



**Clinical Review Criteria  
Hyperbaric Oxygen Therapy**

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**Criteria  
For Medicare Members**

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	<a href="#">Hyperbaric Oxygen Therapy (20.29)</a>
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

**For Non-Medicare Members**

Hyperbaric oxygen may be indicated with a confirmed diagnosis of **ONE or more of the following:**

1. Chronic severe diabetic ulcer, and need for initial treatment, as indicated by **ALL of the following:**
  - a. Must have complete evaluation and treatment for any underlying peripheral vascular or neuropathic disease. To assess vascular status there must be a documented exam of femoral, popliteal, dorsalis pedis and posterior tibial pulses. If absent or reduced, must have documented ABI Scores. If questionable accuracy of ABI score, due to diabetes, a vascular surgeon consult is needed.
  - b. Minimal to no healing present despite conventional wound treatment for minimum of 30 days, including **ALL of the following:**
    - Documentation of adequate diabetic control and most recent HbA1C
    - Pressure reduction or offloading for at least 8 weeks. (Must have documentation at each visit of the use (or of noncompliance) of walker boot, knee, scooter, or wheelchair)
    - Topical wound treatment. Need documentation regarding what specific products have been used, duration, and effectiveness (ie apligraf, dermagraph, saline, hydrogels, hydrocolloids, alginates, or wound vac)
    - Appropriate wound debridement (practitioner must have appropriate training to perform) and
    - Wound is not infected and if the wound was previously infected, the wound has been treated with appropriate antibiotics (may need infectious disease consult)
  - c. Severe wound documented by (Medicare) Wagner grading, as indicated by **one or more of the following:**
    - Grade 3 ulcers are deep and involve abscess(es), osteomyelitis (bone infection) and/or joint sepsis.
    - Grade 4 ulcers include gangrene (decay of body tissues) in the forefoot (anterior third of the foot) or heel region(s).
    - Grade 5 ulcers involve extensive gangrene.
  - d. Transcutaneous tissue oxygenation (PtcO2) levels of **one or more of the following:**
    - PtcO2 of 25 mm Hg (3.3 kPa) or greater on room air
    - PtcO2 value less than 25 mm Hg (3.3 kPa) on room air that meets **one or more of the following:**
      - i. PtcO2 increase of more than 20 mm Hg (2.7 kPa) while breathing 100% oxygen via face mask at normal atmospheric pressure or
      - ii. PtcO2 increase of greater than 200 mm Hg (26.6 kPa) in chamber during hyperbaric oxygen therapy
2. Chronic severe diabetic ulcer, and need for continued treatment, as indicated by **ALL of the following:**

- a. Adherent to hyperbaric oxygen therapy
  - b. Documented evidence of improvement after 24 visits and need for continuing improvement after that point
  - c. Fewer than 40 total treatments
3. Decompression illness or suspected intravascular gas embolism
  4. Carbon monoxide (CO) poisoning is unconscious and has a carboxyhemoglobin level over 40%.
  5. Central retinal artery occlusion
  6. Gas gangrene (inpatient only)
  7. Idiopathic sudden sensorineural hearing loss (will need 20 visits maximum).
  8. Clostridial and non-clostridial myonecrosis: Plan of care indicates use will be in conjunction with other medical/surgical therapies and will not interfere with or delay surgical debridement. (provided for hospital inpatient only)
  9. Necrotizing soft tissue infections (provided for hospital inpatient only)
  10. **Osteoradionecrosis as indicated by ONE or more of the following:**
    - a. Mandibular/maxillary osteoradionecrosis (diagnosis is typically made by a clinical exam with exposed bone, and/or by imaging). History of previous radiation therapy to the mandible or maxilla of at least 5,000-7,000 rads.
    - b. Osteoradionecrosis in other sites, as an adjunct to conventional treatment. Osteoradionecrosis presents some months/years after radiation (sternum, long bones).
    - c. 30 pre/10 post treatments
  11. **Soft tissue radionecrosis** as an adjunct to conventional treatment: Typically bowel, bladder, larynx or wounds in area of prior radiation therapy. Must wait 6 months post completion of radiation therapy. Requires visualization of the damaged area with serial exams to monitor progress (e.g. cystoscopy, laryngoscopy, sigmoidoscopy). Additional health plan review if 30 treatments are exceeded. (40 max). Total radiation dose and field must be documented. Must have **ONE of the following:**
    - a. Radiation-induced proctitis diagnosed by sigmoidoscopy
    - b. Radiation-induced hemorrhagic cystitis diagnosed by cystoscopy
    - c. Radiation-induced head and neck soft tissue injury – soft tissue radionecrosis, typically of the larynx, or in a radiated field.
  12. **Dental extractions** must meet **ALL of the following:**
    - a. Clinical plan on file from the dentist/oral surgeon detailing planned extractions timeline
    - b. History of at least 5,000-7,000 rads received to the teeth planned for the extraction
    - c. Request is for 10 treatments after the extractions (if the initial treatment was 20/10 within 5 years then only 10 more treatments post extractions are required for any additional extractions done within 5 yrs)
  13. Chronic **refractory osteomyelitis**, unresponsive to both conventional medical and surgical treatment. Must have a prior infectious disease consultation and surgical consultation regarding debridement. Any hardware should be removed if feasible. Not indicated for acute osteomyelitis. If involves a distal toe, requires physician consultation prior to auth. Any treatments beyond 30 should have physician consultation. Pelvic bone osteomyelitis from decubiti requires debridement and flap surgery and does not respond well to hyperbaric.

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

## Background

Hyperbaric oxygen therapy consists of placing a patient inside a pressurized chamber in which the patient breathes 100% oxygen under a pressure of greater than one atmosphere. Generally, there is a gradual increase to approximately two-and-a-half times the normal atmospheric pressure. Patients receive up to 40 treatment sessions lasting between 45 and 300 minutes. There are monoplace chambers for one person and multi-place chambers that can accommodate two or more patients. (Leach et al, 1998; Porter & Brian, 1999).

Hyperbaric oxygen therapy has both a mechanical (pressure) and physiological (oxygen) component. The increased pressure causes compression of gas bubbles in the body and is useful for conditions such as decompression illness. Breathing 100% oxygen at increased pressure allows more oxygen to reach non-healing tissue, and helps to prevent tissue from dying to a lack of oxygen and blood (Porter & Brian, 1999).

Potential adverse events of hyperbaric oxygen therapy include myopia lasting for weeks or months, ruptured middle ear, seizures, lung damage and oxygen toxicity. The most common complication is a lack of pressure equalization on both sides of the eardrum which can cause pain and bleeding into the middle ear. The high concentration of oxygen also presents a fire hazard (Porter & Brian, 1999; oral cancer foundation).

## Evidence and Source Documents

[Hyperbaric Oxygen for Treatment of Radiation Induced Cerebral Necrosis](#)

[Hyperbaric Oxygen Therapy for Prophylactic Treatment after Head and Neck Radiation to Prevent Osteoradionecrosis \(ORN\) of the Mandible](#)

[Hyperbaric Oxygen Therapy for Prophylaxis before Breast Surgery](#)

[Hyperbaric Oxygen Therapy for Treatment of Gastrointestinal Bleeding Related to Radiation Enteritis](#)

## Medical Technology Assessment Committee (MTAC)

### ***Hyperbaric Oxygen for Treatment of Radiation Induced Cerebral Necrosis***

#### BACKGROUND

Many types of cerebral cancer are treated with external beam, stereotactically focused or implanted radiation. One of the most common and debilitating sequelae of high dose radiation is tissue destruction and necrosis. Radiation-induced necrosis (RIN) manifests itself as headache, ataxia, cranial nerve palsy, seizures, and visual loss. Necrotic tissue had historically been surgically re-sected when anatomically feasible or left untreated. One proposed method of treatment is the use of hyperbaric oxygen therapy (HBOT) which increases tissue oxygen concentration and may stimulate angiogenesis and establish a new blood supply to healthy cerebral tissue. Typically hyperbaric oxygen is administered by placing patients into a whole-body hyperbaric chamber and exposing them to oxygen concentrations of 2 times normal atmospheric pressure for a period of 2-4 hours, once a day. Treatments are usually repeated usually 20-40 times with symptomatic improvement used as the measure of treatment success.

#### 08/11/1999: MTAC REVIEW

#### **Hyperbaric Oxygen for Treatment of Radiation Induced Cerebral Necrosis**

**Evidence Conclusion:** Evidence identification was conducted by searching MEDLINE from 1996-1999 using terms radiation necrosis, radiation injuries, cerebral necrosis and hyperbaric oxygenation. Dr. Kindwall, the author of a recent review, identified 2 case series (n=10, n=2) as the only published data on hyperbaric oxygen for treating **cerebral** radiation-induced necrosis. The Kaiser Permanente New Technology hotline staff was also unable to identify any additional literature reporting original data. Data from the case series of 10 patients, 8 of whom had biopsy-proven RIN, demonstrated that, with a median follow up of 7 months post HBOT, symptoms completely resolved in 1 patient, improved in 4 patients, did not get worse in 1 patient, and ended up worse in 4 patients. One patient developed ear pain from HBOT and had ear tubes placed and one developed sinusitis and discontinued treatment. Because this study was a case series rather than a randomized trial, it is not possible to determine whether hyperbaric oxygen therapy improves the clinical outcome of patients with radiation-induced cerebral necrosis beyond what would be expected with corticosteroid therapy alone. The best published scientific evidence on treating radiation induced cerebral necrosis with hyperbaric consists of a case series of 10 patients, 8 of whom had biopsy-proven RIN, demonstrated that, with a median follow up of 7 months post HBOT, symptoms completely resolved in 1 patient, improved in 4 patients, did not get worse in 1 patient, and ended up worse in 4 patients. One patient developed ear pain from HBOT and had ear tubes placed and one developed sinusitis and discontinued treatment. Because this study was a case series rather than a randomized trial, it is not possible to determine whether hyperbaric oxygen therapy improves the clinical outcome of patients with radiation-induced cerebral necrosis beyond what would be expected with corticosteroid therapy alone.

**Articles:** Chuba, PJ, et al, Cancer 1997;80:2005-2012

The use of hyperbaric oxygen does not meet *Kaiser Permanente Medical Technology Assessment Criteria*.

### ***Hyperbaric Oxygen Therapy for Prophylactic Treatment after Head and Neck Radiation to Prevent Osteoradionecrosis (ORN) of the Mandible***

#### BACKGROUND

Hyperbaric oxygen therapy consists of placing a patient inside a pressurized chamber in which the patient breathes 100% oxygen under a pressure of greater than one atmosphere. Generally, there is a gradual increase to approximately two-and-a-half times the normal atmospheric pressure. Patients receive up to 40 treatment sessions lasting between 45 and 300 minutes. There are monoplace chambers for one person and multiplace chambers that can accommodate two or more patients. (Leach et al, 1998; Porter & Brian, 1999). Hyperbaric oxygen therapy has both a mechanical (pressure) and physiological (oxygen) component. The increased pressure causes compression of gas bubbles in the body and is useful for conditions such as decompression illness. Breathing 100% oxygen at increased pressure allows more oxygen to reach non-healing tissue, and helps to prevent tissue from dying to a lack of oxygen and blood (Porter & Brian, 1999). Potential adverse events of hyperbaric oxygen therapy include myopia lasting for weeks or months, ruptured middle ear, seizures, lung

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damage and oxygen toxicity. The most common complication is a lack of pressure equalization on both sides of the eardrum that can cause pain and bleeding into the middle ear. The high concentration of oxygen also presents a fire hazard (Porter & Brian, 1999; oral cancer foundation). Osteoradionecrosis (ORN) of the mandible is a potential complication of head and neck irradiation. It is defined as a nonhealing, nonseptic lesion of bone (Clayman, 1997). The underlying cause of ORN is believed to be progressive vascular occlusion and tissue hypoxia after radiation treatment (Porter & Brian, 1999). Three types of ORN have been described. Type 1 occurs when a patient receives radiation therapy within 21 days of tooth extraction or mandibulotomy. Type 2 is induced by trauma. It generally occurs 3-6 years after radiation therapy, usually following a tooth extraction. Type 3 occurs spontaneously 6 months to 2 years after radiation therapy and is associated with higher radiation doses, neutron beam therapy and brachytherapy (Cronje, 1998). Hyperbaric oxygen therapy is generally accepted as a treatment for patients who have ORN. The use of hyperbaric oxygen therapy is also proposed as a prophylactic treatment before dental work to prevent ORN in patients who have had irradiation of the head and neck.

#### **04/09/2003: MTAC REVIEW**

#### **Hyperbaric Oxygen Therapy for Prophylactic Treatment after Head and Neck Radiation to Prevent Osteoradionecrosis (ORN) of the Mandible**

**Evidence Conclusion:** There is weak evidence from one randomized controlled trial (Marx), published in 1985, that prophylactic hyperbaric oxygen treatment of patients with previous head and neck irradiation before tooth removal lowers the incidence of osteoradionecrosis of the mandible compared to patients treated prophylactically with penicillin. The Marx study had a small sample size (n=74) and the methodology was not well described, leaving open the possibility of threats to validity such as selection bias, inadequate randomization and biased assessment of outcomes. The results of the Marx study have not been replicated. Many factors may have changed since 1985 making the findings less relevant including different radiation protocols that alter the likelihood of developing ORN, better alternative prophylactic treatments and better treatments for patients with ORN. Recent authors have questioned the need for prophylactic hyperbaric oxygen treatment before dental surgery for all patients who have received head and neck radiation before dental surgery because the incidence of post-extraction ORN is relatively low and over half of the patients who do develop ORN heal after conservative treatment. The Marx study has also been criticized as including a particularly high-risk group of patients. The incidence of ORN in the Marx study was 30% in the penicillin-treated group compared to a 5.8% incidence in the general population of post-radiation tooth extraction patients and a lower incidence, 2.1% in studies conducted in the 1990s (Clayman, 1997).

**Articles:** The search yielded 35 articles. Many of the articles were reviews or opinion pieces, dealt with technical aspects of the intervention or addressed the treatment of osteoradionecrosis with hyperbaric oxygen rather than prophylaxis. No randomized controlled trials on prophylactic use of hyperbaric oxygen to prevent osteoradionecrosis were included in the search findings. However, an RCT published in 1985 was identified from the reference list of a review article. In addition to the RCT, there were several case reports and small case series (n<30 patients). The RCT was critically appraised: Marx RE, Johnson RP, Kline SN. Prevention of osteoradionecrosis: a randomized prospective clinical trial of hyperbaric oxygen versus penicillin. JADA 1985; 111: 49-54. See [Evidence Table](#).

The use of hyperbaric oxygen in the prevention of osteoradionecrosis of the mandible does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

#### **Hyperbaric Oxygen Therapy for Prophylaxis Before Breast Surgery**

##### **BACKGROUND**

Breast cancer is the most common cancer in women, other than skin cancer, and the second leading cause of cancer death among them. According to the American cancer society, a woman has a 1 in 7 chance of having invasive breast cancer some time during her life. As of the 2004, there are slightly over 2 million women living in the USA who have been treated for breast cancer. Conservative therapy with lumpectomy, axillary dissection, and irradiation, is a frequently used option for treating early breast cancer. This allows the patient to keep her breast and reduce the physical and psychological trauma associated with the modified radical mastectomy. Radiation therapy is also indicated with mastectomy under certain conditions. In both cases, radiotherapy is given in a moderate to high dose and may be associated with mild to severe complications that might have negative influence on the health and quality of life. Among these complications are arm lymphedema, subcutaneous fibrosis, painful hardening of the breast, shoulder pain rib fracture, damage to the lungs and heart and others (Gothard 2003, Feldmeier 1995). These complications may be due to early reactions to radiation, or late effects that occur after at least 90 days after the start of treatment (Pasquier, 2004). Late injuries are irreversible and progressive in the majority of cases. These may cause cellular depletion, reduction in vascular density, fibrosis and atrophy all of which may result in hypoxia, and in turn delayed healing of the wounds. Conservative measures may be adequate for managing moderate cases with minimal necrosis, but cases of extensive necrosis are more

challenging. Hyperbaric oxygen (HBO) was first used for the treatment of radiotherapy patients in the 1950s (Pasquier, 2004). It is defined as the breathing of pure oxygen at pressure exceeding the normal atmospheric pressure of 100 kPa that increases the solubility of oxygen in the blood. HBO treatment is administered within hyperbaric chambers, which are compressed by air (Plafki 1998). Researchers indicate that hyperbaric oxygen therapy stimulates angiogenesis, osteogenesis, fibroblast activity, and collagen formation in irradiated tissues, which would increase the cellular level of oxygen. It has been reported that HBO therapy is associated with a low complication rate, but that there is uncertainty about the best time to start the treatment, and the number of sessions needed (Plafki 1998). There is also uncertainty on the efficacy of the treatment for the different complications, what are its side effects, who would respond to treatment, and for which symptoms.

#### **12/08/2004: MTAC REVIEW**

##### **Hyperbaric Oxygen Therapy for Prophylaxis Before Breast Surgery**

**Evidence Conclusion:** There is no evidence to date on the prophylactic use of hyperbaric oxygen therapy before breast surgery in patients with prior radiation therapy. There is also insufficient evidence on the efficacy of HBO therapy in the treatment of late sequelae in women receiving radiation after breast-conserving surgery. The study reviewed was a case series that provide the least grade of evidence. It was small nonrandomized, and with potential selection and observation bias. The results of the study show that patients who received a hyperbaric oxygen therapy had a significant reduction of pain, edema, and erythema compared to those who refused the therapy. There was no significant difference between the groups in the improvement of fibrosis or telangiectasia.

**Articles:** The search yielded 35 articles. Many were review articles, dealt with technical aspects of the therapy, or the use of hyperbaric oxygen for the treatment of radio-induced lesions in different tissues and organs other than the breast. The search did not reveal any study on the use of Hyperbaric Oxygen Therapy for prophylaxis in breast surgery in patients with prior radiation therapy. There was one prospective case series with a control group on the use of hyperbaric oxygen for the treatment of late sequelae of radiation therapy after breast surgery, a smaller series of 21 patients and control group, and a retrospective review of 23 cases.

The case series with a control group was selected for critical appraisal. Carl UM, Feldmeier JJ, Schmitt, et al. Hyperbaric oxygen therapy for late sequelae in women receiving radiation after breast-conserving surgery. *Int J Radiat Oncol Biol Phys.* 2001; 49:1029-31. See [Evidence Table](#).

The use of hyperbaric oxygen for prophylaxis before breast surgery does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

##### **Hyperbaric Oxygen Therapy for Treatment of Gastrointestinal Bleeding Related to Radiation Enteritis**

###### **BACKGROUND**

Hyperbaric oxygen therapy consists of placing a patient inside a pressurized chamber in which the patient breathes 100% oxygen under a pressure of greater than one atmosphere. Generally, there is a gradual increase to approximately two-and-a-half times the normal atmospheric pressure. Patients receive up to 40 treatment sessions lasting between 45 and 300 minutes. There are monoplace chambers for one person and multiplace chambers that can accommodate two or more patients. (Leach et al, 1998; Porter & Brian, 1999). Hyperbaric oxygen therapy has both a mechanical (pressure) and physiological (oxygen) component. The increased pressure causes compression of gas bubbles in the body and is useful for conditions such as decompression illness. Breathing 100% oxygen at increased pressure allows more oxygen to reach non-healing tissue, and helps to prevent tissue from dying to a lack of oxygen and blood (Porter & Brian, 1999). Potential adverse events of hyperbaric oxygen therapy include myopia lasting for weeks or months, ruptured middle ear, seizures, lung damage and oxygen toxicity. The most common complication is a lack of pressure equalization on both sides of the eardrum which can cause pain and bleeding into the middle ear. The high concentration of oxygen also presents a fire hazard (Porter & Brian, 1999; oral cancer foundation). The treatment of gastrointestinal bleeding related to radiation enteritis is one possible application of hyperbaric oxygen therapy.

#### **04/09/2003: MTAC REVIEW**

##### **Hyperbaric Oxygen Therapy for Treatment of Gastrointestinal Bleeding Related to Radiation Enteritis**

**Evidence Conclusion:** There is no published evidence on the effectiveness of hyperbaric oxygen therapy for the treatment of gastrointestinal bleeding related to radiation enteritis.

**Articles:** There were no published empirical studies. An abstract of a small case series (n=19) was identified in a review article. The abstract was presented at a professional meeting in 1998 and the study was not subsequently published.

The use of hyperbaric oxygen in the treatment of gastrointestinal bleeding related to radiation enteritis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Date Created	Date Reviewed	Date Last Revised
09/1998	01/05/2010 <sup>MDCRPC</sup> , 11/02/2010 <sup>MDCRPC</sup> , 12/07/2010 <sup>MDCRPC</sup> , 10/04/2011 <sup>MDCRPC</sup> , 08/07/2012 <sup>MDCRPC</sup> , 06/04/2013 <sup>MDCRPC</sup> , 04/01/2014 <sup>MPC</sup> , 09/02/2014 <sup>MPC</sup> , 02/03/2015 <sup>MPC</sup> , 12/01/2015 <sup>MPC</sup> , 10/04/2016 <sup>MPC</sup> , 08/01/2017 <sup>MPC</sup>	03/07/2017

<sup>MDCRPC</sup> Medical Director Clinical Review and Policy Committee  
<sup>MPC</sup> Medical Director Clinical Review and Policy Committee

Revision History	Description
12/01/2015	Added one additional indication: treatment of central retinal artery occlusion
03/07/2017	Revised indication to dental extractions (part c)

## Codes

CPT: 413, 99183, A4575, G0277