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RMHP Hyperbaric Oxygen

AUTH: RMHP-A-025027 (AC)

MCG Health
Ambulatory
Care
27th Edition

Link to Codes

Clinical Indications for Procedure

Return to top of *RMHP Hyperbaric Oxygen - AC*

For **RMHP Medicare (CareAdvantage or DSNP Dual Special Needs Plan)** covered members, apply CMS NCD 20.29 Hyperbaric Oxygen Therapy guidelines. See References.

[**Expand All** / **Collapse All**]

- For **RMHP PRIME (Medicaid), CHP+ or Individual and Family Plan (IFP) Commercial** covered members, hyperbaric oxygen may be indicated when **ALL** of the following are present:
  - Confirmed diagnosis of **1 or more** of the following(1):
    - Anemia, as indicated by **ALL** of the following(2)(3):
      - Emergent anemia, as indicated by **1 or more** of the following(4):
        - Active hemolysis with rapidly progressive anemia
        - Active massive hemorrhage
        - Severe signs or symptoms unresponsive to volume replacement (eg, Tachycardia, Hypotension, chest pain, cognitive impairment)
      - Patient unable or unwilling to receive red blood cell transfusions
    - Carbon monoxide poisoning(5)
    - Central retinal artery occlusion(6)
    - Chronic severe diabetic ulcer, and need for initial treatment, as indicated by **ALL** of the following(7)(8)(9)(10)(11):

- Evaluation and treatment of underlying peripheral vascular or neuropathic disease
- Minimal to no healing present (ie, less than 50%) despite conventional wound treatment for 4 weeks, including **ALL** of the following(12):
    - Glycemic management to continue during treatment(13)
    - Pressure reduction or offloading
    - Topical wound treatment (eg, dressings to maintain moist environment, hydrogels, hydrocolloids, alginates)
    - Wound debridement
    - Wound is not infected, or infected wound has been treated with antibiotics.
- Severe wound documented, as indicated by **1 or more** of the following:
    - Deep ulcer to tendon, capsule, or bone
    - Deep ulcer with abscess, osteomyelitis, or joint sepsis
    - Localized gangrene of forefoot or heel

- Chronic severe diabetic ulcer, and need for continued treatment, as indicated by **ALL** of the following(8):
    - Adherent to hyperbaric oxygen therapy
    - Evidence of improvement after 24 treatments
    - Fewer than 40 total treatments
- Crush injury, compartment syndrome, or acute traumatic ischemias(14)
- Decompression illness or suspected intravascular gas embolism(15)(16)(17)(18)(19)
- Idiopathic sudden sensorineural hearing loss(20)(21)

- Intracranial abscess, as indicated by **1 or more** of the following(22)(23):
    - Deep or dominant location
    - Immunocompromised host
    - Multiple abscesses
    - Surgery is contraindicated, or patient is poor surgical candidate.
    - No clinical response or continued deterioration after surgical intervention (1 to 2 needle aspirates) and antibiotic therapy
- Necrotizing soft tissue infections(24)
- Osteomyelitis, refractory to antibiotics and surgery(25)

- Radiation injury (delayed), as indicated by **1 or more** of the following(26):
    - Radiation-induced head and neck soft tissue injury
    - Radiation-induced hemorrhagic cystitis
    - Radiation-induced osteonecrosis before and after extraction of tooth in irradiated field
    - Radiation-induced proctitis
- Skin grafts and flaps (compromised)(27)
- Thermal burns(28)

- No evidence of pneumothorax(29)(30)

Alternatives to Procedure

Return to top of *RMHP Hyperbaric Oxygen - AC*

- Alternatives include:
    - For carbon monoxide poisoning: 100% oxygen at normal atmospheric pressure(31)(32)
    - For cluster headache: medications or oxygen therapy. See Oxygen Therapy, Continuous and Noncontinuous: Home [AC] for further information.
    - For diabetic ulcers or wounds: topical negative pressure. See Negative Pressure Wound Therapy (Vacuum-Assisted Wound Closure) [AC] for further information.
    - For expected anemia resulting from surgery:
        - Allogeneic transfusion
        - Intraoperative red blood cell salvage(33)(34)
    - For idiopathic sudden sensorineural hearing loss: corticosteroids(21)(35)(36)
    - For ischemic ulcers: revascularization
    - For necrotizing soft tissue infection: aggressive surgical debridement and antibiotics(37)
    - For prevention of osteoradionecrosis(38):
        - Dental extraction prior to radiation therapy
        - Oral evaluation prior to radiation therapy
        - Postradiation dental extraction with minimal trauma (ie, alveolectomy, minimal bone trimming, and primary closure)

Evidence Summary

Return to top of *RMHP Hyperbaric Oxygen - AC*

Background

Return to top of *RMHP Hyperbaric Oxygen - AC*

Hyperbaric oxygen therapy is the administration of oxygen at pressures greater than sea level in order to promote oxygen delivery to hypoxic tissues, facilitate the removal of nitrogen bubbles, or facilitate wound healing. Treatment consists of placement of the patient inside a pressurized vessel; to meet the definition of hyperbaric oxygen therapy, pressurization must be at least 1.4 atmospheres with inhalation of 100% oxygen.(39)(40) **(EG 2)**

Criteria

Return to top of *RMHP Hyperbaric Oxygen - AC*

For anemia, Blood transfusion is the conventional standard of medical practice when anemia is severe and life-threatening. However, an evidence-based literature review states that the use of hyperbaric oxygen therapy is an established and effective option for patients with medical barriers or personal objections to transfusion, and its use should be guided by a patient's calculated oxygen debt rather than signs of systemic or individual organ failure.(3) **(EG 2)**

For carbon monoxide poisoning, A specialty society guideline supports the use of hyperbaric oxygen for treatment of carbon monoxide poisoning.(5) **(EG 2)** A systematic review identified 6 randomized controlled trials involving 1361 participants and concluded that the evidence does not yet clearly establish whether the administration of hyperbaric oxygen therapy to patients with carbon monoxide poisoning reduces the incidence of adverse neurologic outcomes. Published trials have conflicting outcomes regarding benefit, are generally supported by weak evidence, and have design or analytical flaws. The authors noted that although a pooled meta-analysis did not suggest a benefit from hyperbaric oxygen therapy, those results should be interpreted with caution. A multicenter randomized controlled trial was recommended to better define the role of hyperbaric oxygen therapy for the prevention of neurologic injury in patients with carbon monoxide poisoning.(41) **(EG 1)** A review article on hyperbaric oxygen therapy for carbon monoxide poisoning noted that further study is needed regarding the optimal pressure, number of treatments, and timing of treatments after poisoning; the author identified one trial that reported improved cognitive outcomes when 3 hyperbaric oxygen treatments were given in a 24-hour period.(42) **(EG 2)** A specialty society policy supports the use of hyperbaric or high-flow normobaric oxygen for the treatment of acute carbon monoxide poisoning but notes that large high-quality multicenter trials are necessary to definitively compare the efficacy of the 2 therapies.(31) **(EG 2)**

For central retinal artery occlusion, A specialty society guideline supports the use of hyperbaric oxygen for central retinal artery occlusion for patients presenting within 24 hours of onset.(6) **(EG 2)** Another specialty society guideline states that hyperbaric oxygen may be used as an interim measure to facilitate passive diffusion of oxygen from the choroidal circulation to the retina while awaiting definitive reperfusion therapy.(43) **(EG 2)** An evidence-based literature review found that although hyperbaric oxygen therapy may prevent permanent visual loss if administered within 24 hours of the onset of acute visual loss, the evidence supporting its efficacy is only fair to good and is based upon retrospective case studies, not randomized controlled trials.(44) **(EG 2)** A single-center retrospective review of 128 patients with central retinal artery occlusion who presented with a symptom duration of less than 20 hours found significant improvement in mean best-corrected visual acuity after hyperbaric oxygen therapy. The finding of a cherry red spot on funduscopy at presentation was associated with less visual acuity improvement after hyperbaric oxygen therapy.(45) **(EG 2)**

For chronic severe diabetic ulcers, A systematic review of 10 randomized trials concluded that the addition of hyperbaric oxygen therapy to a standard wound care regimen in people with diabetic foot ulcers resulted in a significant improvement in wound healing by 6 weeks, but this benefit was not evident in longer-term follow-up at 1 year or longer. Also, the rate of minor amputation was not significantly improved, and a potentially important effect on major amputation could not be confirmed.(7) **(EG 1)** Another systematic review of 13 studies (including 7 prospective randomized trials) showed that adjunctive hyperbaric oxygen treatment resulted in a higher proportion of healed ulcers in the short term (less than 6 months) and long term (more than 1 year), as well as a reduced risk of major amputations.(46) **(EG 1)** A systematic review and meta-analysis of adjunctive therapies for diabetic foot ulcers found that treatment with hyperbaric oxygen therapy plus comprehensive wound care was associated with a lower major amputation rate and an improved healing rate as compared with comprehensive wound care alone.(47) **(EG 1)** A double-blind randomized controlled trial assigned 107 diabetes mellitus patients who had Wagner grade 2 to 4 foot ulcers of at least 1 month's duration to usual care plus 30 sessions of hyperbaric oxygen or sham treatment; major amputation rate and rate of healing were similar in both study arms.(48) **(EG 1)** A retrospective study of 1006 diabetic patients selected for hyperbaric oxygen therapy based on transcutaneous oxygen levels demonstrated that 73.8% of wounds granulated or healed after a mean of 34 treatments, and hyperbaric oxygen therapy was discontinued after a mean of 24 treatments in patients who failed to show any improvement. The authors acknowledged that there is diminished benefit after a total of 35 to 40 treatments.(8) **(EG 2)** Hyperbaric oxygen therapy has been demonstrated to improve quality of life in such patients.(10)(49) **(EG 1)** An evidence-based specialty society guideline states that, based on very low-quality to moderate-quality evidence, hyperbaric oxygen is recommended for Wagner grade 3 or higher diabetic foot ulcers following surgical debridement or when ulcers fail to heal after 30 days of conventional therapy due to its impact on major amputations and healing.(50) **(EG 1)**

For crush injury, compartment syndrome, or acute traumatic ischemias, A specialty society guideline supports the use of hyperbaric oxygen for crush injury, compartment syndrome, or acute traumatic ischemias.(14) **(EG 2)** A systematic review identified a trial of 36 patients with crush injuries that showed significantly improved healing and reduced tissue necrosis with hyperbaric oxygen as compared with sham treatment. However, this trial suffered from an unclear or high risk of bias, and additional high-quality randomized controlled trials were recommended.(51) **(EG 1)**

For decompression illness or suspected intravascular gas embolism, Early hyperbaric treatment is considered a standard of care, and it results in complete resolution of decompression illness as well as gas embolism from other causes, such as manipulation of central venous catheters or cardiac surgery with cardiopulmonary bypass.(15)(16)(17)(18) **(EG 1)** Because clinical presentations vary, and the window of opportunity for a successful outcome is unknown, treatment should be initiated once the diagnosis is suspected to reduce the risk of residual symptoms.(18) **(EG 2)** An observational study of 5269 cases of decompression illness found that a longer delay in treatment was associated with a lower rate of complete recovery (94% complete recovery at 1 to 6-hour delay vs 76% complete recovery at greater than 36-hour delay).(19) **(EG 2)** A review article noted that most patients with decompression illness resolve their symptoms with one hyperbaric oxygen treatment; however, if residual symptoms are present at the end of the hyperbaric oxygen treatment, additional hyperbaric oxygen sessions are recommended as long as improvement occurs.(52) **(EG 2)**

For idiopathic sensorineural hearing loss, A systematic review of 7 studies (392 patients) found that although hyperbaric oxygen therapy significantly improved hearing for patients with acute (generally 2 weeks or less) idiopathic sensorineural hearing loss, no evidence was identified that addressed hyperbaric oxygen therapy in chronic idiopathic sensorineural hearing loss (ie, 6 months or more).(53) **(EG 1)** Uncontrolled case series have demonstrated conflicting results after the use of adjuvant hyperbaric oxygen therapy. Improvement in hearing was associated with the presence of profound hearing loss (greater than 91 dB) and initiation of treatment within 10 days of symptom onset.(54)(55)(56) **(EG 2)** A specialty society guideline supports the use of hyperbaric oxygen for the treatment of idiopathic sudden sensorineural hearing loss.(20) **(EG 2)** An evidence-based practice guideline concludes that hyperbaric oxygen is an option when combined with steroid therapy for either initial treatment (within 2 weeks) or salvage therapy (within 1 month) for sudden sensorineural hearing loss.(21) **(EG 2)**

For intracranial abscess, A specialty society guideline supports the use of hyperbaric oxygen for treatment of intracranial abscess with any of the following characteristics: multiple abscesses, deep or dominant location, immunocompromised host, contraindication to surgery or poor surgical candidate, and no clinical response or continued deterioration after surgical intervention (1 to 2 needle aspirates) and antibiotic therapy.(22) **(EG 2)** Case studies suggest decreased mortality with the use of hyperbaric oxygen.(23) **(EG 2)**

For necrotizing soft tissue infections, A systematic review and meta-analysis evaluating hyperbaric oxygen therapy in adults with necrotizing soft tissue infection (21 studies, 48,744 patients) found decreased in-hospital mortality in patients receiving hyperbaric oxygen compared with patients not receiving hyperbaric oxygen therapy. The authors note that some studies suffered from incomplete population and outcomes reporting, that the optimal dose of hyperbaric oxygen therapy needs to be determined, and that randomized controlled trials are warranted.(57) **(EG 1)** A national database analysis of patients with necrotizing soft tissue infections compared 405 patients who underwent hyperbaric oxygen therapy to 45,500 patients who did not and found, after multivariate adjustment, that patients who received hyperbaric oxygen therapy had significantly reduced rates of in-hospital mortality and other complications. The authors recommended multicenter randomized controlled trials to confirm the findings.(58) **(EG 2)** A retrospective cohort study of 80 patients with necrotizing soft tissue infections in various anatomic locations treated with or without adjunctive hyperbaric oxygen therapy found that there was no significant difference between groups with regard to in-hospital mortality; for those patients who had extremity involvement, there was no significant difference in amputation rates. The authors concluded that additional evidence of efficacy was required before hyperbaric oxygen therapy could be considered a standard of care for necrotizing soft tissue infections.(59) **(EG 2)** Review articles found that although there are no randomized controlled trials, some studies suggest that hyperbaric oxygen therapy may reduce morbidity and mortality from necrotizing fasciitis and clostridial myonecrosis (gas gangrene) when used as an adjunctive treatment to surgical debridement.(29)(60) **(EG 2)** Other review articles noted that the use of hyperbaric oxygen in the treatment of necrotizing fasciitis is controversial and that the evidence consists of retrospective uncontrolled studies in small populations with outcomes that are conflicting; definitive treatment with surgical debridement should be the priority.(61)(37) **(EG 2)** For soft tissue complications of venomous snake bites, studies are limited to case reports and series of patients also receiving antivenin and surgical therapy, making it difficult to isolate and confirm the effectiveness or incremental benefit of hyperbaric oxygen alone.(62) **(EG 2)**

For osteomyelitis, A specialty society guideline supports the use of hyperbaric oxygen for osteomyelitis that is refractory to antibiotics and surgery.(25) **(EG 2)** A systematic review found no randomized controlled trials, and it also found that existing studies comparing hyperbaric oxygen therapy to surgical debridement demonstrate conflicting results. The authors concluded that hyperbaric oxygen therapy may help promote remission of refractory osteomyelitis when used in conjunction with surgery and antibiotics, but more research is needed.(63) **(EG 1)** A review article reported that 15 observational studies suggested that hyperbaric oxygen may be useful as an adjunct for chronic refractory osteomyelitis; the authors noted that randomized controlled trials would help to confirm efficacy.(30) **(EG 2)**

For radiation injury (delayed), A systematic review found that although hyperbaric oxygen therapy may improve outcomes for radiation-induced head and neck soft tissue injury, radiation-induced proctitis, and osteoradionecrosis after extraction of a tooth in an irradiated field (based on one randomized controlled trial of the use of hyperbaric oxygen before and after tooth extraction),

additional high-quality studies are recommended to determine appropriate candidates and timing of treatment.(64) **(EG 1)** A subsequent systematic review found insufficient evidence to support the use of hyperbaric oxygen to prevent postextraction osteoradionecrosis.(65) **(EG 2)** A scoping review that included 16 studies (one randomized controlled trial) evaluating the efficacy of hyperbaric oxygen in 602 patients for the treatment of radiation-induced hemorrhagic cystitis found that 84% of patients had partial or complete resolution.(66) **(EG 1)** A multicenter randomized controlled trial evaluated standard postoperative care with or without 30 sessions of perioperative hyperbaric oxygen (20 preoperative and 10 postoperative sessions) in 100 evaluable patients with prior mandibular radiation therapy and reported no difference in the incidence of osteoradionecrosis by blinded central assessor at 6 months in the hyperbaric oxygen arm compared with the control arm.(67) **(EG 1)** A randomized, controlled, double-blind, crossover study of 120 patients with refractory radiation proctitis comparing hyperbaric oxygen therapy to sham treatment found, at 1-year follow-up, that hyperbaric oxygen therapy was associated with decreased LENT-SOMA scores (an anatomic-specific morbidity scoring system), generating an absolute risk reduction of 32%.(68) **(EG 1)** However, a double-blind randomized controlled trial of hyperbaric oxygen vs sham pressurized air in 84 adults with chronic gastrointestinal symptoms after pelvic radiation therapy reported similar rectal and intestine functional outcomes on the Inflammatory Bowel Disease Questionnaire and similar nonsignificant decreases in subjective symptoms by LENT-SOMA score at 12-month follow-up.(69) **(EG 1)** A specialty society guideline supports the use of hyperbaric oxygen for the treatment of delayed radiation injury to soft tissue and bone.(26) **(EG 2)** Other specialty society guidelines support the use of hyperbaric oxygen to reduce bleeding in patients with chronic radiation proctitis.(70)(71) **(EG 2)**

For skin grafts and flaps (compromised), A specialty society guideline supports the use of hyperbaric oxygen for compromised skin grafts and flaps.(27) **(EG 2)** A systematic review found a lack of high-quality evidence to support the use of hyperbaric oxygen for this indication. Two small trials reported improved survival of split skin grafts in burn wounds; however, two other studies reported that hyperbaric oxygen therapy was of no benefit for either skin grafting or free flap surgery. Additional high-quality randomized controlled trials were recommended.(51) **(EG 1)**

For thermal burns, A specialty society guideline supports the use of hyperbaric oxygen for thermal burns that encompass at least 20% of total body surface area or involve hands, face, feet, or perineum.(28) **(EG 2)** Studies suggest that the use of hyperbaric oxygen therapy can result in improved healing, decreased infection, decreased length of stay, and reduced mortality.(72) **(EG 2)** A systematic review found insufficient evidence to support or refute the value of hyperbaric oxygen therapy for thermal burns; further research is needed.(73) **(EG 1)**

Inconclusive or Non-Supportive Evidence

Return to top of *RMHP Hyperbaric Oxygen - AC*

For autism, Based upon existing evidence, a specialty society does not recommend hyperbaric oxygen therapy for autism spectrum disorders. Additional trials are recommended.(74) **(EG 2)** A systematic review of hyperbaric oxygen therapy in autism spectrum disorder identified one low-quality randomized controlled trial (60 children); no differences in social interactions, behavioral problems, communication and linguistic abilities, or cognitive function were observed between hyperbaric oxygen therapy and sham pressurized air therapy.(75) **(EG 1)** A specialty society guideline on autism notes that evidence from clinical trials does not support the use of hyperbaric oxygen therapy for treating autism spectrum disorder.(76) **(EG 2)**

For Bell palsy, A systematic review found no randomized trials evaluating the use of hyperbaric oxygen therapy for this indication. There is insufficient evidence to recommend the use of hyperbaric oxygen therapy for Bell palsy at this time.(77) **(EG 2)**

For cancers of the head and neck or uterine cervix, A systematic review found that although hyperbaric oxygen therapy may improve outcomes such as local tumor control, mortality, or recurrence for head and neck cancer using selected radiotherapy protocols, it was associated with significant adverse effects, including oxygen toxic seizures and severe tissue radiation injury. There was little evidence available concerning malignancies at other anatomic sites (eg, uterine cervix, urinary bladder) on which to base a recommendation regarding hyperbaric oxygen therapy. Additional studies were recommended.(78) **(EG 1)**

For cerebral palsy in children, A systematic review of available studies concluded that there was insufficient evidence to establish net benefit or harm of hyperbaric oxygen therapy for treatment of cerebral palsy.(79) **(EG 1)** Upon review of a randomized controlled trial of hyperbaric oxygen therapy, a scientific advisory committee recommended that no further clinical trials in children with cerebral palsy be undertaken until more basic science data on the mechanism of action of hyperbaric oxygen therapy are available.(80) **(EG 2)** A double-blind randomized controlled trial of 46 children with cerebral palsy who were exposed to either hyperbaric oxygen or hyperbaric air found, at 6-month follow-up, that there were no significant differences in pretreatment and post-treatment gross motor function scores in either group or between groups. Although both groups showed an improvement in pediatric disability scores, there was no significant difference between the groups. The study was terminated by the monitoring board when it was clear that the probability of showing a difference between the groups was less than 1.6%.(81) **(EG 1)**

For chronic fatigue syndrome, An observational study of 16 patients who received hyperbaric oxygen therapy found, at 3-week follow-up (15 sessions), that there was significant improvement in the visual analog fatigue scale, Fatigue Severity Scale, and Fatigue Quality of Life Score. The authors recommended performance of additional controlled studies of larger size and with longer follow-up for confirmation of results.(82) **(EG 2)**

For coronary artery disease, A systematic review found that although small studies with significant structural problems suggest that hyperbaric oxygen therapy may reduce the volume of damaged muscle, risk of adverse coronary events, and time to relief of ischemic pain, its use in acute coronary syndrome did not reduce mortality. Additional studies to define patient populations most likely to benefit from treatment were recommended; high-quality, appropriately powered studies are also needed.(83) **(EG 1)**

For femoral head necrosis, A double-blind randomized controlled study of 19 patients found, at 6-week follow-up, that hyperbaric oxygen therapy was associated with increased range of motion. In the observational portion of the study (no control group) at 7-year follow-up, 17 patients reported minimum pain and no changes in activities of daily living. None of the 17 patients required hip arthroplasty. Additional studies were recommended to determine the frequency and duration of treatment.(84) **(EG 1)** A review of treatment options for femoral head necrosis found that few hyperbaric oxygen therapy studies had been conducted and on that basis concluded that additional research was needed before hyperbaric oxygen therapy could be recommended.(85) **(EG 2)**

For fracture healing, A systematic review failed to find any relevant clinical evidence to support or refute the efficacy of hyperbaric oxygen therapy for delayed union or established nonunion of bony fractures. Performance of clinical trials was recommended.(86) **(EG 1)**

For ischemic stroke, A systematic review of 11 randomized controlled trials (with a total of 705 patients) of hyperbaric oxygen therapy for acute ischemic stroke found no evidence that hyperbaric oxygen therapy improved clinical outcomes, including mortality at 6 months, and called for further research.(87) **(EG 1)** In a randomized controlled trial, 74 patients who had sustained either ischemic or hemorrhagic stroke between 6 and 36 months prior to the study and had at least one motor dysfunction were treated with 40 sessions of hyperbaric oxygen over a 2-month study period. The authors noted improvement in neurologic function for those treated with hyperbaric oxygen and recommended performance of additional research to confirm these results and help determine appropriate populations for treatment.(88) **(EG 1)**

For medication-related osteonecrosis of the jaw, A systematic review of interventions for treating bisphosphonate-related osteonecrosis of the jaw identified one small, low-quality, randomized controlled trial (49 patients) of hyperbaric oxygen vs usual care; the authors concluded that there is insufficient evidence to guide treatment.(89) **(EG 1)** A systematic review and meta-analysis identified one randomized controlled trial evaluating hyperbaric oxygen added to standard care vs standard care alone to treat medication-related osteonecrosis in 46 patients using bisphosphonates; no significant difference in healing was observed between treatment arms. The authors concluded that the evidence was insufficient to determine the utility of hyperbaric oxygen therapy for treating medication-related osteonecrosis.(90) **(EG 1)**

For meningioma, A randomized controlled study of 232 patients with conspicuous peritumoral brain edema after meningioma resection found significant improvement in neurologic function and encephalomalacia 6 months postoperatively, but the results of this single study have yet to be confirmed.(91) **(EG 1)**

For migraine and cluster headaches, A systematic review concluded that there was some evidence that hyperbaric oxygen therapy was effective in terminating acute migraine headaches; however, there was no evidence that it could reduce the incidence of nausea and vomiting or the need for rescue medication for migraines, or that it was superior to medical treatment of cluster headaches. Additional research on patients unresponsive to standard therapy was recommended.(92) **(EG 1)**

For multiple sclerosis, A systematic review of the use of hyperbaric oxygen therapy for multiple sclerosis found no consistent evidence to confirm a beneficial effect, and the authors concluded that its routine use was not justified.(93) **(EG 1)**

For otitis externa (malignant), A systematic review found that although hyperbaric oxygen therapy is increasingly being utilized as adjunctive treatment for malignant otitis externa, there are no published trials regarding its efficacy. Additional research was recommended.(94) **(EG 1)**

For prevention of erectile dysfunction following radical prostatectomy, A double-blind randomized placebo-controlled trial evaluated the efficacy of 9 sessions (ie, consecutive weekdays) of hyperbaric oxygen vs pressurized air to prevent erectile dysfunction in 109 patients who underwent radical prostatectomy; treatment started 1 day after hospital discharge. Of 83 patients available at 18-month follow-up, no significant difference in erectile recovery, as measured by the International Index of Erectile Function, was observed between the groups. Patients in the control group received 5 sessions of treatment.(95) **(EG 1)**

For radiation-induced lymphedema of the arm, A randomized controlled study of 58 patients found no evidence of benefit in terms of limb volume from hyperbaric oxygen therapy after treatment with primary surgery and adjuvant radiotherapy for early breast cancer.(96) **(EG 1)**

For radiation-induced neurologic injury, A systematic review of hyperbaric oxygen therapy for late radiation injuries found no evidence of any important clinical effect on either central or peripheral nervous system injury.(64) **(EG 1)**

For radiation-induced retinopathy, A review article found insufficient published studies to justify the use of hyperbaric oxygen for this indication.(97) **(EG 2)**

For retinitis pigmentosa, Evidence is limited to a 10-year single-center randomized trial that found a statistically significant benefit in preservation of initial visual acuity for patients treated with hyperbaric oxygen. The authors concluded that hyperbaric oxygen therapy may be a safe alternative approach for retinitis pigmentosa patients to stabilize visual acuity and visual fields.(98) **(EG 1)**

For traumatic brain injury, A systematic review concluded that the addition of hyperbaric oxygen therapy significantly reduced the risk of death but not of unfavorable clinical outcomes; the routine application of hyperbaric oxygen therapy could not be justified from this review. Additional trials were recommended to define which patients can be expected to benefit from hyperbaric oxygen therapy.(99) **(EG 1)** A phase II, multicenter, randomized, double-blind trial of 72 military participants with mild traumatic brain injury and at least 4 months of persistent symptoms compared standard postconcussion care alone with the addition of hyperbaric oxygen therapy or sham pressurized air therapy; the authors reported no symptomatic improvement in the hyperbaric oxygen arm over sham therapy, and both arms improved as compared with standard postconcussion care alone. The authors concluded that the findings may represent placebo effects and did not recommend conducting a phase III study.(100) **(EG 1)**

For vascular dementia, A systematic review identified only one randomized controlled trial (64 patients) of poor methodological quality that reported a benefit from the use of hyperbaric oxygen therapy for this indication. The authors concluded that the evidence

was insufficient to determine efficacy, and additional double-blind randomized trials comparing hyperbaric oxygen therapy to sham therapy were recommended.(101) **(EG 1)**

Reviewer Guidance

Return to top of *RMHP Hyperbaric Oxygen - AC*

For Members with **RMHP Medicare (CareAdvantage and DSNP Dual Special Needs Plan)** health plan coverage, apply National Coverage Determination (NCD) for Hyperbaric Oxygen Therapy (20.29), Effective Date 4/3/2017, reviewed 10/26/2023.

Note: LCD Hyperbaric Oxygen (HBO) Therapy L35021, original effective date 10/01/2015 and Article A56714 original effective date 7/25/2019 both were RETIRED by CMS on 8/27/2020.

Policy History

Return to top of *RMHP Hyperbaric Oxygen - AC*

HISTORY SUMMARY - 7/14/17 RMHP-AC 5019 deactivated. This MCG A-0250 21st edition guideline adopted 7/14/17 for all non-Medicare Plans with no change. Medicare plan to continue to follow current LCD/NCD guidelines. 08/08/2017 Moved to 21st edition MCG. 9/6/2018 Annual review - no changes made. 9/6/2019 Upgraded to MCG 23rd edition with added LCD/LCA information. 9/14/2020 Upgraded to 24th edition MCG with NCD for Medicare. 9/23/2021 Upgraded to 25th edition MCG with NCD for Medicare. 9/4/2022 Annual review, no changes.

10/26/2023 annual review and upgrade to 27th edition MCG with NCD for Medicare.

References

Return to top of *RMHP Hyperbaric Oxygen - AC*

The Center for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) for Hyperbaric Oxygen Therapy (20.29), Effective Date 4/3/2017, reviewed 10/26/2023.

Medicare Reference Note: LCD Hyperbaric Oxygen (HBO) Therapy L35021, original effective date 10/01/2015 and Article A56714 original effective date 7/25/2019 both were RETIRED by CMS on 8/27/2020.

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Return to top of *RMHP Hyperbaric Oxygen - AC*

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