

Final Key Questions

Hyperbaric Oxygen (HBO2) Treatment for Tissue Damage Including Wound Care and Treatment of Central Nervous System (CNS) Conditions

Introduction

The Washington State Health Care Authority (HCA) has selected hyperbaric oxygen (HBO2) treatment to undergo a health technology assessment by an independent vendor who will systematically review the evidence available on its safety, efficacy, and cost-effectiveness.

Hyperbaric oxygen (HBO2) treatment involves the systemic administration of pure gaseous oxygen under pressures greater than 1 atmosphere in a specialized chamber. Hyperbaric oxygen may also be administered in a multiplace chamber in which patients breathe 100% oxygen through a facemask or similar device with the surrounding air pressure increased to 2 to 3 times the atmospheric pressure. The elevated concentration and pressure of the oxygen allows higher levels of oxygen absorption by blood, creating hyperoxygenation in the tissues.

Potential benefits of hyperbaric therapy include that it may reduce edema, promote antimicrobial activity, enhance the immune response, and facilitate the formation of collagen, blood vessels, and other tissues. For chronic conditions, HBO2 treatment is typically employed as an adjunct to surgical or pharmacological interventions. HBO2 treatment is a relatively safe procedure, but does carry some risks due to the increased pressure and hyperoxia. The only absolute contraindication is an untreated tension pneumothorax. Relative contraindications include impaired pressure equalization and cardiac disease.

Policy Context

For HBO2 treatment, important questions center on the effectiveness of treatment for some conditions, as well as the frequency, dose and duration treatment. The list of applications for HBO2 treatment has expanded beyond those approved by the Food and Drug Administration (FDA) or currently covered by the Center for Medicare Services (CMS).

Scope of This HTA

Key questions guide the development of the evidence report. HTA seeks to identify the appropriate clinical topics (e.g., population, indications, comparators, outcomes) to address the statutory elements of evidence on safety, efficacy, and cost effectiveness relevant to coverage determinations.

Population: Adults and children with the following indications for HBO2 treatment:

- Diabetic non-healing wounds including foot ulcers
- Other non-healing wounds including skin and tissue grafts, thermal burns and surgical wounds
- Refractory osteomyelitis
- Radiation tissue damage
- Chronic brain injury
- Cerebral palsy
- Headache/migraine
- Multiple sclerosis
- Sensorineural hearing loss

Intervention: Hyperbaric oxygen treatment, delivered via a hyperbaric oxygen chamber

Comparator: Standard treatment alone, a competing alternative, or sham treatments

Outcomes: Patient-centered outcomes including:

- Incidence of healing
- Time to healing
- Secondary wound closure
- Infection rates
- Wound recurrence
- Pain
- Disease specific patient-centered health outcomes
- Mortality
- Depression
- Functional status
- Quality of life (QOL)
- Return to work
- Cost/cost-effectiveness

Draft Key Questions

1. Is HBO2 treatment effective in improving patient-centered outcomes for individuals with the following conditions:
 - Diabetic non-healing wounds including foot ulcers
 - Other non-healing wounds including skin and tissue grafts, thermal burns and surgical wounds
 - Refractory osteomyelitis
 - Radiation tissue damage
 - Chronic brain injury
 - Cerebral palsy
 - Headache/migraine

- Multiple sclerosis
- Sensorineural hearing loss

- 1a What is the optimal frequency, dose and duration of HBO2 treatment?
2. What harms are associated with HBO2 treatment?
3. What is the differential effectiveness and safety of HBO2 treatment according to factors such as age, sex, race or ethnicity, disability, comorbidities, wound or injury duration and severity, and treatment setting?
4. What are the cost implications of HBO2 treatment, including the cost-effectiveness compared to alternative treatments?

Public Comment and Response

See *Key Question Public Comment and Response* document published separately.

[For additional information on key questions and public comment.](#)