review of the available information, it was determined that administration of HBO at this point might not help and may possibly expose the patient to potential dangers. However, if the member can be proven, e.g. with transcutaneous oxygen measurements, that he is physiologically capable to respond with increased/appropriate periwound tocm measurements with a hyperbaric oxygen challenge, then this decision can be revised. In the absence of a positive response to an oxygen challenge, the member is showing that he has no physiologic capacity to heal with hyperbaric oxygen.

The private review agent stated that "According to the submitted policy and the clinical information provided, the criteria for medical necessity for HBOT have been met. Specifically, the patient has a non healing flap, as the plantar flap of the transmetatarsal amputation is indeed a flap, and it is clearly compromised. In addition, the wound on the foot clearly qualifies as a Wagner 3 diabetic foot wound, meeting a second, Independent criterion for the use of the HBOT.

This case presents a dilemma. It is not appropriate to declare that the peripheral arterial disease is not intervenable. It is certainly can be intervened upon, but doing so will impose a risk of worsening renal failure. One cannot be certain that renal failure will be impacted, and if it is indeed impacted, the deterioration may be

temporary or permanent, and the deterioration may be minor or major (culminating in dialysis).

In other words, this is all a risk to benefit assessment, and one that the patient must help to guide. Without revascularization, amputation of the foot is likely to be the end result regardless of the use of HBOT. With revascularization, there is a significantly better opportunity to salvage the foot, although it still not a guarantee by any means, but there is a risk of accelerated loss of renal function.

Steps can be taken to minimize the risk to renal function by 'pushing' hydration before and after the procedure, and possibly through use acetyl cysteine before and after the procedure, but these steps cannot guarantee that renal function will be protected. Of course, even without revascularization, a diabetic, especially without good control, is always at risk of declining renal function.

The bottom line is that that patient is in a difficult situation, one which the individual prioritization of limb salvage versus preservation of renal function must be considered, while acknowledging that there are no guarantees either way, it is not likely that HBOT is going to materially change these considerations, and the delay in revascularization accompanying a long course of HBOT may only worsen the likelihood of limb salvage in the event of later revascularization as the foot may continue to deteriorate even with HBOT.

Therefore, based on the submitted guidelines and clinical information provided, the patient does meet the criteria for HBOT; however, the criteria cannot take into account the many overlying issues and competing priorities in a case such as this."

Petitioner's Argument

In a letter dated July 8, 2016 accompanying the request for an external review, Petitioner's physician explained the medical necessity for HBOT:

I am writing this letter for a second time on behalf of [Petitioner] as a result of the unfavorable decision for adjunctive hyperbaric oxygen therapy. Since our initial authorization request we have continued to treat this patient and have continued to see the flap and ulceration worsen. Since our initial visit we have been treating a flap and ulceration of mixed etiology, that being compromised not only by inoperable vascular disease (as documented by the vascular surgeon) but that the patient required the initial amputation and revision as a result of an abscess and diabetic ulceration. Since the revision surgery the patient has had an open diabetic Wagner grade 3 ulceration. Given that our attempts at obtaining authorization have failed for 30 days despite an

aggressive plan to promote healing, this patient meets the medical necessity of a Wagner grade 3 diabetic ulceration ... I feel that we have treated this patient and had identified an appropriate diagnosis that meets medical necessity within the guidelines outlined and defined by CMS within the National Coverage Determination for this service request and that a continued denial would be doing a disservice to the patient ultimately resulting in further extensive amputation.

Director's Review

Humana's *Individual HMO Medical Policy* excludes coverage for services that are not medically necessary. The *Policy* (page 79) defines medical necessity as:

healthcare services that a healthcare practitioner exercising prudent clinical judgment would provide to his/her patient for the purpose of preventing, evaluating, diagnosing, or treating a sickness or bodily injury or its symptoms. The fact that a healthcare practitioner may prescribe, authorize or direct a service does not of itself make it medically necessary or covered under this policy. Such healthcare service, treatment or procedure must be:

1. In accordance with nationally recognized standards of medical practice;
2. Clinically appropriate in terms of type, frequency, extent, setting, and duration and considered effective for the patient's sickness or bodily injury;
3. Not primarily for the convenience of the patient or healthcare practitioner or other healthcare provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the patient's sickness or bodily injury.

For the purpose of medically necessary, generally accepted standards of medical practice means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations, the views of healthcare practitioners practicing in relevant clinical areas, and any other relevant factors.

The question of whether HBOT is medically necessary for treatment of the Petitioner's condition was presented by the Director to an independent review

organization (IRO) for analysis as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO reviewer is a licensed podiatrist in active practice who is board certified in foot and ankle surgery and is published in peer review medical literature. The IRO report included the following analysis and recommendation:

Hyperbaric oxygen therapy (HBOT) has been promoted as an effective treatment for diabetic foot wounds, and the first controlled trial for this indication was reported over twenty years ago. Advocates have suggested that the experimentally demonstrated effects of HBOT on improving wound tissue hypoxia, enhancing perfusion, reducing edema, downregulating inflammatory cytokines, promoting fibroblast proliferation, collagen production, and angiogenesis make it a useful adjunct in clinical practice for "problem wounds", such as diabetic foot ulcers. HBOT is also touted for eradicating difficult to treat soft tissue and bone infections by mechanisms that include killing microorganisms, improving leukocyte and macrophage function, and enhancing the effect of antimicrobials.

[Description of relevant medical studies omitted.]

In the treatment of diabetic patients with compromised vascularity and diabetic foot ulcerations, HBOT is medically indicated. At the time for this enrollee, he was status post flap compromise, but he was also diagnosed with a deep ulceration of the foot for which HBOT is a frequently-used adjunctive therapy. This treatment is available at many large hospitals and at free-standing wound care centers. HBOT is definitely within the standard of care for treatment of wounds such as were present in this case.

The enrollee was vascularly compromised, had renal insufficiency, and was an insulin-dependent diabetic with a limb-threatening Wagner grade 3-4 wound of the foot. Although there was a failed graft flap, the fact remains that the enrollee had a deep wound for which HBOT was indicated. It is fair to say that the literature does find a low to moderate level of evidence that HBOT promotes successful "take" of compromised flaps and grafts; however, this case presented a deep ulceration and the treatment is considered a limb salvage attempt. Therefore, for the reasons noted above, HBOT is medically necessary for this enrollee.

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). However, the recommendation is afforded deference by the Director. In a decision to uphold or reverse an adverse determination, the Director must cite "the principal reason or reasons why the [Director]

did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b). The Director, discerning no reason why the IRO's recommendation should be rejected in this case, finds that HBOT is medically necessary for the Petitioner's treatment and is therefore a benefit under the terms of Humana's *Individual HMO Medical Policy*.

V. ORDER

The Director reverses Humana's final adverse determination.

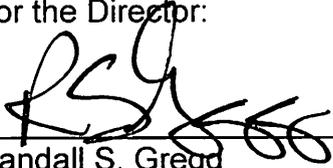
Humana shall immediately provide coverage for the Petitioner's HBOT treatment. See MCL 550.1911(17). Further, Humana shall, within seven days of providing coverage, furnish the Director with proof it has implemented this order.

To enforce this order, the Petitioner may report any complaint regarding its implementation to the Department of Insurance and Financial Services, Health Care Appeals Section, at this toll free number: (877) 999-6422.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this order may seek judicial review no later than 60 days from the date of this order in the circuit court for the Michigan county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Department of Insurance and Financial Services, Office of General Counsel, Post Office Box 30220, Lansing, MI 48909-7720.

Patrick M. McPharlin
Director

For the Director:



Randall S. Gregg
Special Deputy Director