Hyperbaric Oxygen Therapy for Selected Indications

Assessing Signals for Update

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Health Technology Assessment Program (HTA)

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This report is based on research conducted by the RTI–University of North Carolina Evidence-based Practice Center through a contract between RTI International and the State of Washington Health Care Authority (HCA). The findings and conclusions in this document are those of the authors, who are responsible for its contents. The findings and conclusions do not represent the views of the Washington HCA and no statement in this report should be construed as an official position of Washington HCA.

The information in this report is intended to help the State of Washington Health Care Authority make decisions. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information (i.e., in the context of available resources and circumstances presented by individual patients).

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List of Abbreviations

AE adverse event

ATA atmospheres absolute (a measure of pressure)

CMS Centers for Medicare & Medicaid Services

ECHM European Committee for Hyperbaric Medicine

ETRS European Tissue Repair Society

FDA United States Food and Drug Administration

HBOT hyperbaric oxygen therapy

HTA health technology assessment

HTCC Health Technology Clinical Committee

KQ key question

NCD National Coverage Determination

NRSI nonrandomized studies of interventions

QOL quality of life

RCT randomized controlled trial

RR risk ratio

SAE serious adverse events

SR systematic review

UHMS Undersea and Hyperbaric Medical Society

VA Department of Veterans Affairs

Executive Summary

Background

Hyperbaric oxygen therapy (HBOT) is recommended by several professional societies and covered by several payors for multiple clinical indications. In 2013, The State of Washington Health Technology Clinical Committee (HTCC) determined that HBOT should be covered for several indications. In this signal search, we focus on 2 indications for HBOT (thermal burns and myositis). Thermal burns is currently a noncovered indication, and myositis was not included in the State of Washington Health Care Authority's 2013 health technology assessment (HTA) on HBOT. We also searched for a signal on harms across all HBOT indications to determine whether an updated HTA should be considered.

Methods

We searched MEDLINE® (via PubMed) for relevant English-language studies (primary studies and systematic reviews), guidelines, and consensus statements published between January 1, 2013, and April 24, 2025. Using a modified Ottawa approach, we evaluated the identified information to determine whether a signal suggesting a need for an updated HTA was present.

Results

Nine primary studies of HBOT for thermal burns reported evidence of benefit on healing outcomes, patient-centered outcomes such as pain and patient satisfaction, and decreased length of stay for patients receiving HBOT treatment compared with usual care. The majority of studies were nonrandomized studies of interventions and 1 study evaluated optimal protocols for HBOT. Findings on harms such as infection or graft failure were mixed, reporting either more or fewer harms in the HBOT group compared with usual care or no difference between the groups. Serious adverse events such as mortality or the need for critical care were higher in the HBOT group for 1 study, which had serious study limitations. The 1 study of costs reported lower costs for HBOT treatment compared with usual care.

We identified 1 case report of HBOT used to treat ulcerations in a single patient with dermatomyositis. In this case report, ulcerations were healed after treatment with HBOT.

One meta-analysis of 24 randomized controlled trials (n = 1,497) of HBOT for various indications reported a higher risk of harms for HBOT compared with usual care or sham HBOT. The most common harm was ear discomfort. One serious adverse event, seizure, was reported among the pooled study population.

Conclusions

This signal search identified a small number of primary studies or systematic reviews evaluating HBOT for thermal burns, myositis, or harms across indications. We identified a signal for an HTA update on HBOT for thermal burns, which is currently not a covered indication, based on new evidence suggesting benefits. We conclude there is no signal for an HTA update on HBOT for myositis or for other indications.

1. Introduction

In 2013, the State of Washington Health Technology Clinical Committee (HTCC) made coverage decisions for the use of hyperbaric oxygen therapy (HBOT) for several indications. The current signal search includes 2 indications for HBOT and a search for harms across various clinical indications. Details on the selection of indications for this signal search are found in the ***Methods*** section of this report and are detailed in ***Appendix A***. Below we review the 2 selected indications and the role of HBOT in their treatment.

1.1 Indication

Thermal Burns

In the United States, approximately 600,000 people annually suffer acute thermal burns that require medical treatment.[2] Surveys estimate over 29,000 burn admission per year with an overall mortality of 2.7%.[3,4] Standard treatment of thermal wounds includes excision, grafting, and antimicrobial therapy. After acute resuscitation, patients with larger burns require management of inflammation, infection, and nutritional deficiencies resulting from a catabolic state, all of which impair wound healing. Delays in wound healing may increase risk of secondary infections and osteomyelitis.[5] In some cases, HBOT can be considered an adjunctive treatment.

HBOT increases the oxygen saturation of burn tissues and potentially improves wound healing via several mechanisms, most of which have been gleaned from animal studies.[6] Higher oxygen levels have bactericidal properties, killing anaerobic bacteria and preventing the production of clostridial toxin.[7] Oxygen reduces the edema associated with hypoxic tissue injury, acts an immunomodulator, and prevents reperfusion injury, which can further damage tissues.[8] Elevated levels of oxygen can also improve fibroblast function, which is needed for collagen synthesis and angiogenesis.[7] Improved revascularization can improve nutrient delivery to damaged tissues.[8]

Myositis

Inflammatory myopathies are autoimmune disorders characterized by muscle inflammation and weakness and can be associated with skin findings or extramuscular organ involvement. Inflammatory myopathies are relatively rare and include polymyositis, dermatomyositis, inclusion body myositis, and antisynthetase myositis. Clostridial myositis and myonecrosis are indications requiring emergency interventions and are excluded from this signal search (***Appendix A***). The mechanism of action of HBOT in myositis in unclear but is likely related to impairment of inflammatory cells.[9]

1.2 Technology

HBOT is a treatment in which a patient is placed in a closed chamber filled with nearly pure oxygen pressurized above atmospheric pressure, defined as atmospheres absolute (ATA). The Undersea and Hyperbaric Medical Society (UHMS) specifically defines HBOT as “a medical procedure requiring physician prescription and oversight,” in which the patient’s whole body is

within a chamber of at least 2.0 ATA with medical grade oxygen (>99% oxygen purity). Topical oxygen treatments, room air concentrations of oxygen, or use of other gases is not considered HBOT by UHMS. The United States Food and Drug Administration (FDA) advises patients to seek HBOT at facilities that have UHMS accreditation.[10] The duration and frequency of HBOT sessions is indication specific.

1.3 Policy Context

The HTCC considered the evidence for thermal burns among other indications reported in a 2013 health technology assessment (HTA).[11,12] For thermal burns, the committee issued a *not-covered benefit* determination. At the time, 1 systematic review (SR) including 2 studies of HBOT for thermal burns was identified, both published in the 1970s. The 2 studies reported an improvement in time to healing, but no difference in length of stay, number of surgeries, or mortality. The certainty of evidence was assessed as *Very Low*. Additionally, a review of payor policies at that time showed that no policies provided coverage for HBOT as a treatment for thermal burns. Myositis was not included in the 2013 HTA or the HTCC coverage determination. In March 2025, the HTCC determined that HBOT is a covered benefit for sudden sensorineural hearing loss based on an HTA focused exclusively on that indication.[13]

1.4 Scope and Key Questions of the 2013 HTA

The key questions guiding the previous 2013 HTA and this signal search are listed below.

Key Question 1 (KQ1): Is HBOT effective in improving patient-centered outcomes for individuals with the following indications:

- Diabetic nonhealing wounds, including foot ulcers
- Other nonhealing wounds, including skin and tissue grafts, thermal burns, and surgical wounds
- Refractory osteomyelitis
- Late radiation tissue injury
- Brain injury (including traumatic brain injury and other brain injuries but excluding stroke)
- Cerebral palsy
- Headache/migraine
- Multiple sclerosis
- Sensorineural hearing loss

KQ1a. What is the optimal frequency, dose, and duration of HBOT treatment?

Key Question 2 (KQ2): What harms are associated with HBOT?

Key Question 3 (KQ3): What is the differential effectiveness and safety of HBOT according to factors such as age, sex, race or ethnicity, disability, comorbidities, wound or injury duration and severity, and treatment setting?

Key Question 4 (KQ4): What are the cost implications of HBOT, including the cost-effectiveness compared with alternative treatments?

The inclusion criteria for the 2013 HTA were as follows:

Population

Patients with 1 of the indications for treatment above.

Intervention

HBOT delivered via a hyperbaric oxygen chamber.

Comparators

Usual care (e.g., fluids, excision/grafting), sham treatments, and other treatments.

Outcomes

- Healing (incidence of healing, time to healing)
- Secondary wound closure
- Complications (infection rates, wound recurrence)
- Pain
- Disease-specific patient-centered health outcomes
- Length of hospital stay
- Mortality
- Harms
- Cost

1.5 Objectives

The primary aim of this signal search was to determine whether new evidence suggests a need to update the 2013 HTA. It was focused on new evidence for the efficacy, safety, or cost-effectiveness of HBOT for thermal burns (a noncovered indication in 2013), myositis (not included in the 2013 HTA), or harms across all indications.

2. Methods

We used a modified Ottawa approach[14,15] to determine whether a signal for an update was present. The prior HTA evaluated 9 indications for which coverage decisions were made. On review of current recommendations from relevant professional societies and government agencies, including the most recent National Coverage Determination (NCD) by the Centers for Medicare & Medicaid Services (CMS), we identified 12 additional indications in which at least 2 of the aforementioned entities had issued a recommendation or coverage determination (see ***Appendix A***). After discussion with the HCA and State of Washington Agency Medical Directors, 2 indications were chosen to evaluate for a signal for effectiveness, harms, and cost: thermal burns and myositis.

Thermal burns were a noncovered indication in the 2013 HTCC determination because of insufficient evidence for effectiveness or harms. The UHMS, from which the FDA recommends accreditation for facilities delivering HBOT, recommends the use of HBOT for thermal burns, as do the European Committee for Hyperbaric Medicine (ECHM), the European Tissue Repair Society (ETRS), and the United States Department of Veterans Affairs (VA). Given the discrepancy between the 2013 coverage determination for thermal burns and the recommendations of the entities above, thermal burns was chosen as in indication for a signal search of effectiveness and harms. Among indications not previously reviewed, myositis was an indication recommended for HBOT by the UHMS and VA but was not included in the 2013 HTA.

HTCC coverage determinations for the remaining indications evaluated in the 2013 HTA are consistent with current society recommendations and coverage decisions; thus, these indications are included in this signal search for harm outcomes only. Given that we expect that harms of HBOT will not substantially vary by indication, we did not perform searches for harms by indication. Rather, we identified literature reviewing general harms of HBOT across indications for this signal search. Among indications for which HBOT is generally recommended that were not evaluated in the 2013 HTA, all but immune-mediated or idiopathic myositis are indications treated as medical emergencies and were thus excluded from this search (***Appendix A***).

2.1. Literature Search

We searched MEDLINE® (via PubMed) for relevant English-language studies between January 1, 2013, and April 24, 2025. The search strategy is described in ***Appendix B***. We searched for both primary studies and SRs. In addition to PubMed, we reviewed references of guidelines and consensus statements for additional studies. We searched ClinicalTrials.gov for ongoing studies on May 2, 2025.

2.2. Study Selection

We used the inclusion and exclusion criteria presented in ***Table 1***. The criteria used in the 2013 HA were broader because of the number of indications reviewed. The criteria for this signal search were adapted for disease-specific outcomes related to thermal burns and myositis, and harms across all indications. Our preliminary searches yielded few SRs, so the search was expanded to include primary literature.

Table 1. Inclusion and exclusion criteria for signal search

PICOTS Category	Inclusion Criteria	Exclusion Criteria
Population	Thermal burns: burn, scalds, burn injury, burn wound, thermal insult, thermal insult, thermal wound	Nonhuman In vitro Wound other than a thermal burn
	Myositis, autoimmune or idiopathic: inflammatory myopathy, polymyositis, dermatomyositis, inclusion body myositis, antisynthetase myositis	Myositis secondary to trauma Clostridial myositis Myonecrosis
	Harms of HBOT: any indication eligible	None

PICOTS Category	Inclusion Criteria	Exclusion Criteria
Intervention	HBOT delivered via a hyperbaric oxygen chamber	Topical oxygen therapy
Comparators	Usual care (fluids, excision/grafting) Sham treatments No comparator	None
Outcomes	Healing • Incidence of healing • Time to healing • Graft uptake • Secondary wound closure Patient-centered outcomes • Pain • QOL • Patient satisfaction Utilization • Length of hospital stay Complications • Infection (includes sepsis) • Wound recurrence • Graft failure • Subsequent surgery Harms • Adverse and serious events • Need for critical care • Mortality Costs/cost-effectiveness	Imaging, biomarkers
Study Design	Thermal burns and myositis • SR • RCT • NRSI—comparative or single arm	Nonsystematic review, editorials, commentaries, abstracts
	General harms • SR only	Same as above Primary studies • RCT • NRSI
Year(s) conducted	2013 to present	2012 or before

Abbreviations: HBOT = hyperbaric oxygen therapy; NRSI = nonrandomized studies of interventions; QOL = quality of life; RCT = randomized controlled trial; SR=systematic review.

2.3. Data Abstraction and Signal Assessment

One reviewer evaluated titles and abstracts retrieved by our search; the same reviewer assessed the full text of primary and SR articles to determine if they met selection criteria and reported relevant findings. One reviewer abstracted data and a second reviewer confirmed that the abstraction data was accurate. We abstracted study characteristics including study design, sample size (and number of studies for SRs), and the country in which the study was conducted. For each study, we also abstracted the indication of HBOT, comparator, and the presence of eligible outcomes. Results were summarized in narrative format as benefit, harm, or no difference in the use of HBOT compared with the specific study comparator (if present) and direction of effect to determine if a signal was present.

3. Results

3.1. Search Yield and Overview of Studies

Our search identified 244 publications. Twenty-nine full-text articles were reviewed and 12 studies were included in the signal search. We were unable to retrieve the full text for 1 SR publication that focused on the harms of HBOT across indications.[16] We identified 9 studies of HBOT for thermal burns[1,5,17-23], 1 study of HBOT for myositis[24] and 2 studies on the general harms of HBOT across indications.[25,26] All publications were primary studies, with the exception of 1 SR examining the harms of HBOT across indications.[26] We did not identify any ongoing or recently completed studies of HBOT for thermal burns or myositis in the ClinicalTrials.gov registry.

3.2. Study Characteristics

Table 2 and ***Table 3*** present an overview of the study characteristics for primary studies and SRs, respectively. In brief, for the indication of thermal burns, 7 of the 9 studies had a comparative study design with the comparator of usual care.[1,17-19,21-23] The 1 study on the use of HBOT for myositis was a case report.[24] The 1 primary study reporting the harms of HBOT across indications was a retrospective analysis of a cohort of patients at 1 institution outside of the United States.[25] There was 1 SR of HBOT harms across indications (***Table 3***), which included 24 studies, was limited to randomized controlled trial (RCT) study designs, and included comparators of usual care and sham HBOT.[26]

Table 2. Summary of study characteristics of primary studies by indication

Study Characteristics	Thermal Burns (k = 9)	Myositis (k = 1)	General Harms (k = 1)
Country			
U.S.	2	1	0
Non-U.S.	7	0	1
Study Design			
RCT	2	0	0
NRSI—comparative	5	0	0
NRSI—single arm	2	1	1
Sample size (range)	7 to 13,044	1	2,334
Comparator			
Usual care	7	0	0
No comparator	2	1	1

Abbreviations: k = number of studies; NRSI = nonrandomized studies of interventions; RCT = randomized controlled trial.

Table 3. Summary of study characteristics of the systematic review on general harms

Study Characteristics	Harms Across Indications
Number of included studies	24
Indications	Included indications: cerebral palsy, childhood autism, stroke, sudden sensorineural hearing loss, fibromyalgia syndrome, persistent post-concussion symptoms, diabetes with nonhealing ulcers of the lower limb, chronic bowel dysfunction after pelvic radiotherapy, prostate cancer, adhesive postoperative small bowel obstruction, chronic venous leg ulcers, radiation-induced cystitis, osteoradionecrosis, mild traumatic brain injury, central airway stenosis after lung transplantation, post-traumatic stress disorder, and chronic nonhealing ulcer.
Study Designs RCT NRSI—comparative NRSI—single arm	 24 0 0
Sample size	1,497 across all studies
Comparator Usual care Sham HBOT	 19 5

Abbreviations: HBOT = hyperbaric oxygen therapy; NRSI = nonrandomized studies of intervention; RCT = randomized controlled trial.

3.3 Findings

An overview of the yield by KQ is presented in ***Table 4***. All studies reported effectiveness outcomes (KQ1) with the exception of the SR on the harms of HBOT across indications. One primary study of the harms of HBOT analyzed outcomes by different HBOT protocols (KQ1a).[25] A total of 10 studies reported harms (KQ2) for thermal burns[1,5,17,19-23] and general harms.[25,26] No studies reported outcomes by subgroups (KQ3). Only 1 study reported cost outcomes (KQ4).[17]

Table 4. Number of studies by indication

Key Question (KQ)	Thermal Burns (k=9)	Myositis (k=1)	Harms Across Indications (k=2)
KQ1 (effectiveness)	9	1	0
KQ1a (alternative protocols)	0	0	1
KQ2 (harms)	8	0	2
KQ3 (effectiveness and harms in subgroups)	0	0	0
KQ4 (cost and cost-effectiveness)	1	0	0

Table 5 provides a summary of the signals identified; detailed information about these studies is provided in ***Appendix C***.

Table 5. Summary of evidence by indication

	Thermal Burns	Myositis	Harms Across Indications
Benefit	Evidence of benefit for: • Healing outcomes (k = 6) • Patient-centered outcomes (k = 3) • Utilization outcomes (k = 6)	Unable to determine based on a single case report	NA

	Thermal Burns	Myositis	Harms Across Indications
Harm	Mixed results on harms: • Infection (k = 4) • Treatment failure (k=3) • SAEs (k = 2)	No information	Evidence of more adverse events in HBOT groups vs. control groups (k = 1, SR)
Cost	Evidence for benefit, though limited data (n = 1)	No information	NA

Abbreviations: HBOT = hyperbaric oxygen therapy; k = number of studies; NA = not applicable SAE = serious adverse event; SR = systematic review.

Thermal Burns

Among studies of thermal burns, there was evidence of benefit for several outcomes. In comparative studies,[1,17,19-23] participants receiving HBOT were more likely to have improved wound healing, including higher rates of graft uptake, and shorter times to epithelization and overall healing. Three studies reported improvements in patient-centered outcomes, including higher patient satisfaction for patients in the HBOT group compared with those receiving usual care[17,23] and reduced pain.[5,23] Individuals receiving HBOT had shorter length of hospital stays in 6 studies.[17,19-23] Single-arm studies reported complete healing of wounds,[5,18] and patients reported reduced pain after HBOT.[5]

With respect to the harms of HBOT used for thermal burns, findings were mixed. For infection, 1 study reported improved sepsis control[21] and 2 studies reported no difference in infections[17,23] for individuals receiving HBOT compared with those receiving usual care. One study reported only 1 infection per group.[1] Three studies reported on graft failure, which was generally higher in the comparator group compared with the HBOT group, though the number of events in these studies was small.[1,21,22] A study using the National Burn Repository compared patients receiving HBOT with those not receiving HBOT. HBOT-receiving patients had a higher mortality (29.9% vs. 17.5%, p=0.01), though the authors noted that this analysis was based on a very small number of patients and data on co-injuries were not available to adjust for confounding.[19] It is possible that patients who were offered HBOT therapy had more extensive co-injuries associated with their burns.

One study reported cost outcomes.[17] In this study, the mean cost of care was lower in the HBOT group compared with those receiving usual care.[17]

Myositis

The 1 publication on myositis was a case report on the use of HBOT to treat ulcerations in a single patient with dermatomyositis; ulcerations were healed after therapy.[24]

Harms Across Indications

We identified 1 systemic review that included 24 RCTs of HBOT for 16 different indications (see ***Table 3***). The comparator used in most studies was usual care or sham HBOT.[26] A meta-analysis showed the incidence of any adverse events (AEs) was higher in the HBOT group compared with control group (30.1% vs. 10.4%, risk ratio [RR] = 2.89; 95% CI, 1.77 to 3.50, p<0.05). The AEs that were statistically significantly higher in the HBOT group compared with

the control group were ear discomfort (RR = 3.38; 95% CI, 1.16 to 4.41, $p<0.01$) and ocular side effects (RR = 2.37; 95% CI, 1.29 to 3.32, $p<0.01$). Other AEs, including sinus pain, claustrophobia, headache, and fatigue, were no different between treatment groups. Across the 24 included studies (n = 1,497), 1 serious adverse event (SAE, seizure) was reported in the HBOT group. The 1 primary study of harms across indications was a single-arm study in which 17.4% of patients experienced an AE, the most common of which was middle ear barotrauma.[25] This study also analyzed harms by the pressure used in the HBOT protocol; counterintuitively, HBOT protocols using pressures of 1.5 ATA had higher frequency of AEs compared with protocols using pressures of greater than or equal to 2.0 ATA.[25]

4. Discussion and Conclusions

Our signal search identified evidence on HBOT for the specific indications of thermal burns and myositis. We also identified publications on the harms of HBOT across indications.

The 2013 HTCC decision on HBOT for thermal burns was a noncoverage determination. The 2013 HTA cited a SR, which included 2 studies conducted in the 1970s and reported improvement in time to healing but no difference in length of stay, number of surgeries, or mortality. The HTA authors rated certainty of evidence as *Very Low* for a lack of low risk-of-bias studies and inconsistent results. Our signal search shows a clearer signal for the benefits of HBOT than was assessed in the prior HTA with more primary studies finding benefits across various outcomes. An updated HTA with this new evidence would likely still result in a low or very low certainty of evidence given that the majority of studies are nonrandomized studies of interventions (NRSIs). However, a consistent benefit across multiple outcomes might be sufficient for a reconsideration of the coverage determination.

The harms of HBOT treatment for thermal burns were either lower in the HBOT group or no different than the comparator, though the number of events was small for many studies. One NRSI of HBOT for thermal burns showed a higher mortality in the HBOT group, though the authors noted the lack of data on co-injuries, which could not be adjusted for.[19]

Only 1 study, a case report, was identified for myositis. Based on the lack of studies, there is no signal to update the HTA on HBOT to include myositis as an indication.

Our search for harms across indications identified 1 primary study and 1 SR. The primary study on harms of HBOT was a single-arm NRSI which reported that 17.4% of patients experienced an AE, most commonly ear barotrauma. The SR reported elevated risk of ear and ocular AEs that are known to be associated with HBOT. One SAE was identified in this SR.. The findings from this SR align with findings of the 2013 HTA, which assessed that there was “moderate-certainty evidence from across studies that harms associated with HBOT are usually mild, self-limiting, and with most resolving after the termination of treatment. The most common harms include myopia, barotrauma, claustrophobia, and oxygen toxicity. Life-threatening AEs are rare but do occur on occasion and can include seizures and death.” An updated HTA that includes the harms of HBOT for specific indications that are already covered is unlikely to influence the existing coverage determination.

4.1 Limitations

This signal search has several limitations. First, we searched a single electronic database (PubMed); therefore, we may have missed relevant SRs or studies published in journals not indexed in PubMed. Second, we conducted a limited data abstraction, and we did not conduct risk-of-bias assessments. We also did not perform GRADE certainty of evidence assessments. Additionally, we limited the search from 2013 to the present. The search of the 2013 HTA was conducted prior to 2013 and was limited to SRs only. Primary studies published prior to 2013 were not included in the 2013 HTA or in the current signal search.

4.2 Conclusions

This signal search identified a small number of primary studies or SRs evaluating HBOT for thermal burns, myositis, or harms across indications. We identified a signal for an HTA update on HBOT for thermal burns, which is currently not a covered indication based on new evidence suggesting benefits. We conclude there is no signal for an HTA update on HBOT for myositis or for indications that are covered by the HTCC's existing coverage determinations.

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Appendix A. Determination of Indications for Signal Search

For indications that had a coverage determination in 2013 (***Table A1***), we compared the State of Washington Health Technology Clinical Committee (HTCC) coverage determination with the coverage determinations by the Centers for Medicare & Medicaid Services (CMS), the United States Department of Veterans Affairs (VA), and the Department of Defense (DoD). We also compared the HBOT coverage decisions with recommendations from hyperbaric oxygen therapy HBOT societies, including the Undersea and Hyperbaric Medical Society and the European Committee for Hyperbaric Medicine (ECHM) and the European Tissue Repair Society (ETRS). The Food and Drug Administration advises patients to seek HBOT at facilities that have UHMS accreditation.[10]

Indications with coverage determinations or recommendations that were not included in the 2013 HTA were also considered for inclusion in the signal search (***Table A-1***). Indications requiring emergency care were not included because the State of Washington Health Care Authority (HCA) generally considers emergency care reasonable and necessary and out of the scope of HTCC coverage determinations. Based on comparison of indications with a coverage determination, the coverage determination for thermal burns (noncovered) was discordant with recommendations by UHMS and ECHM/ETRS, and coverage by the VA, and was included in this signal search. Myositis was not reviewed in the 2013 HTA and is recommended by the UHMS and covered by the VA and was also included in this signal search. We excluded myositis secondary to trauma, clostridial myositis, and myonecrosis because these indications would be considered medical emergencies.

Table A-1. Indications reviewed for 2013 State of Washington HTA

	State of WA HTCC (2013)[12]	CMS NCD (2017)[27]	UHMS (2019)[28]	ECHM/ETRD (2017)[29]	VA (2019)[30]	DoD (2022)[31]	Inclusion in Signal Search
Nonhealing diabetic wounds	Covered	Covered	Recommended	Recommended	None	Covered	Yes—Harms
Crush injuries	Covered	Covered	Recommended	Recommended	Covered	Covered	No[a]
Chronic refractory osteomyelitis	Covered	Covered	Recommended	Recommended	Covered	None	Yes—Harms
Osteoradione-crosis	Covered	Covered	Recommended	Recommended	Covered	None	Yes—Harms
Prevention of osteoradione-crosis in radiated field	Covered	None	None	Recommended	None	None	Yes—Harms
Soft tissue radionecrosis	Covered	Covered	None	Recommended	Covered	None	Yes—Harms
Compromised skin grafts and flaps	Covered	Covered	Recommended	Recommended	Covered	Covered	Yes—Harms
Nonhealing venous, arterial, and pressure ulcers	Not covered	Not covered	None	Recommended	Not covered	Not covered	Yes—Harms[b]
Thermal burns	Not covered	Not covered	Recommended	Recommended	Covered	Not covered	Yes—Effectiveness and harms
Brain injury including traumatic (TBI)	Not covered	None	None	Recommended	Not covered	Not covered	Yes—Harms[c]
Cerebral palsy	Not covered	None	None	Not recommended	Not covered	Not covered	Yes—Harms
Multiple sclerosis	Not covered	None	None	Not recommended	Not covered	None	Yes—Harms
Migraine or cluster headaches	Not covered	None	None	None	None	None	Yes—Harms

Abbreviations: CMS = Centers for Medicare & Medicaid Services; DoD = Department of Defense; ECHM = European Committee for Hyperbaric Medicine; ETRS = European Tissue Repair Society; HBOT = hyperbaric oxygen therapy; HCA = Health Care Authority; HTA = health technology assessment; HTCC = Health Technology Clinical Committee;

NCD = National Coverage Determination; TBI = traumatic brain injury; UHMS = Undersea and Hyperbaric Medical Society; VA = Department of Veterans Affairs (CHAMPVA policy).

[a] This is a medical emergency. which is out of scope of HTCC determinations.

[b] Though there is a discrepancy between HCA coverage and society recommendation, this indication is not covered by CMS or VA and was not further considered as eligible for the signal search.

[c] Though there is a discrepancy between HCA coverage and society recommendation, current VA policy does not cover HBOT for TBI per the 2021 TBI guidelines,[32] based on effectiveness review. Legislation was introduced 2025 for a pilot program[33] offering HBOT to veterans with TBI, though it is not widely available.

Table A-2. Indications not included in the 2013 HTA and no coverage decision by the HTCC

	State of WA HTCC (2013)[11]	CMS NCD (2017)[27]	UHMS (2019)[28]	ECHM/ETRD (2017)[29]	VA (2019)[30]	DoD (2022)[31]	Inclusion in Signal Search
Myositis	None	None	Recommended	None	Yes	None	Yes—Effectiveness and harms
Medical Emergencies[a]							
Central retinal artery occlusion	None	None	Recommended	None	Covered	None	No
Gas gangrene	None	Covered	Recommended	None	Covered	None	No
Compartment syndrome	None	None	Recommended	None	Covered	Recommended	No
Necrotizing soft tissue infections	None	Covered	Recommended	Recommended	Covered	None	No
Hydrogen sulfide poisoning	None	None	Recommended	None	None	None	No
Carbon monoxide poisoning	None	Covered	None	Recommended	Covered	Recommended	No
Cyanide poisoning	None	Covered	None	None	Covered	None	No
Air of gas embolism	None	Covered	None	Recommended	Covered	Recommended	No
Decompression sickness	None	Covered	Recommended	Recommended	Covered	None	No
Profound anemia from blood loss	None	Not covered	None	None	Covered	Recommended	No
Intracranial abscess	None	None	None	Recommended	Covered	None	No

Abbreviations: CMS = Centers for Medicare & Medicaid Services; DoD = Department of Defense; ECHM = European Committee for Hyperbaric Medicine; ETRS = European Tissue Repair Society; NCD = National Coverage Determination; UHMS = Undersea and Hyperbaric Medical Society; VA = Department of Veterans Affairs.

[a] This is a medical emergency. which is out of scope of HTCC determinations. Not eligible for review in the current signal search.

Appendix B. Search Strategy

Source: PubMed
Date of Search: April 24, 2025

Thermal Burns
#1 "hyperbaric oxygenation"[MeSH Terms] OR "hyperbaric oxygen"[All Fields] Filters: English 13,049
#2 "burn*"[All Fields] OR "burn injury"[All Fields] OR "burn wound*"[All Fields] OR "thermal burn"[All Fields] OR "thermal injury"[All Fields] OR "thermal insult"[All Fields] OR "thermal wound*"[All Fields] OR burns[MeSH Terms] OR scalds[All Fields] Filters: English 253,738
#3 #1 AND #2 Filters: English 378
#4 Address[Publication Type] OR Bibliography[Publication Type] OR Case Reports[Publication Type] OR Comment[Publication Type] OR Editorial[Publication Type] OR Lecture[Publication Type] OR Legal Case[Publication Type] OR Letter[Publication Type] OR News[Publication Type] OR Newspaper Article[Publication Type] Filters: English 4,218,828
#5 Disease Models, Animal[MeSH] OR mice[TI] OR mouse[TI] OR murine[TI] OR rat[TI] OR animal[TI] Filters: English 1,570,417
#6 (#3 NOT (#4 OR #5)) AND ("2013/01/01"[Date - Publication] : "3000"[Date - Publication]) Filters: English **139**

Thermal Burns SRs
#7 #6 AND ((("Review"[Publication Type] OR "Review Literature as Topic"[Mesh]) AND "systematic"[Title/Abstract]) OR "Systematic Review"[Publication Type] OR "Systematic Reviews as Topic"[Mesh] OR "systematic review"[All Fields] OR "Meta-Analysis"[Publication Type] OR "Meta-Analysis as Topic"[Mesh] OR "meta-analysis"[All Fields]) Filters: English **17**

Myositis
#1 "hyperbaric oxygenation"[MeSH Terms] OR "hyperbaric oxygen"[All Fields] Filters: English 13,049
#2 "Myositis"[MeSH Terms] OR "dermatomyositis"[MeSH Terms] OR "Polymyositis"[MeSH Terms] OR Myositis[All Fields] OR myositides[All Fields] OR dermatomyositis[All Fields] OR Polymyositis[All Fields] Filters: English 26,487
#3 #1 AND #2 Filters: English 34
#4 Address[Publication Type] OR Bibliography[Publication Type] OR Case Reports[Publication Type] OR Comment[Publication Type] OR Editorial[Publication Type] OR Lecture[Publication Type] OR Legal Case[Publication Type] OR Letter[Publication Type] OR News[Publication Type] OR Newspaper Article[Publication Type] Filters: English 4,218,828
#5 Disease Models, Animal[MeSH] OR mice[TI] OR mouse[TI] OR murine[TI] OR rat[TI] OR animal[TI] Filters: English 1,570,417
#6 (#3 NOT (#4 OR #5)) AND ("2013/01/01"[Date - Publication] : "3000"[Date - Publication]) Filters: English **5**

Myositis SRs
#7 #6 AND ((("Review"[Publication Type] OR "Review Literature as Topic"[Mesh]) AND "systematic"[Title/Abstract]) OR "Systematic Review"[Publication Type] OR "Systematic

Reviews as Topic"[Mesh] OR "systematic review"[All Fields] OR "Meta-Analysis"[Publication Type] OR "Meta-Analysis as Topic"[Mesh] OR "meta-analysis"[All Fields]) Filters: English **0**

Harms SRs Only
#1 "hyperbaric oxygenation"[MeSH Terms] OR "hyperbaric oxygen"[All Fields] Filters: English 13,049
#2 harm*[All Fields] OR "adverse events"[All Fields] OR "side effects"[All Fields] OR tolerability[All Fields] Filters: English 1,362,405
#3 #1 AND #2 Filters: English 785
#4 Address[Publication Type] OR Bibliography[Publication Type] OR Case Reports[Publication Type] OR Comment[Publication Type] OR Editorial[Publication Type] OR Lecture[Publication Type] OR Legal Case[Publication Type] OR Letter[Publication Type] OR News[Publication Type] OR Newspaper Article[Publication Type] Filters: English 4,218,828
#5 Disease Models, Animal[MeSH] OR mice[TI] OR mouse[TI] OR murine[TI] OR rat[TI] OR animal[TI] Filters: English 1,570,417
#6 (#3 NOT (#4 OR #5)) AND ("2013/01/01"[Date - Publication] : "3000"[Date - Publication]) Filters: English 360
#7 #6 AND ((("Review"[Publication Type] OR "Review Literature as Topic"[Mesh]) AND "systematic"[Title/Abstract]) OR "Systematic Review"[Publication Type] OR "Systematic Reviews as Topic"[Mesh] OR "systematic review"[All Fields] OR "Meta-Analysis"[Publication Type] OR "Meta-Analysis as Topic"[Mesh] OR "meta-analysis"[All Fields]) Filters: English **77**

Appendix C. Results for Individual Studies

Table C-1. Results for individual studies

Study Information Author, year Sample size (n) Study Design Comparator	Effectiveness Outcomes	Harms Outcomes	Cost Outcomes
Thermal Burns			
Uniyal, 2025[1] n = 64 RCT Usual care	Healing *Graft uptake:* Significant improvement in graft uptake percentage for HBOT group vs. comparator *Time to donor site recovery:* Improved donor site healing for HBOT group vs. comparator	Complications *Infection:* Infection occurred in one patient in HBOT group. One patient in control group died due to sepsis. *Graft failure*: In the comparator group, floating grafts were found in 2 patients and flap necrosis occurred in 4 patients. In HBOT group, significant graft contracture occurred in 1 patient.	No outcomes reported
Mago, 2024[5] n =106 NRSI—single arm No comparator	Healing Complete healing of ulcers in patients with venous ulcers Patient-centered outcomes *Pain*: Improvement in pain for patients with arterial disorders *QOL*: Improvement in pain and QOL for mucormycosis patients	Harms *Adverse events:* Four patients reported ear symptoms; 1 reported claustrophobia.	No outcomes reported
Ozdemir, 2023[17] n = 60 NRSI—comparative Usual care	Healing *Graft uptake*: Need for grafting was significantly lower in patients for HBOT vs. comparator *Epithelization*: Significantly shorter epithelialization time for HBOT group vs. comparator Patient-centered outcomes *Patient satisfaction*: Higher satisfaction for HBOT group vs. comparator Utilization *Length of stay:* Shorter hospital stay for HBOT group vs. comparator	Complications *Infections:* No significant difference in rate of infection between groups. *Surgery:* Need for surgery significantly lower in patients who received HBOT vs. comparator.	Mean cost lower in HBOT group vs. comparator

Study Information Author, year Sample size (n) Study Design Comparator	Effectiveness Outcomes	Harms Outcomes	Cost Outcomes
Oley, 2022[18] n = 7 NRSI—single arm No comparator	Healing *Time to healing*: Graft was fully healed after 3 months.	No outcomes reported.	No outcomes reported
Nygaard, 2021[19] n=13044 NRSI—comparative Usual care	Utilization *Number of days in hospital*: Total hospital days were similar between groups	Harms *ICU care*: Significantly higher percentage of ICU care and more average ICU days in HBOT group. *Mechanical ventilation*: Significantly higher percentage of mechanical ventilation and more average ventilator days in HBOT group. *Mortality*: HBOT patients had significantly higher mortality.	No outcomes reported
Oley, 2020[20] n = 20 RCT Usual care	Healing *Epithelialization*: More patients experienced complete epithelialization in HBOT group vs. control group Utilization *Length of hospital stay*: Significantly reduced for HBOT group vs. control group	Complications *Wound complications*: Significantly reduced for HBOT group vs. control group (0% vs. 60%).	No outcomes reported
Chiang, 2016[21] n = 53 NRSI—comparative Usual care	Complications *Number of skin graft operations*: No difference between groups Utilization *Number of days in hospital*: No difference between groups	Complications *Infection:* Improved sepsis control for HBOT group vs. comparator. *Graft failure:* Number of skin graft operations: No difference between groups. Harms *Serious adverse events:* Time spent in ICU: No difference between groups.	No outcomes reported

Study Information Author, year Sample size (n) Study Design Comparator	Effectiveness Outcomes	Harms Outcomes	Cost Outcomes
Jones, 117[22] n = 18 NRSI—comparative Usual care	Healing *Graft uptake*: Skin grafting avoided for all patients in HBOT group; 1 graft failure in comparison group Utilization *Number of days in hospital*: Significantly higher in HBOT group vs. comparator (21 vs. 8 days)	Complications *Graft failure*: One patient in comparator group required skin grafting and was readmitted for graft failure, infection, and eventually amputation. *Surgery*: No amputations in HBOT group vs. 1 in comparator group.	No outcomes reported
Chen, 2018[23] n = 35 NRSI—comparative Usual care	Patient-centered outcomes *Patient satisfaction*: Statistically significant improvement in satisfaction for HBOT group vs. comparator, clinical significance unclear *Pain*: Statistically significant higher satisfaction for HBOT group vs. comparator, clinical significance unclear Utilization *Number of days in hospital*: No significant difference between groups	Complications *Infection*: No significant difference between groups.	No outcomes reported
Myositis			
Jeter, 2019[24] n=1 NRSI—single arm No comparator	Healing *Incidence of healing*: ulcerations were nearly healed at end of treatment Patient-centered outcomes *Pain*: Pain improved	No outcomes reported.	No outcomes reported

Study Information Author, year Sample size (n) Study Design Comparator	Effectiveness Outcomes	Harms Outcomes	Cost Outcomes
Harms Across Indications			
Xhang, 2023[26] n = 1,497 Systematic review (k = 24, all RCTs, search 2012 to 2022) Usual care or modified HBOT	No outcomes reported	Harms *Adverse events:* Incidence of AEs higher in HBOT group vs. control group. Difference in overall AEs, ear discomfort, and ocular side effects statistically significant.	No outcomes reported
Hadanny, 2016[25] n = 2,334 NRSI—single arm No comparator	No outcomes reported	Harms *Adverse events:* 406 (17.4%) patients experienced any AE. Most common complaint was middle ear barotrauma. *Analysis by protocol:* HBOT protocols using pressures of 1.5 ATAhad higher frequency of AEs compared with protocols using pressures of ≤ 2.0 ATM, primarily due to barotrauma.	No outcomes reported

Abbreviations: AE = adverse event; HBOT = hyperbaric oxygen therapy; k = number of studies; NRSI = nonrandomized studies of intervention; QOL = quality of life.