BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 12/30/15**
SECTION: MEDICINE	**LAST REVIEW DATE: 01/22/19**
	LAST CRITERIA REVISION DATE:
	ARCHIVE DATE:

OXYGEN THERAPY

- **Hyperbaric Oxygen Therapy (HBO_2)**
- **Mild Hyperbaric Therapy**
- **Topical Oxygen Therapy**

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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OXYGEN THERAPY (cont.)

Description:

Hyperbaric Oxygen Therapy (HBOT, HBO_2):
Individual is entirely enclosed in a pressure chamber and breathes 100% oxygen at a pressure greater than oxygen pressure at sea level. The pressurized oxygen is forced to affected tissues, infections, injuries and sources of disease to aid the body in healing.

Mild Hyperbaric Therapy (mHBT, mHBOT):
Individual is enclosed in an inflatable chamber and breathes filtered ambient air at increased atmospheric pressure. May be supplemented with additional oxygen.

Topical Oxygen Therapy:
A specially designed inflatable, clear plastic bag is positioned and secured around the wound area creating a "topical hyperbaric oxygen chamber". 100% oxygen at a pressure greater than oxygen pressure at sea level is then pumped into the bag directly to the open, moist wound.

Definitions:

Chronic Wound:
A wound or condition present for at least 30 days despite standard medical and surgical management.

Refractory Wound:
A wound or condition that is resistant to or has failed standard medical or surgical management.

Wagner Classification System of Wounds:

- Grade 0: No open lesion
- Grade I: Superficial ulcer without penetration to deeper layers
- Grade II: Ulcer penetrates to tendon, bone or joint
- Grade III: Lesion has penetrated deeper than grade II and there is abscess, osteomyelitis, pyarthrosis, plantar space abscess, or infection of the tendon and tendon sheaths
- Grade IV: Wet or dry gangrene in the toes or forefoot
- Grade V: Gangrene involves the whole foot or such a percentage that no local procedures are possible and amputation (at least at the below the knee level) is indicated

OXYGEN THERAPY (cont.)

Criteria:

Hyperbaric Oxygen Therapy:

- Hyperbaric oxygen therapy (HBO_2, HBOT) is considered ***medically necessary*** for treatment of **ANY** of the following:

  1. Exceptional blood loss anemia and transfusion is impossible or must be delayed
  2. Carbon monoxide poisoning, acute
  3. Compromised skin grafts or flaps
  4. Cyanide poisoning, acute
  5. Decompression illness
  6. Gas embolism, acute
  7. Gas gangrene
  8. Mycoses, refractory (mucormycosis, actinomycosis, canidiobolus coronato)
  9. Necrotizing infections, progressive (e.g., necrotizing fasciitis)
  10. Nonhealing diabetic wounds of the lower extremities with documentation of **ALL** of the following:

      - Type I or II diabetes with a lower-extremity wound due to diabetes
      - Wound is classified as Wagner grade III or greater
      - No measurable signs of healing after a 30 day course of standard wound therapy

  11. Osteomyelitis, acute or chronic refractory
  12. Peripheral ischemia resulting from acute trauma (e.g., crushing injuries, reperfusion injury, compartment syndrome, suturing of severed limbs)
  13. Radiation injuries (cystitis enteritis, mucositis, myelitis or proctitis)
  14. Radiation necrosis (osteoradionecrosis, myoradionecrosis, and other soft tissue radiation necrosis)

OXYGEN THERAPY (cont.)

Criteria: (cont.)

Hyperbaric Oxygen Therapy: (cont.)

- Hyperbaric oxygen therapy (HBO_2, HBOT) for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net heath outcome, and
  3. Insufficient evidence to support improvement of the net heath outcome as much as, or more than, established alternatives.

  These indications include, *but are not limited to:*

  - Acute ischemic stroke
  - Acute surgical and traumatic wounds
  - Amyotrophic lateral sclerosis (ALS)
  - Arterial peripheral insufficiency, acute
  - Autism spectrum disorders
  - Bell's palsy
  - Bisphosphonate-related osteonecrosis of the jaw
  - Bone grafts
  - Brain injury resulting from trauma
  - Brown recluse spider bites
  - Carbon tetrachloride poisoning, acute
  - Cerebral edema, acute
  - Cerebral Palsy
  - Cerebrovascular accident/disease, acute (thrombotic or embolic) or chronic
  - Coronary syndromes, acute or as an adjunct to percutaneous coronary interventions and cardiopulmonary bypass
  - Delayed onset muscle soreness
  - Diabetic ulcers, Grade I or II
  - Early treatment (beginning at completion of radiotherapy) to reduce adverse effects of radiotherapy
  - Femoral neck necrosis, idiopathic
  - Fibromyalgia
  - Fracture healing
  - Herpes zoster
  - Hydrogen sulfide poisoning
  - Inflammatory bowel disease (Crohn disease or ulcerative colitis)
  - Intra-abdominal and intra-cranial abscesses
  - In vitro fertilization

OXYGEN THERAPY (cont.)

Criteria: (cont.)

Hyperbaric Oxygen Therapy: (cont.)

- Hyperbaric oxygen therapy (HBO_2, HBOT) for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net heath outcome, and
  3. Insufficient evidence to support improvement of the net heath outcome as much as, or more than, established alternatives.

  These indications include, *but are not limited to:* (cont.)

  - Lepromatous leprosy
  - Lymphedema, chronic arm, following radiotherapy for cancer
  - Meningitis
  - Mental illness (e.g., depression, generalized anxiety disorder, posttraumatic stress disorder)
  - Migraine
  - Motor dysfunction associated with stroke
  - Multiple sclerosis
  - Pseudomembranous colitis (antimicrobial agent-induced colitis)
  - Pyoderma gangrenosum
  - Retinal artery insufficiency, acute
  - Retinopathy, adjunct to scleral buckling procedures in patients with sickle cell peripheral retinopathy and retinal detachment
  - Sensorineural hearing loss, acute idiopathic
  - Sickle cell crisis and/or hematuria
  - Spinal cord injury
  - Thermal burns, acute
  - Tumor sensitization for cancer treatments (radiotherapy or chemotherapy)
  - Vascular dementia
  - Wounds, chronic

Mild Hyperbaric Therapy:

- Mild hyperbaric therapy (mHBOT, mHBT) for all indications is considered ***not medically necessary*** and ***not eligible for coverage***.

OXYGEN THERAPY (cont.)

Criteria: (cont.)

Topical Oxygen Therapy:

- Topical oxygen therapy is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net heath outcome, and
  3. Insufficient evidence to support improvement of the net heath outcome as much as, or more than, established alternatives.

Resources:

Literature reviewed 02/20/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

1. 2.01.04 BCBS Association Medical Policy Reference Manual. Hyperbaric Oxygen Pressurization. Re-issue date 01/11/2018; issue date 12/01/1995.

2. (AHRQ) AfHRaQ, Resources USDoHaH. Hyperbaric Oxygen Therapy for Brain Injury, Cerebral Palsy, and Stroke. *Evidence Report/Technology Assessment: Number 85.* 2003, accessed 11/06/2007 2003.

3. Adamides AA, Winter CD, Lewis PM, Cooper DJ, Kossmann T, Rosenfeld JV. Current controversies in the management of patients with severe traumatic brain injury. *ANZ J Surg.* 2006 Mar 2006;76(3):163-174.

4. BCBS Association Technology Assessment Program. Hyperbaric Oxygen Therapy for Wound Healing-Part I. August 1999;14(13).

5. BCBS Association Technology Assessment Program. Hyperbaric Oxygen Therapy for Wound Healing-Part II. December 1999;14(15).

6. Bennett MH, Trytko B, B J. Hyperbaric oxygen therapy for the adjunctive treatment of traumatic brain injury. 2004, accessed 11/6/2007 2004.

7. Bouquot JE, McMahon RE. Ischemic Osteonecrosis in Facial Pain Syndromes, A Review of NICO (Neuralgia-Inducing Cavitational Osteonecrosis) Based on Experience with More than 2000 Patients. 1996 1996.

OXYGEN THERAPY (cont.)

Resources: (cont.)

8. Carson S, McDonagh M, Russman B, Helfand M. Hyperbaric oxygen therapy for stroke: a systematic review of the evidence. *Clin Rehabil.* 2005 Dec 2005;19(8):819-833.

9. Center for Medicare & Medicaid Services. Hyperbaric Oxygen Therapy 20.29, Version 3. 06/19/2006.

10. Center for Medicare and Medicaid Services. Hyperbaric Oxygen Therapy 35-10. Accessed 11/21/2000.

11. Center for Medicare and Medicaid Services. Decision Memorandum for Hyberbaric Oxygen Therapy in the Treatment of Hypoxic Wounds and Diabetic Wounds of the Lower Extremities,. 08/30/2002.

12. Golden Z, Golden CJ, Neubauer RA. Improving neuropsychological function after chronic brain injury with hyperbaric oxygen. *Disabil Rehabil.* 2006 Nov 30 2006;28(22):1379-1386.

13. Goldstein LJ. Hyperbaric oxygen for chronic wounds. *Dermatol Ther.* May-Jun 2013;26(3):207-214.

14. Kranke P, Bennett MH, Martyn-St James M, Schnabel A, Debus SE, Weibel S. Hyperbaric oxygen therapy for chronic wounds. *Cochrane Database Syst Rev.* 2015;6:CD004123.

15. National Institute of Neurological Disorders and Stroke (NINDS). Cerebral Palsy: Hope Through Research. October 16, 2007 2007.

16. Steele CL, Cridge C, Edgar JD. A novel treatment in X-linked agammaglobulinaemia - hyperbaric oxygen therapy in refractory chronic wounds. *J Clin Immunol.* Oct 2014;34(7):784-787.

17. The Wound Healing Society. Chronic Wound Care Guidelines. December 2006.

18. Undersea & Hyperbaric Medical Society. Indications for Hyperbaric Oxygen Therapy. accessed 05/15/08, 09/17/14.

19. Undersea and Hyperbaric Medical Society. Quality Assurance Program Suggestions. 1996 1996.

20. Undersea and Hyperbaric Medical Society Position Statement. Hyperbaric Oxygen Therapy for Chronic Brain Injury. November 2003, accesssed 11/05/2007 2003.

21. UpToDate.com. Hyperbaric oxygen therapy. 08/27/2014.

22. UpToDate.com. Basic principles of wound management. 05/11/2015.

OXYGEN THERAPY (cont.)

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nílínigíí Blue Cross Blue Shield of Arizona haada yit'éego bína'ídíłkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yína'ídíłkidgo beehaz'áanii hólǫ díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo bąąh ílínígóó. Ata' halne'ígíí kojį' bich'į' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:
إن كان لديك أو لدى شخص تساعده أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون اية تكلفة. للتحدث مع مترجم اتصل ب 877-475-4799.

OXYGEN THERAPY (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulangan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:
اگر شما، یا کسی که شما به او کمک میکنید ، سوال در مورد Blue Cross Blue Shield of Arizona ، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799
.[تماس حاصل نمایید.

Assyrian:
ܐܝ ܐܢܬܘܢ، ܡܢ ܡܢ ܩܛܝܢܐ ܕܡܣܥܪܝܢ ܠܗ، ܐܢܬܘܢ ܕܥܬܝܕܝܢ ܕܫܐܠܬܐ ܥܠ Blue Cross Blue Shield of Arizona، ܐܝܬܘܢ ܐܢܬܘܢ ܙܟܝܐܝܬܐ ܕܡܬܚܢܢܐ ܕܣܝܥܬܐ ܕܡܬܚܢܢܐ ܕܝܠܟܘܢ. ܟܕܡܪܝܢܐ ܟܬ ܡܢ ܡܬܪܓܡܢܐ، ܩܪܘܢܘ ܠܡܠܦܘܢ ܡܢܝܢܐ 877-475-4799.

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคณ หรอคนทคณกาลงชวยเหลอมคาถามเกยวกบ Blue Cross Blue Shield of Arizona คณมสทธทจะไดรบความชวยเหลอและขอมลในภาษา ของคณไดโดยไมมคาใชจาย พดคยกบลาม โทร 877-475-4799