Hyperbaric Oxygen Therapy, Topical Oxygen Therapy

Medicare Advantage Medical Coverage Policy

Table of Contents

Related Medical/Pharmacy Coverage Policies
Related Documents
Description
Coverage Determination
Coverage Limitations
Coding Information
References
Appendix
Change Summary

Disclaimer
The Coverage Summaries are reviewed by the iCare Medicare Utilization Management Committee. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT® codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from iCare.

Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents
Please refer to CMS website for the most current applicable National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

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Hyperbaric Oxygen Therapy, Topical Oxygen Therapy

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<td>JJ - Palmetto GBA (Part A/B MAC)</td>
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**Description**

During **hyperbaric oxygen therapy (HBOT)**, an individual is placed in a specially designed chamber that is pressurized to greater than sea level (one atmosphere absolute [1 ATA]) and breathes near 100% oxygen. The result of this direct pressure and hyperoxygenation is an increase in alveolar oxygen and a rise in dissolved plasma oxygen content promoting enhanced tissue oxygen delivery and healing. Other purported benefits of therapy include antimicrobial activity, attenuation of reperfusion injury, neovascularization and vasoconstriction.

Treatment may take place in a monoplace chamber or a multiplace chamber. The monoplace chamber accommodates one individual in the supine position and is pressurized with 100% oxygen, allowing the ambient chamber air to be inhaled directly. A multiplace chamber accommodates two or more individuals where the ambient pressurized atmosphere is normal air. Individual receives 100% oxygen through an endotracheal tube, hood or mask. The advantage of a multiperson chamber is that specially trained personnel may accompany the individual in the chamber and provide necessary treatments and care during the HBOT session. Regardless of which type of chamber is used, the amount of pressure and the length of time under pressure are determined by the condition being treated. Treatment pressures are usually between two to three times ATA and may last from one to two hours at full pressure.

HBOT is used to treat certain conditions or diseases that may respond to increased tissue oxygenation when baseline tissue oxygen levels are too low for spontaneous healing. HBOT is indicated as primary treatment for some conditions; however, it may also serve as adjunctive therapy for other treatment modalities.

**Topical oxygen therapy** (also known as continuous diffusion of oxygen [CDO] therapy) involves direct application of 100% oxygen to promote wound healing. Examples of topical oxygen therapy systems include, but may not be limited to, the EPIFLO, Hyper-Box, TransCu O2 and VHT-200 system.

**Coverage Determination**
iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

**Hyperbaric oxygen therapy (HBOT),** will be limited to that which is administered in a chamber (including the one man unit), will be considered medically reasonable and necessary and is limited to the following conditions:

- Actinomycosis (bacterial infection caused by Actinomyces israelii)\(^3\), only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment; OR

- Acute carbon monoxide intoxication; OR

- Acute peripheral arterial insufficiency (suddenly slows or stops blood flow and is a medical emergency that needs immediate care), with vascular study that confirms vessel obstruction by clot/embolus and location; OR

- Acute traumatic peripheral ischemia (suddenly slows or stops blood flow and is a medical emergency that needs immediate care). HBO therapy is a valuable adjunctive treatment to be used in combination with accepted standard therapeutic measures when loss of function, limb, or life is threatened; OR

- Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management, in patients who meet the following criteria:
  - Documentation of bone culture or X-ray/imaging confirmation of osteomyelitis; AND
  - Completion (approximately six weeks) of antibiotic course (ie, parenteral); AND
  - Surgical eradication (surgical debridement/excision of the infected nidus of bone) or documentation that site is not amenable to surgical intervention; OR

- Crush injuries and suturing of severed limbs. As in the previous conditions, HBO therapy would be an adjunctive treatment when loss of function, limb, or life is threatened; OR

- Cyanide poisoning; OR

- Decompression illness; OR

- Diabetic wounds* of the lower extremities in patients who meet the following three criteria:
  - Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes; OR
Hyperbaric Oxygen Therapy, Topical Oxygen Therapy

- Patient has a wound classified as Wagner grade III or higher; AND
- Patient has failed an adequate course of standard wound therapy; OR

*The use of HBO therapy is covered as adjunctive therapy only after there are no measurable signs of healing for at least 30 days of treatment with standard wound therapy and must be used in addition to standard wound care. Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

- Gas embolism; OR

- Gas gangrene (bacterial infection, C. perfringens is the most common, that destroys blood cells and soft tissues); OR

- Osteoradionecrosis as an adjunct to conventional treatment; OR

- Preparation and preservation of compromised skin grafts (not for primary management of wounds, prophylactic maintenance of grafts or solely for preparation of a wound bed for receiving a graft); OR

- Progressive necrotizing infections (necrotizing fasciitis - bacterial infection that attacks the soft tissue and the fascia); OR

- Soft tissue radionecrosis (destruction of living tissue by radiation)\(^5\)\(^4\) as an adjunct to conventional treatment\(^1\)\(^0\)

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

**Coverage Limitations**

**US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage**

Hyperbaric oxygen therapy (HBOT) in the treatment of the following conditions will not be considered medically reasonable and necessary:

- Acute cerebral edema
- Acute or chronic cerebral vascular insufficiency
- Acute thermal and chemical pulmonary damage, i.e., smoke inhalation with pulmonary insufficiency
- Aerobic septicemia
• Anaerobic septicemia and infection other than clostridial
• Arthritic Diseases
• Cardiogenic shock
• Chronic peripheral vascular insufficiency
• Cutaneous, decubitus, and stasis ulcers
• Exceptional blood loss anemia
• Hepatic necrosis
• Multiple Sclerosis
• Myocardial infarction
• Nonvascular causes of chronic brain syndrome (Pick’s disease, Alzheimer’s disease, Korsakoff’s disease)
• Organ storage
• Organ transplantation
• Pulmonary emphysema
• Senility
• Sickle cell anemia
• Skin burns (thermal)
• Systemic aerobic infection
• Tetanus

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Topical oxygen therapy will not be considered medically reasonable and necessary for any indication.

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Summary of Evidence

Hyperbaric Oxygen Therapy
There is limited evidence from randomized controlled trials that hyperbaric oxygen therapy may stimulate healing in nondiabetic patients with chronic wounds and increase graft survival in some patients with skin grafts or flaps. However, the available studies have limitations in design and size that preclude definitive conclusions regarding optimal treatment protocols, patient selection criteria, and the appropriate role of hyperbaric oxygen therapy for these indications. The evidence regarding the efficacy of hyperbaric oxygen therapy for patients with thermal burns or necrotizing infections failed to demonstrate a beneficial effect of hyperbaric oxygen therapy, and there was very little evidence regarding the use of hyperbaric oxygen therapy in patients with chronic refractory primary osteomyelitis. Well-designed, randomized controlled
trials are required to establish efficacy, define patient selection criteria, and determine the benefits of adjuvant hyperbaric oxygen therapy.\textsuperscript{25}

Several other potential HBO uses remain poorly validated and require more rigorous evaluation. Preliminary animal and human studies evaluating uses in syndromes as disparate as acute coronary syndrome, including myocardial infarction, the systemic inflammatory response syndrome, traumatic brain or spinal cord injury, sickle cell crisis, fibromyalgia, and acute stroke have been conducted, with variable results. Further investigation will need to be conducted.\textsuperscript{52}

**Topical Oxygen Therapy**

Topical oxygen therapy may provide an incremental benefit to standard wound care for complete healing of chronic DFU that have failed to respond to wound care alone; however, not all studies reported a benefit. Further, there is currently insufficient data on amputation, quality of life, and time to complete healing to inform conclusions. Safety data are lacking, but the reported complications do not suggest potential harm.

Evidence is insufficient to inform evidence-based conclusions regarding the use of topical oxygen therapy for other wound indications. As no studies meeting the inclusion criteria addressed the efficacy or safety of topical oxygen therapy incremental to standard wound management for any indication, the evidence is insufficient to inform evidence-based conclusions regarding those applications.\textsuperscript{31}

**Coding Information**

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

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<td>Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session</td>
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<tr>
<td>99199</td>
<td>Unlisted special service, procedure or report</td>
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<td>Topical hyperbaric oxygen chamber, disposable</td>
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<td>Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories</td>
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<td>G0277</td>
<td>Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval</td>
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References


Appendix

Appendix A
Standard care of diabetic wounds include:

- Appropriate offloading; **AND**

- Assessment of an individual’s vascular status and correction of any amenable vascular problems; **AND**

- Debridement by any means to remove devitalized tissue and infected bone; **AND**

- Improvement of glucose control with glycosylated hemoglobin level (HbA1c) ideally less than 9.0% or blood glucose records demonstrating efforts to sustain blood sugar less than 200 mg/dL as clinically indicated; **AND**

- Maintenance of a clean, moist wound bed with appropriate dressings (eg, alginate, films, foams, hydrocolloid, hydrogels that provide a moist wound environment); **AND**

- Necessary treatment to resolve any infection that may be present, including surgical management of osteomyelitis; **AND**

- Optimization of nutritional status as wound healing best occurs when pre-albumin level is greater than 20 mg/dL or albumin level is greater than 3.4 g/dL)
Appendix B

Wagner Grading System\textsuperscript{66}

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<thead>
<tr>
<th>Grade</th>
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<tr>
<td>1</td>
<td>Superficial ulcer without penetration of deep layers</td>
</tr>
<tr>
<td>2</td>
<td>Deeper ulcer, reaching tendon, bone or joint capsule</td>
</tr>
<tr>
<td>3</td>
<td>Deeper tissues are involved and there is abscess, osteomyelitis or tendonitis</td>
</tr>
<tr>
<td>4</td>
<td>There is gangrene of some part of the toe(s) and/or forefoot</td>
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<td>5</td>
<td>Gangrene involves the whole foot or enough of the foot that no local procedures are possible and below knee amputation (BKA) is indicated</td>
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Appendix C

Treatment for established ORN:

- **Stage I**: 30 HBOT sessions prior to bony debridement, followed by 10 sessions immediately postoperatively; OR
- **Stage II** (failure of treatment for stage I or newly diagnosed stage II): 30 HBOT sessions prior to radical surgical debridement (maintaining mandibular continuity), followed by 10 sessions immediately postoperative; OR
- **Stage III** (failure of treatment for stages I and/or II or newly diagnosed stage III): 30 HBOT sessions prior to mandibular resection, followed by 10 sessions immediately postoperative. May need an additional 10 sessions to support initial tissue metabolic demands if reconstruction of the mandible occurs;

Change Summary

- 01/01/2024 New Policy.