Subject: Hyperbaric Oxygen Therapy (HBOT)	Original Effective Date: 4/30/2008
Policy Number: MCR-050	**Revision Date(s):** 12/16/09, 1/14/10, 10/31/12, 3/11/15, 6/20/16 *This MCR is no longer scheduled for revisions.*
Review Date: 12/16/15, 6/20/16, 9/19/17, 3/8/18, 6/19/19	
MCPC Approval Date: 3/8/18, 6/19/19	

DISCLAIMER

This Molina Clinical Review (MCR) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Review (MCR) document and provide the directive for all Medicare members.[3]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

The Undersea and Hyperbaric Medical Society defines systemic hyperbaric oxygen therapy (HBOT) as a treatment in which a patient breathes near 100% oxygen intermittently while inside a treatment chamber at a pressure higher than sea level pressure (i.e., >1 atmosphere absolute; atm abs). Treatment can be carried out in either a mono- or multiplace chamber. The former accommodates a single patient; the entire chamber is pressurized with near 100% oxygen, and the patient breathes the ambient chamber oxygen directly. The latter holds two or more people (patients, observers, and/or support personnel); the chamber is pressurized with compressed air while the patients breathe near 100% oxygen via masks, head hoods, or endotracheal tubes. [52]

No standard protocol has been identified for HBOT sessions. Regardless of the type of chamber used, the interval between sessions and the total number of treatments varies according to the severity of the condition and physician treatment plan. HBOT may begin with 1 to 3 treatments per day for up to 1 week and may continue daily for several days to several months. For each treatment, the pressure in the chamber is increased slowly and then held constant for 30 minutes to several hours. [40-49]

Topical oxygen therapy involves the application of gaseous oxygen to a cutaneous wound and can be administered on an outpatient basis in a clinic or medical office setting. To treat an affected hand or foot, a

mitten or boot-shaped plastic bag with a gas inlet is attached to the arm or leg with adhesive tape, and the bag is then pumped full of pure oxygen. Cutaneous lesions that are not located on hands or feet can be treated with a plastic sheet that is sealed around the edges and then filled with oxygen. Regardless of the location of the lesion, oxygen is pumped into the bag or plastic sheet until the pressure reaches 1.004 to 1.04 atmospheres, since the elevated pressure is believed to facilitate diffusion of oxygen into the wound. A pressurized bag sealed around an extremity can exert a tourniquet-like effect; during treatment, some practitioners continuously cycle bag pressure from full pressure to no pressure and back to full every 40 seconds to limit this effect. Treatment protocols vary somewhat but wounds are typically exposed to gaseous oxygen for 16 to 21 hours spread over 4 to 14 treatment sessions per week for 2 to 4 weeks. [41]

The FDA regulates hyperbaric oxygen (HBO) chambers as Class II medical devices, and there are a number of different chambers (both monoplace and multiplace chambers) that have been cleared for marketing via the 510(k) process (Product Code CBF, hyperbaric chamber). Devices that are not implantable and pose no risk of fatal outcome to the consumer should they malfunction are assigned Class II status and must meet FDA performance standards. Topical oxygen therapy devices are regulated by the FDA as Class II devices, and several devices have been approved via the FDA 510(k) process. [1]

RECOMMENDATION [3 8 14 18 20 25 26 29-31 42 44 46 50-52]

1. *Systemic hyperbaric oxygen therapy* is considered medically necessary and may be authorized for any of the following conditions:

   - ❑ Acute cyanide poisoning
   - ❑ Acute peripheral artery insufficiency
   - ❑ Acute traumatic peripheral ischemia or severe crush injuries (Grade III) as an adjunct to conventional treatment when loss of function, limb, or life is threatened
   - ❑ Actinomycosis refractory to antibiotics and surgical treatment
   - ❑ Air or gas embolism
   - ❑ Chronic refractory osteomyelitis as an adjunctive therapy when ***all*** of the following criteria are met:
     - documentation of refractory stage 3B or 4B osteomyelitis; and
     - osteomyelitic lesions persist for more than six weeks after treatment is initiated; and
     - no improvement after adequate antibiotic treatments and operative procedure (if a surgical candidate) are performed
   - ❑ Gas Gangrene (clostridial myositis and myonecrosis) as an adjunctive therapy to antibiotics and surgical management
   - ❑ Necrotizing soft tissue infections (necrotizing fasciitis)
   - ❑ Osteoradionecrosis as an adjunct to conventional treatment

- ❑ Preparation and preservation of compromised skin, preexisting grafts or flaps that are showing signs of failure or necrosis, (not for primary management of wounds)

- ❑ Soft tissue radionecrosis as an adjunct to conventional treatment

- ❑ Severe carbon monoxide poisoning

- ❑ Severe decompression sickness

2. *As an adjunctive treatment in wound care:*
   HBOT therapy is considered medically necessary as adjunctive therapy only if there are no measurable signs of healing for minimally 30 days of standard conventional treatment and must be used in addition to standard wound care for all of the following conditions: [ALL]

   - ❑ Severe non-healing Type 1 or 2 Diabetes Mellitus (DM) lower extremity wound due to DM when the following criteria are met:

     - Severe wound documented by Wagner grading with 1 or more of the following:
       - Wagner grade 3 wound, deep ulcer to tendon, capsule or bone
       - Wagner grade 4, deep ulcer with abscess, osteomyelitis, or joint sepsis
       - Wagner grade 5, localized gangrene of forefoot or heel; ***and***

     - Minimal to no healing following 30 consecutive days of appropriate wound care utilizing moist retentive wound care including ***ALL*** of the following:
       - Antibiotic treatment when indicated
       - Evaluation and correction of underlying peripheral vascular disease or neuropathic disease (if applicable)
       - Optimal glycemic control;
       - Optimal nutritional status;
       - Pressure reduction or off-loading
       - Topical wound treatment (e.g., saline, hydrogels, hydrocolloids, alginates)
       - Wound debridement by any means to remove devitalized tissue

CONTINUATION OF THERAPY [3 8 14 18 20 25 26 29-31 42 44 46]

Wounds must be evaluated at least every 30 days during administration of HBOT. After initial authorization of up to 30 days of treatment and or 30 treatments total a progress report must be requested prior to authorization of additional HBO treatment.

Continued treatment with HBO therapy is not considered medically necessary if measurable signs of healing have not been demonstrated within any 30 day period of treatment.

COVERAGE EXCLUSIONS [2 3 5-7 9-13 15-17 19 21-24 27 28 32-35 43 44 47-49]

1. *Topical hyperbaric oxygen therapy* is considered experimental, investigational, and unproven because the clinical efficacy has not been proven for any condition. [3 41 52]

2. *Systemic hyperbaric oxygen therapy* is considered not medically necessary and excluded because there is insufficient evidence in the peer reviewed medical literature for any of the following conditions that include but are not limited to:
   - ❑ 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
   - ❑ AIDS/HIV
   - ❑ Alzheimer's Disease
   - ❑ Asthma
   - ❑ Bell's Palsy
   - ❑ Cardiogenic shock
   - ❑ Cerebral Palsy
   - ❑ Chronic peripheral vascular insufficiency
   - ❑ Cutaneous, decubitus, and stasis ulcers
   - ❑ Depression
   - ❑ Exceptional blood loss anemia
   - ❑ Hepatic necrosis
   - ❑ Migraines
   - ❑ Multiple Sclerosis
   - ❑ Myocardial infarction
   - ❑ Nonvascular causes of chronic brain syndrome (Pick's disease, Alzheimer's disease, Korsakoff's disease).
   - ❑ Organ storage.
   - ❑ Organ transplantation
   - ❑ Parkinson's
   - ❑ Pulmonary emphysema
   - ❑ Senility
   - ❑ Sickle cell anemia.
   - ❑ Skin burns (thermal)
   - ❑ Spinal cord injury
   - ❑ Sports injury
   - ❑ Stroke
   - ❑ Systemic aerobic infection
   - ❑ Tetanus

3. *Absolute Contraindications include ALL of the following conditions:*
   - ❑ Pneumothorax
   - ❑ Concurrent administration of disulfiram or the antineoplastic agents, bleomycin, cisplatin, doxorubicin, or sulfamylon

SUMMARY OF MEDICAL EVIDENCE 5-35 40-50

There is a large body of published peer-reviewed scientific literature, including systematic reviews and randomized controlled trials that support the effectiveness, safety and improvement of net health outcomes of

HBOT for many conditions including: decompression illness, arterial or air gas embolism, cyanide and carbon monoxide poisoning, gas gangrene, necrotizing infections, soft tissue radionecrosis and osteoradionecrosis, non-healing wounds in diabetes mellitus, peripheral artery insufficiency, actinomycosis, skin grafts and flaps, acute traumatic ischemia or crush injuries and osteomyelitis. [8 14 18 20 25 26 29-31 42 44 46 51-52]

There is insufficient evidence in the published peer-reviewed scientific literature to support HBOT for any of the conditions outlined in the coverage exclusions section above. The published literature is from low quality studies and primarily consists of case series and retrospective reviews with small heterogeneous patient populations, short-term follow-ups and has reported conflicting and various outcome data. [5-7 9-13 15-17 19 21-24 27 28 32-35 43 45 47-49]

There is insufficient evidence in the peer reviewed medical literature for any condition treated with topical oxygen therapy. [41 52]

CODING INFORMATION THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
99183	Physician attendance and supervision of hyperbaric oxygen therapy, per session
HCPCS	**Description**
G0277	Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval
ICD-10	**Description: [For dates of service on or after 10/01/2015]**
A42.0-A42.9	Actinomycosis
A48.0	Gas gangrene
E08-E11.9	Diabetes mellitus
I73.89-I73.9	Other peripheral vascular disease
L97-L97.929 M86.30-M86.9	Non-pressure chronic ulcer of lower limb Chronic osteomyelitis
S07-S07.9	Crushing injury of head
S17-S17.9	Crushing injury of neck
S28-S28.0	Crushing injury chest
S38-S38.1	Crushing injury of abdomen, lower back and pelvis
S47-S47.9	Crushing injury of shoulder and upper arm
S57-S57.82	Crush injury of elbow and forearm
S67-S67.92	Crush injury of wrist, hand and fingers
S77-S77.22	Crush injury of hip and thigh
S87-S87.82	Crush injury of lower leg
S97-S97.82	Crush injury of ankle and foot
T79.0	Air embolism traumatic initial encounter
T58-T58.94	Toxic effect of carbon monoxide
T65-T65.0x4	Toxic effect cyanides
T70.3	Decompression sickness Caisson disease initial encounter
T86.82-T86.829	Complications of skin graft

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Revision/Review History: 3/8/18 & 6/19/19: Policy reviewed, no changes to criteria.