Medical Coverage Policy | Hyperbaric Oxygen Therapy



EFFECTIVE DATE:08|21|2017 **POLICY LAST UPDATED:** 04|04|2017

Overview

Hyperbaric oxygen therapy (HBOT) involves breathing 100% oxygen at pressures between 1.5 and 3.0 atmospheres (atm). It is generally applied systemically with the patient inside a hyperbaric chamber. HBOT can also be applied topically; that is, the body part to be treated is isolated (eg, in an inflatable bag and exposed to pure oxygen). HBOT has been investigated for various conditions that have potential to respond to increased oxygen delivery to the tissues,

MEDICAL CRITERIA

Blue CHiP for Medicare and Commercial

Hyperbaric oxygen therapy (HBOT) is medically necessary when one of the following criteria are met:

1. Failure* to respond to standard wound care

*Failure to respond to standard wound care is defined as no measurable signs of healing after a minimum of 30 consecutive days of treatment. In addition, the clinical information submitted must document that all of the following have been addressed:

- assessment of a patient's vascular status and correction of any vascular problems in the affected limb if possible,
- nutritional status,
- glucose control (if diabetic),
- debridement by any means to remove devitalized tissue,
- maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, appropriate offloading, and
- necessary treatment to resolve any infection that might be present.

2. Claims filed with a covered diagnosis noted in the attachment <u>Covered HBO diagnosis</u>

PRIOR AUTHORIZATION:

Blue CHiP for Medicare and Commercial

Prior authorization is required for BlueChip for Medicare and recommended for Commercial Products via the online tool for participating providers. See the Related Policies section

No preauthorization needed for claims filed with a covered diagnosis noted in the attachment in the medical criteria section.

POLICY STATEMENT:

Blue CHiP for Medicare and Commercial

HBOT is medically necessary medical criteria is met. HBOT is not medically necessary for services not meeting the medical criteria or diagnosis list as the evidence is insufficient to determine the effects of the technology on health outcomes.

Topical hyperbaric oxygen therapy is not medically necessary its clinical efficacy has not been established.

For simultaneous use of systemic HBOT and Negative Pressure wound closure, medical criteria for each service must be met using the web based authorization tool.

COVERAGE:

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, or Benefit Booklet for applicable Medical Treatment coverage.

BACKGROUND

Hyperbaric oxygen therapy (HBOT) is a technique of delivering higher pressures of oxygen to the tissues. Two methods of administration are available. In systemic or large hyperbaric oxygen chamber, the patient is entirely enclosed in a pressure chamber and breathes oxygen at a pressure greater than 1 atmosphere (atm; the pressure of oxygen at sea level). Thus, this technique relies on

systemic circulation to deliver highly oxygenated blood to the target site, typically a wound. In addition, systemic HBOT can be used to treat systemic illness, such as air or gas embolism, carbon monoxide poisoning, or clostridial gas

gangrene. Treatment may be carried out either in a monoplace chamber pressurized with pure oxygen or in a larger, multiplace chamber pressurized with compressed air, in which case the patient receives pure oxygen by mask, head tent, or endotracheal tube.

Topical hyperbaric therapy is a technique of delivering 100% oxygen directly to an open, moist wound at a pressure slightly higher than atmospheric pressure. It is hypothesized that the high concentrations of oxygen diffuse directly into the wound to increase the local cellular oxygen tension, which in turn

promotes wound healing. Devices consist of an appliance to enclose the wound area (frequently an extremity) and a source of oxygen; conventional oxygen tanks may be used. The appliances may be disposable and may be used without supervision in the home by well-trained patients. Topical hyperbaric

therapy has been investigated as a treatment of skin ulcerations resulting from diabetes, venous stasis, postsurgical infection, gangrenous lesion, decubitus ulcers, amputations, skin graft, burns, or frostbite.Note that this evidence review does not address topical oxygen therapy in the absence of pressurization.

The evidence for the use of systemic HBOT in individuals with nonhealing diabetic wounds of the lower extremities, acute traumatic ischemia, soft-tissue radiation necrosis (eg, radiation enteritis, cystitis, proctitis), osteoradionecrosis (ie, pre- and posttreatment), planned dental surgery (non-implant-related) of

an irradiated jaw, gas gangrene, and profound anemia with exceptional blood loss when blood transfusion is impossible or must be delayed includes systematic reviews and/or recommendations from the Undersea and Hyperbaric Medical Society's (UHMS). Relevant outcomes include overall survival,

symptoms, change in disease status, and functional outcomes. For all indications in the PICO note, evidence and/or USMS guidelines support use of HBOT. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in health outcomes.

The evidence for the use of systemic HBOT in individuals with any condition other than those specified in the policy are not medically necessary as the available studies do not demonstrate that HBOT improves relevant outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for the use of topical HBOT in individuals who might respond to increased oxygen delivery to tissues includes primarily of case series and case reports. Relevant outcomes are symptoms and change in disease status. Only 1 randomized controlled trial (RCT) was published on any indication. This

study, in patients with diabetic foot ulcers, had a small sample size and did not find a significant benefit of topical HBOT. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODING:

Blue CHiP for Medicare and Commercial

The following codes are medically necessary when filed with a covered diagnosis listed below or medical criteria above has been met:

99183 Physician attendance and supervision of hyperbaric oxygen therapy, per session **G0277** Hyperbaric oxygen under pressure full body chamber, per 30 minutes

Covered HBO diagnosis

The following codes are not medically necessary:

A4575 Topical hyperbaric oxygen chamber, disposable

E0446 Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories

RELATED POLICIES

Preauthorization via Web-Based Tool for Procedures

PUBLISHED

Provider Update, October 2017 Provider Update, September 2016 Provider Update, November 2015 Provider Update, January 2015 Provider Update, September 2012 Provider Update, September 2010 Provider Update, December 2010 Provider Update, January 2010 Policy Update, October 2007 Policy Update, October 2006 Policy Update, January 2006 Policy Update, May 2004

REFERENCES

1. Federal Food and Drug Administration. Hyperbaric Oxygen Therapy: Don't Be Misled. 2013;

http://www.fda.gov/forconsumers/consumerupdates/ucm364687.htm. Accessed December, 2016.

2. Heng MC, Pilgrim JP, Beck FW. A simplified hyperbaric oxygen technique for leg ulcers. Arch Dermatol. May 1984;120(5):640-645. PMID 6721526

3. Landau Z. Topical hyperbaric oxygen and low energy laser for the treatment of diabetic foot ulcers. Arch Orthop Trauma Surg. 1998;117(3):156-158. PMID 9521521

4. Leslie CA, Sapico FL, Ginunas VJ, et al. Randomized controlled trial of topical hyperbaric oxygen for treatment of diabetic foot ulcers. Diabetes Care. Feb 1988;11(2):111-115. PMID 3289861

5. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Hyperbaric oxygen thearpy for wound healing. Part I. TEC Assessments. 1999;Volume 14:Tab 13.

6. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Hyperbaric oxygen therapy for wound healing. Part II. TEC Assessments. 1999;Volume 14:Tab 15.

7. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Hyperbaric oxygen therapy for wound healing. Part III. TEC Assessments. 1999;Volume 14:Tab 16.

8. Kranke P, Bennett MH, Martyn-St James M, et al. Hyperbaric oxygen therapy for chronic wounds. Cochrane Database Syst Rev. Jun 24 2015(6):CD004123. PMID 26106870

9. Elraiyah T, Tsapas A, Prutsky G, et al. A systematic review and meta-analysis of adjunctive therapies in diabetic foot ulcers. J Vasc Surg. Feb 2016;63(2 Suppl):46S-58S e41-42. PMID 26804368

10. Buckley NA, Juurlink DN, Isbister G, et al. Hyperbaric oxygen for carbon monoxide poisoning. Cochrane Database Syst Rev. 2011(4):CD002041. PMID 21491385

11. Bennett MH, Feldmeier J, Hampson NB, et al. Hyperbaric oxygen therapy for late radiation tissue injury. Cochrane Database Syst Rev. Apr 28 2016;4:CD005005. PMID 27123955

12. Maynor ML, Moon RE, Camporesi EM, et al. Chronic osteomyelitis of the tibia: treatment with hyperbaric oxygen and autogenous microsurgical muscle transplantation. J South Orthop Assoc. Spring 1998;7(1):43-57. PMID 9570731

13. Davis JC, Heckman JD, DeLee JC, et al. Chronic non-hematogenous osteomyelitis treated with adjuvant hyperbaric oxygen. J Bone Joint Surg Am. Oct 1986;68(8):1210-1217. PMID 3771602

14. Chen CE, Ko JY, Fu TH, et al. Results of chronic osteomyelitis of the femur treated with hyperbaric oxygen: a preliminary report. Chang Gung Med J. Feb 2004;27(2):91-97. PMID 15095953

15. Chen CE, Shih ST, Fu TH, et al. Hyperbaric oxygen therapy in the treatment of chronic refractory osteomyelitis: a preliminary report. Chang Gung Med J. Feb 2003;26(2):114-121. PMID 12718388

16. Chen CY, Lee SS, Chan YS, et al. Chronic refractory tibia osteomyelitis treated with adjuvent hyperbaric oxygen: a preliminary report. Changgeng Yi Xue Za Zhi. Jun 1998;21(2):165-171. PMID 9729650

17. Villanueva E, Bennett MH, Wasiak J, et al. Hyperbaric oxygen therapy for thermal burns. Cochrane Database Syst Rev. 2004(3):CD004727. PMID 15266540

18. Eskes A, Vermeulen H, Lucas C, et al. Hyperbaric oxygen therapy for treating acute surgical and traumatic wounds. Cochrane Database Syst Rev. 2013;12:CD008059. PMID 24343585

19. Dauwe PB, Pulikkottil BJ, Lavery L, et al. Does hyperbaric oxygen therapy work in facilitating acute wound healing: a systematic review. Plast Reconstr Surg. Feb 2014;133(2):208e-215e. PMID 24469192

20. Freiberger JJ, Padilla-Burgos R, McGraw T, et al. What is the role of hyperbaric oxygen in the management of bisphosphonaterelated osteonecrosis of the jaw: a randomized controlled trial of hyperbaric oxygen as an adjunct to surgery and antibiotics. J Oral Maxillofac Surg. Jul 2012;70(7):1573-1583. PMID 22698292 21. Levett D, Bennett MH, Millar I. Adjunctive hyperbaric oxygen for necrotizing fasciitis. Cochrane Database Syst Rev. 2015;1:CD007937. PMID 25879088

22. Jallali N, Withey S, Butler PE. Hyperbaric oxygen as adjuvant therapy in the management of necrotizing fasciitis. Am J Surg. Apr 2005;189(4):462-466. PMID 15820462

23. George ME, Rueth NM, Skarda DE, et al. Hyperbaric oxygen does not improve outcome in patients with necrotizing soft tissue infection. Surg Infect (Larchmt). Feb 2009;10(1):21-28. PMID 18991520

24. Bennett MH, Lehm JP, Jepson N. Hyperbaric oxygen therapy for acute coronary syndrome. Cochrane Database Syst Rev. Jul 23 2015(7):CD004818. PMID 26202854

25. Bennett MH, Weibel S, Wasiak J, et al. Hyperbaric oxygen therapy for acute ischaemic stroke. Cochrane Database Syst Rev. 2014;11:CD004954. PMID 25387992

26. Efrati S, Fishlev G, Bechor Y, et al. Hyperbaric oxygen induces late neuroplasticity in post stroke patients--randomized, prospective trial. PLoS One. 2013;8(1):e53716. PMID 23335971

27. Holland NJ, Bernstein JM, Hamilton JW. Hyperbaric oxygen therapy for Bell's palsy. Cochrane Database Syst Rev. 2012;2:CD007288. PMID 22336830

28. Wang F, Wang Y, Sun T, et al. Hyperbaric oxygen therapy for the treatment of traumatic brain injury: a meta-analysis. Neurol Sci. May 2016;37(5):693-701. PMID 26746238

29. Crawford C, Teo L, Yang E, et al. Is hyperbaric oxygen therapy effective for traumatic brain injury? a rapid evidence assessment of the literature and recommendations for the field. J Head Trauma Rehabil. Sep 06 2016. PMID 27603765

30. Bennett MH, Trytko B, Jonker B. Hyperbaric oxygen therapy for the adjunctive treatment of traumatic brain injury. Cochrane Database Syst Rev. 2012;12:CD004609. PMID 23235612

31. Wolf G, Cifu D, Baugh L, et al. The effect of hyperbaric oxygen on symptoms after mild traumatic brain injury. J Neurotrauma. Nov 20 2012;29(17):2606-2612. PMID 23031217

32. Cifu DX, Walker WC, West SL, et al. Hyperbaric oxygen for blast-related postconcussion syndrome: three-month outcomes. Ann Neurol. Feb 2014;75(2):277-286. PMID 24255008

 Miller RS, Weaver LK, Bahraini N, et al. Effects of hyperbaric oxygen on symptoms and quality of life among service members with persistent postconcussion symptoms: a randomized clinical trial. JAMA Intern Med. Jan 2015;175(1):43-52. PMID 25401463
Marois P, Mukherjee A, Ballaz L. Hyperbaric oxygen treatment for persistent postconcussion symptoms-a placebo effect? JAMA Intern Med. Jul 1 2015;175(7):1239-1240. PMID 26146912

35. Dulai PS, Gleeson MW, Taylor D, et al. Systematic review: The safety and efficacy of hyperbaric oxygen therapy for inflammatory bowel disease. Aliment Pharmacol Ther. Jun 2014;39(11):1266-1275. PMID 24738651

36. Pagoldh M, Hultgren E, Arnell P, et al. Hyperbaric oxygen therapy does not improve the effects of standardized treatment in a severe attack of ulcerative colitis: a prospective randomized study. Scand J Gastroenterol. Sep 2013;48(9):1033-1040. PMID 23879825 37. Lewis JD, Chuai S, Nessel L, et al. Use of the noninvasive components of the Mayo score to assess clinical response in ulcerative colitis. Inflamm Bowel Dis. Dec 2008;14(12):1660-1666. PMID 18623174

38. Bennett MH, Kertesz T, Perleth M, et al. Hyperbaric oxygen for idiopathic sudden sensorineural hearing loss and tinnitus. Cochrane Database Syst Rev. 2012;10:CD004739. PMID 23076907

39. Cvorovic L, Jovanovic MB, Milutinovic Z, et al. Randomized prospective trial of hyperbaric oxygen therapy and intratympanic steroid injection as salvage treatment of sudden sensorineural hearing loss. Otol Neurotol. Aug 2013;34(6):1021-1026. PMID 23820795

40. Bennett M, Best TM, Babul S, et al. Hyperbaric oxygen therapy for delayed onset muscle soreness and closed soft tissue injury. Cochrane Database Syst Rev. 2005(4):CD004713. PMID 16235376

41. Xiong T, Chen H, Luo R, et al. Hyperbaric oxygen therapy for people with autism spectrum disorder (ASD). Cochrane Database Syst Rev. Oct 13 2016;10:CD010922. PMID 27737490

42. Sampanthavivat M, Singkhwa W, Chaiyakul T, et al. Hyperbaric oxygen in the treatment of childhood autism: a randomised controlled trial. Diving Hyperb Med. Sep 2012;42(3):128-133. PMID 22987458

43. Rossignol DA, Rossignol LW, Smith S, et al. Hyperbaric treatment for children with autism: a multicenter, randomized, doubleblind, controlled trial. BMC Pediatr. 2009;9:21. PMID 19284641

44. Lacey DJ, Stolfi A, Pilati LE. Effects of hyperbaric oxygen on motor function in children with cerebral palsy. Ann Neurol. Nov 2012;72(5):695-703. PMID 23071074

45. Collet JP, Vanasse M, Marois P, et al. Hyperbaric oxygen for children with cerebral palsy: a randomised multicentre trial. HBO-CP Research Group. Lancet. Feb 24 2001;357(9256):582-586. PMID 11558483

46. Xiao Y, Wang J, Jiang S, et al. Hyperbaric oxygen therapy for vascular dementia. Cochrane Database Syst Rev. 2012;7:CD009425. PMID 22786527

47. Spiegelberg L, Djasim UM, van Neck HW, et al. Hyperbaric oxygen therapy in the management of radiation-induced injury in the head and neck region: a review of the literature. J Oral Maxillofac Surg. Aug 2010;68(8):1732-1739. PMID 20493616

48. Teguh DN, Levendag PC, Noever I, et al. Early hyperbaric oxygen therapy for reducing radiotherapy side effects: early results of a randomized trial in oropharyngeal and nasopharyngeal cancer. Int J Radiat Oncol Biol Phys. Nov 1 2009;75(3):711-716. PMID 19386439

49. Gothard L, Haviland J, Bryson P, et al. Randomised phase II trial of hyperbaric oxygen therapy in patients with chronic arm lymphoedema after radiotherapy for cancer. Radiother Oncol. Oct 2010;97(1):101-107. PMID 20605648

50. Camporesi EM, Vezzani G, Bosco G, et al. Hyperbaric oxygen therapy in femoral head necrosis. J Arthroplasty. Sep 2010;25(6 Suppl):118-123. PMID 20637561

51. Bennett MH, French C, Schnabel A, et al. Normobaric and hyperbaric oxygen therapy for the treatment and prevention of migraine and cluster headache. Cochrane Database Syst Rev. Dec 28 2015(12):CD005219. PMID 26709672

52. Peng Z, Wang S, Huang X, et al. Effect of hyperbaric oxygen therapy on patients with herpes zoster. Undersea Hyperb Med. Nov-Dec 2012;39(6):1083-1087. PMID 23342765

53. Yildiz S, Kiralp MZ, Akin A, et al. A new treatment modality for fibromyalgia syndrome: hyperbaric oxygen therapy. J Int Med Res. May-Jun 2004;32(3):263-267. PMID 15174219

54. Efrati S, Golan H, Bechor Y, et al. Hyperbaric oxygen therapy can diminish fibromyalgia syndrome - prospective clinical trial. PLoS One. 2015;10(5):e0127012. PMID 26010952

55. Bennett M, Heard R. Hyperbaric oxygen therapy for multiple sclerosis. Cochrane Database Syst Rev. 2004(1):CD003057. PMID 14974004

56. Heys SD, Smith IC, Ross JA, et al. A pilot study with long term follow up of hyperbaric oxygen pretreatment in patients with locally advanced breast cancer undergoing neo-adjuvant chemotherapy. Undersea Hyperb Med. Jan-Feb 2006;33(1):33-43. PMID 16602255

57. Bennett M, Feldmeier J, Smee R, et al. Hyperbaric oxygenation for tumour sensitisation to radiotherapy. Cochrane Database Syst Rev. 2005(4):CD005007. PMID 16235387

58. Huang ET, Mansouri J, Murad MH, et al. A clinical practice guideline for the use of hyperbaric oxygen therapy in the treatment of diabetic foot ulcers. Undersea Hyperb Med. May-Jun 2015;42(3):205-247. PMID 26152105

59. Weaver LK, editor. Hyperbaric Oxygen Therapy Indications. 13th ed. North Palm Beach, FL: Undersea and Hyperbaric Medical Society; 2014.

60. American Academy of Otolaryngology-Head and Neck Surgery. Clinical practice guideline: sudden hearing loss. 2012; http://www.guideline.gov/content.aspx?id=36054&search=sudden+hearing+loss. Accessed December, 2016.

Services CfMaM. National Coverage Determination (NCD) for Hyperbaric Oxygen Therapy (20.29). 2006;

https://www.cms.gov/medicare-coverage-database/details/ncd-

details.aspx?NCDId=12&ncdver=3&bc=AAAAgAAAAAAAAA%3d%3d&.

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.



500 EXCHANGE STREET, PROVIDENCE, RI 02903-2699 (401) 274-4848 WWW.BCBSRI.COM