Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

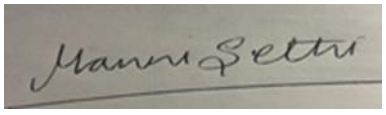
Plan: Keystone First	Submission Date:1/1/2026
Policy Number: CCP.1182	Effective Date:1/5/2016 Revision Date:12/1/2025
Policy Name: Topical oxygen therapy	

Type of Submission:

☐ New Policy	☒ Prior Authorization Policy
☒ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☒ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Topical oxygen therapy

Clinical Policy ID: CCP.1182

Recent review date: 12/2025

Next review date: 4/2027

Policy contains: chronic wound care, diabetic foot ulcer, pressure ulcer, topical oxygen, non-healing wounds, venous ulcer.

Keystone First- CHIP has developed clinical policies to assist with making coverage determinations. Keystone First- CHIP's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First- CHIP, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First- CHIP's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First- CHIP's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First- CHIP will update its clinical policies as necessary. Keystone First- CHIP's clinical policies are not guarantees of payment.

Coverage policy

Topical oxygen therapy is investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Debridement of necrotic tissue.
- Revascularization surgery.
- Mechanical offloading.
- Blood glucose management.
- Foot care education.
- Mechanical compression.
- Limb elevation.
- Saline-moistened cotton gauze (wet-to-moist) dressing.
- Advanced dressings (e.g., hydrocolloid, foam, film, alginate, hydrofiber, hydrogel sheets, and collagen-based dressings).

- Full-body hyperbaric oxygen therapy.

Background

Chronic wounds represent a significant and growing health burden in the United States (Nussbaum, 2018). Common chronic skin and soft tissue wounds include diabetic foot ulcers, pressure ulcers, and venous stasis ulcers of the lower extremity. Other chronic wounds include radiation ulcers caused by the acute or chronic effects of ionizing radiation. The injury may involve the skin, underlying soft tissue, and even deep structures, such as bone (Nagle, 2025).

The presence of oxygen is necessary for normal wound healing. A disrupted or compromised vasculature surrounding the wound can limit the oxygen supply and increase oxygen demands used to fight infection and repair tissue. This can lead to extreme tissue hypoxia. Noninvasive measurement of transcutaneous oxygen pressure applied to the skin of adjacent areas of a wound is used to estimate the oxygen tension of the wound (Oropallo, 2025.

Oxygen has been offered as a therapeutic modality to assist and hasten wound healing. Introduced in the 1960s, systemic hyperbaric oxygen therapy increases the concentration of dissolved oxygen in the blood plasma, thereby enhancing the amount of oxygen perfusion in body tissues. The lack of availability of hyperbaric oxygen therapy facilities, contraindications, patient transfer requirements, and the risk of undesired systemic side effects limit its use (Wernick, 2025). Pressurized topical oxygen therapy was introduced to address these limitations.

Topical oxygen therapy administers pure oxygen to the wound area using a portable inflatable device that encases the limb at normobaric conditions or at a pressure slightly greater than atmospheric pressure. Unlike hyperbaric oxygen therapy, the effectiveness of topical oxygen therapy is independent of the wound's microcirculation. Other purported advantages are lower costs, a potentially lower risk of oxygen toxicity, and the possibility of home treatment (Oropallo, 2025).

The U.S. Food and Drug Administration classifies topical oxygen therapy as an oxygen chamber for extremities, which is intended to surround a patient's limb and apply humidified oxygen topically. This is performed at a pressure slightly greater than atmospheric pressure to aid in the healing of chronic skin ulcers. It is designated as a class II device with special controls (U.S. Code of Federal Regulations 21CFR878.5650, 2025). Several devices have been approved for commercial use (U.S. Food and Drug Administration, 2025).

The U.S. Food and Drug Administration has approved topical oxygen therapy for chronic skin ulcerations due to diabetes, venous stasis, postsurgical infections, gangrenous lesions, and decubitus ulcers; amputations/infected stumps; skin grafts; burns; and frostbite. Disposable, single-use devices are self-administered, which permit at-home use (Copeland, 2017).

Findings

Guidelines

The International Working Group on the Diabetic Foot issued a conditional recommendation for topical oxygen as an adjunct to standard wound care, where standard of care alone has failed and resources exist to support this intervention. The Group’s recommendation was based on low certainty evidence from three double-blinded, randomized controlled trials. One trial was terminated early, and the other two trials showed conflicting results. The group agreed that, on balance, the treatment effects favored use of topical oxygen with a moderate benefit on achieving absolute wound healing and reduction in ulcer area. There was no evidence for reduction in amputation up to 12 weeks. However, undesirable effects were poorly reported, although likely trivial based on

expert opinion, and cost effectiveness data were lacking. Different devices were used to deliver topical oxygen, and the superiority of any one device could not be determined (Chen, 2024b).

The Wound Healing Society's diabetic foot ulcer treatment guideline states "Topical oxygen has been shown to increase the incidence of healing and decrease the time to heal" based on level I evidence from meta-analysis or at least two randomized controlled trials supporting the intervention (Lavery, 2024). The Society found insufficient evidence supporting topical oxygen for arterial ulcers (Federman, 2024) or venous ulcers (Marston, 2015).

No other recent guideline endorses topical oxygen therapy using U.S. Food and Drug Administration-approved products.

Evidence reviews

The evidence from randomized controlled trials examined the effectiveness of standard wound care with and without topical oxygen therapy for difficult-to-heal diabetic foot ulcers. Standard wound care usually included debridement and off-loading. Topical oxygen therapy technologies consisted of topical wound oxygen, transcutaneous oxygen therapy, and continuous diffusion oxygen. Although adjunctive topical oxygen therapy appears to be safe and may improve wound healing rates over standard care alone, its effect on adverse events, resource use, healing time, quality of life, or amputation rates is less clear. The evidence is insufficient to support the effectiveness of topical oxygen therapy for other chronic wound types.

A network meta-analysis compared various gas therapies for diabetic foot ulcers. The interventions were hyperbaric oxygen therapy, topical oxygen therapy, topical hyperbaric oxygen therapy, ozone therapy, oxygen-ozone therapy, carbon dioxide therapy, nitric oxide , and cold atmospheric plasma therapy. Of the 34 included randomized controlled trials, eight assessed topical oxygen therapy, and all had a moderate or unclear risk of bias. The authors recommended hyperbaric oxygen for its improved ulcer healing rates and greater ulcer area reduction based on consistent results from several trials; however, it was also associated with a higher amputation rate and adverse event rate (Yang, 2025).

A comprehensive systematic review examined all randomized controlled trials published up to October 2022 of all interventions to support 2023 guidelines recommendations of the International Working Group on the Diabetic Foot. Three double-blinded randomized, sham-controlled trials and seven non-blinded studies (total n = 792) investigated topical oxygen. While topical oxygen therapy appeared to have a positive effect on wound healing, the effect size was variable among trials. Most trials were of short duration, which prevented an assessment of amputation rates. The supporting evidence for topical oxygen therapy and other adjunctive therapies to promote wound healing was graded very low to low quality, and investigators called for higher quality studies (Chen, 2024a).

Putri (2024) qualitatively combined the results of seven randomized controlled trials (n = 692) and two controlled observational studies (n = 111) of adjunctive topical oxygen therapy for all chronic wound types: diabetic foot ulcers (seven studies); venous stasis ulcers (one study); and pressure ulcers (one study). In the randomized controlled trials, adjunctive topical oxygen therapy significantly increased the number of healed wounds of all wound types (relative risk = 1.77, 95% confidence interval 1.18 to 2.64, $P = .005$) and significantly decreased the percentage of wound area (mean difference = 15.64 square centimeters, 95% confidence interval 5.22 to 26.06 square centimeters, $P = .003$). Results of observational studies confirmed improvement in wound healing rates. Treatment duration was up to 12 weeks. Follow up data beyond 12 months were limited, which prevented analysis of other secondary outcomes.

Since 2016, four randomized controlled trials (n = 494) have been conducted in the United States. A systematic review of these trials examined the effectiveness of standard wound care with and without adjunctive topical oxygen therapy for chronic nonischemic diabetic foot ulcers (Wagner 1 and 2) and not adequately responding to

standard wound care alone of at least four weeks duration. Each study was of 12 weeks duration, and different topical oxygen delivery systems were used. One trial was rated as low risk of bias, and the remaining three were rated as moderate risk of bias. Across studies, adverse events were similar in both study arms, but the absolute rates varied considerably. The differences in complete wound healing rates at 12 weeks ranged from 5% to 27%, favoring the topical oxygen therapy arm. In only one trial was the difference statistically significant. On meta-analysis, the difference between groups in the proportion of wounds healed at 12 weeks was significant (risk ratio = 1.59, 95% confidence interval 1.07 to 2.37, *P* = .021) (Carter, 2023).

A large-scale review included charts of 3,462 patients, representing care of 4,127 total wounds with topical oxygen therapy from 2007 to 2016. The purpose of the study was to assess the efficacy of topical oxygen therapy in healing chronic wounds in the home setting. All wounds were at least one square centimeter and treated with topical oxygen for at least two weeks. Participants were mostly Medicare and Medicaid enrollees (42.3% and 35.6%, respectively). The most common location of wounds was the foot (46%); of foot and toe wounds, about half were diabetes-related. The noncompliance rate was 4.1%. A majority (59.4%) of wounds experienced a reduction in size, with 27.5% completely healed. Median wound size decreased from 6 to 2 square centimeters. The proportion of cases with the largest (> 16 square centimeters) wounds fell from 24.4% to 16.2% after treatment. The greatest healing benefit occurred in chronic wounds that were smaller, less than one year old, were exposed to a longer treatment duration. The overall amputation rate for wounds treated with topical oxygen therapy was 2.4% (Copeland, 2017).

In 2022, we updated the references and deleted several older references that were analyzed in the included systematic reviews or have been archived. No policy changes are warranted.

In 2023, we updated the references. No policy changes are warranted.

In 2024, we updated the references, added new systematic reviews, and deleted older references. No policy changes are warranted.

In 2025, we updated the references. No policy changes are warranted.

References

On October 15, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “continuous diffusion of oxygen,” “transcutaneous oxygen therapy,” “topical oxygen,” “chronic wound,” and “diabetic ulcer.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

Carter MJ, Frykberg RG, Oropallo A, et al. Efficacy of topical wound oxygen therapy in healing chronic diabetic foot ulcers: Systematic review and meta-analysis. *Adv Wound Care (New Rochelle)*. 2023;12(4):177-186. Doi: 10.1089/wound.2022.0041.

Chen P, Vilorio NC, Dhatariya K, et al. Effectiveness of interventions to enhance healing of chronic foot ulcers in diabetes: A systematic review. *Diabetes Metab Res Rev*. 2024;40(3):e3786. Doi: 10.1002/dmrr.3786. (a)

Chen P, Vilorio NC, Dhatariya K, et al. Guidelines on interventions to enhance healing of foot ulcers in people with diabetes (IWGDF 2023 update). *Diabetes Metab Res Rev*. 2024;40(3):e3644. Doi: 10.1002/dmrr.3644. (b)

Copeland K, Purvis AR. A retrospective chart review of chronic wound patients treated with topical oxygen therapy. *Adv Wound Care (New Rochelle)*. 2017;6(5):143-152. Doi: 10.1089/wound.2017.0729.

Federman DG, Dardik A, Shapshak D, et al. Wound Healing Society 2023 update on guidelines for arterial ulcers. *Wound Repair Regen*. 2024;32(5):619-629. Doi: 10.1111/wrr.13204.

Lavery LA, Suludere MA, Attinger CE, et al. WHS (Wound Healing Society) guidelines update: Diabetic foot ulcer treatment guidelines. *Wound Repair Regen*. 2024;32(1):34-46. Doi: 10.1111/wrr.13133.

Marston W, Tang J, Kirsner RS, Ennis W. Wound Healing Society 2015 update on guidelines for venous ulcers. *Wound Repair Regen*. 2016;24(1):136-44. Doi: 10.1111/wrr.12394.

Nagle SM, Stevens KA, Wilbraham SC. Wound Assessment. In: *StatPearls* [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. https://www.ncbi.nlm.nih.gov/books/NBK482198/. Updated June 26, 2023.

Nussbaum SR, Carter MJ, Fife CE, et al. An economic evaluation of the impact, cost, and Medicare policy implications of chronic non-healing wounds. *Value Health.* 2018;21(1):27-32. Doi: 10.1016/j.val.2017.07.007.

Oropallo A, Andersen CA. Topical oxygen. In: *StatPearls* [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. https://www.ncbi.nlm.nih.gov/books/NBK574579/. Updated August 28, 2023.

Putri IL, Alyssa A, Aisyah IF, Permatasari A, Pramanasari R, Wungu CDK. The efficacy of topical oxygen therapy for wound healing: A meta-analysis of randomized controlled trials and observational studies. *Int Wound J*. 2024;21(7):e14960. Doi: 10.1111/iwj.14960.

U.S. Code of Federal Regulations. 21CFR878.5650. Topical oxygen chamber for extremities. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=878.5650. Page last updated September 29, 2025.

U.S. Food and Drug Administration. 510(k) Premarket Notification database search using product code KPJ. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Page last updated October 13, 2025.

Wernick B, Nahirniak P, Stawicki SP. Impaired Wound Healing. In: *StatPearls* [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. https://www.ncbi.nlm.nih.gov/books/NBK482254/. Updated August 28, 2023.

Yang J, Ning P, Huang J, et al. Comparative efficacy of gas therapy for diabetic foot ulcers using network meta-analysis. *PeerJ*. 2025;13:e19571. Doi: 10.7717/peerj.19571.

Policy updates

8/2015: initial review date and clinical policy effective date: 1/2016

8/2016: Policy references updated.

8/2017: Policy references updated.

8/2018: Policy references updated.

12/2019: Policy references updated. Policy ID changed to CCP.1182.

12/2020: Policy references updated.

12/2021: Policy references updated.

12/2022: Policy references updated.

12/2023: Policy references updated.

12/2024: Policy references updated.

12/2025: Policy references updated.