Hyperbaric Oxygen Therapy, Topical Oxygen Therapy

INDEPENDENT CARE HEALTH PLAN

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Medicare Advantage Medical Coverage Policy

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to CMS website for the most current applicable National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

Type	Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
NCD	Hyperbaric Oxygen Therapy	20.29		
NCD	Treatment of Decubitus Ulcers	270.4		

LCA	Billing and Coding: Topical HBO and Physician Related Service Billing and Coding Guidelines	A56025	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
LCA	Billing and Coding: Topical HBO and Physician Related Service Billing and Coding Guidelines	A56026	JF - Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
LCD LCA	Topical Oxygen Therapy Billing and Coding: Topical Oxygen Therapy	L37873 A56431	JJ - Palmetto GBA (Part A/B MAC) JM - Palmetto GBA (Part A/B MAC)	AL, GA, TN NC, SC, VA, WV

Description

During **hyperbaric oxygen therapy (HBOT)**, an individual is placed in a specially designed chamber that is pressurized to greater than sea level (one atmosphere absolute [1 ATA]) and breathes near 100% oxygen. The result of this direct pressure and hyperoxygenation is an increase in alveolar oxygen and a rise in dissolved plasma oxygen content promoting enhanced tissue oxygen delivery and healing. Other purported benefits of therapy include antimicrobial activity, attenuation of reperfusion injury, neovascularization and vasoconstriction.

Treatment may take place in a monoplace chamber or a multiplace chamber. The monoplace chamber accommodates one individual in the supine position and is pressurized with 100% oxygen, allowing the ambient chamber air to be inhaled directly. A multiplace chamber accommodates two or more individuals where the ambient pressurized atmosphere is normal air. Individual receives 100% oxygen through an endotracheal tube, hood or mask. The advantage of a multiperson chamber is that specially trained personnel may accompany the individual in the chamber and provide necessary treatments and care during the HBOT session. Regardless of which type of chamber is used, the amount of pressure and the length of time under pressure are determined by the condition being treated. Treatment pressures are usually between two to three times ATA and may last from one to two hours at full pressure.

HBOT is used to treat certain conditions or diseases that may respond to increased tissue oxygenation when baseline tissue oxygen levels are too low for spontaneous healing. HBOT is indicated as primary treatment for some conditions; however, it may also serve as adjunctive therapy for other treatment modalities.

Topical oxygen therapy (also known as continuous diffusion of oxygen [CDO] therapy) involves direct application of 100% oxygen to promote wound healing. Examples of topical oxygen therapy systems include, but may not be limited to, the EPIFLO, Hyper-Box, TransCu O2 and VHT-200 system.

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

Hyperbaric oxygen therapy (HBOT), will be limited to that which is administered in a chamber (including the one man unit), will be considered medically reasonable and necessary and is limited to the following conditions:

- Actinomycosis (bacterial infection caused by Actinomyces israelii)[39,] only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment; **OR**

- Acute carbon monoxide intoxication; **OR**

- Acute peripheral arterial insufficiency (suddenly slows or stops blood flow and is a medical emergency that needs immediate care), with vascular study that confirms vessel obstruction by clot/embolus and location; **OR**

- Acute traumatic peripheral ischemia (suddenly slows or stops blood flow and is a medical emergency that needs immediate care). HBO therapy is a valuable adjunctive treatment to be used in combination with accepted standard therapeutic measures when loss of function, limb, or life is threatened; **OR**

- Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management, in patients who meet the following criteria:

    - Documentation of bone culture or X-ray/imaging confirmation of osteomyelitis; **AND**

    - Completion (approximately six weeks) of antibiotic course (ie, parenteral); **AND**

    - Surgical eradication (surgical debridement/excision of the infected nidus of bone) or documentation that site is not amenable to surgical intervention; **OR**

- Crush injuries and suturing of severed limbs. As in the previous conditions, HBO therapy would be an adjunctive treatment when loss of function, limb, or life is threatened; **OR**

- Cyanide poisoning; **OR**

- Decompression illness; **OR**

- Diabetic wounds* of the lower extremities in patients who meet the following three criteria:

    - Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes; **OR**

- Patient has a wound classified as Wagner grade III or higher; **AND**
- Patient has failed an adequate course of standard wound therapy; **OR**

*The use of HBO therapy is covered as adjunctive therapy only after there are no measurable signs of healing for at least 30 days of treatment with standard wound therapy and must be used in addition to standard wound care. Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

- Gas embolism; **OR**
- Gas gangrene (bacterial infection, C. perfringens is the most common, that destroys blood cells and soft tissues); **OR**
- Osteoradionecrosis as an adjunct to conventional treatment; **OR**
- Preparation and preservation of compromised skin grafts (not for primary management of wounds, prophylactic maintenance of grafts or solely for preparation of a wound bed for receiving a graft); **OR**
- Progressive necrotizing infections (necrotizing fasciitis - bacterial infection that attacks the soft tissue and the fascia); **OR**
- Soft tissue radionecrosis (destruction of living tissue by radiation)[54] as an adjunct to conventional treatment[10]

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

Hyperbaric oxygen therapy (HBOT) in the treatment of the following conditions will not be considered medically reasonable and necessary:

- 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
- Cardiogenic shock
- Chronic peripheral vascular insufficiency
- Cutaneous, decubitus, and stasis ulcers
- Exceptional blood loss anemia
- Hepatic necrosis
- Multiple Sclerosis
- Myocardial infarction
- Nonvascular causes of chronic brain syndrome (Pick's disease, Alzheimer's disease, Korsakoff's disease)
- Organ storage
- Organ transplantation
- Pulmonary emphysema
- Senility
- Sickle cell anemia
- Skin burns (thermal)
- Systemic aerobic infection
- Tetanus[10]

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Topical oxygen therapy will not be considered medically reasonable and necessary for any indication.[11]

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Summary of Evidence

Hyperbaric Oxygen Therapy

There is limited evidence from randomized controlled trials that hyperbaric oxygen therapy may stimulate healing in nondiabetic patients with chronic wounds and increase graft survival in some patients with skin grafts or flaps. However, the available studies have limitations in design and size that preclude definitive conclusions regarding optimal treatment protocols, patient selection criteria, and the appropriate role of hyperbaric oxygen therapy for these indications. The evidence regarding the efficacy of hyperbaric oxygen therapy for patients with thermal burns or necrotizing infections failed to demonstrate a beneficial effect of hyperbaric oxygen therapy, and there was very little evidence regarding the use of hyperbaric oxygen therapy in patients with chronic refractory primary osteomyelitis. Well-designed, randomized controlled

trials are required to establish efficacy, define patient selection criteria, and determine the benefits of adjuvant hyperbaric oxygen therapy.[25]

Several other potential HBO uses remain poorly validated and require more rigorous evaluation. Preliminary animal and human studies evaluating uses in syndromes as disparate as acute coronary syndrome, including myocardial infarction, the systemic inflammatory response syndrome, traumatic brain or spinal cord injury, sickle cell crisis, fibromyalgia, and acute stroke have been conducted, with variable results. Further investigation will need to be conducted.[52]

Topical Oxygen Therapy

Topical oxygen therapy may provide an incremental benefit to standard wound care for complete healing of chronic DFU that have failed to respond to wound care alone; however, not all studies reported a benefit. Further, there is currently insufficient data on amputation, quality of life, and time to complete healing to inform conclusions. Safety data are lacking, but the reported complications do not suggest potential harm.

Evidence is insufficient to inform evidence-based conclusions regarding the use of topical oxygen therapy for other wound indications. As no studies meeting the inclusion criteria addressed the efficacy or safety of topical oxygen therapy incremental to standard wound management for any indication, the evidence is insufficient to inform evidence-based conclusions regarding those applications.[31]

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
99183	Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session	
99199	Unlisted special service, procedure or report	
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
A4575	Topical hyperbaric oxygen chamber, disposable	
E0446	Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories	
G0277	Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval	

References

1. American Academy of Orthopaedic Surgeons (AAOS). Prevention of surgical site infections after major extremity trauma: evidence-based clinical practice guideline. https://www.aaos.org. Published March 21, 2022. Accessed May 1, 2023.

2. American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS). Clinical Practice Guideline. Sudden hearing loss (update). https://www.entnet.org. Published August 1, 2019. Accessed May 1, 2023.

3. American College of Emergency Physicians (ACEP). Clinical Policy. Critical issues in the evaluation and management of adult patients presenting to the emergency department with acute carbon monoxide poisoning. https://www.acep.org. Published January 2017. Accessed May 1, 2023.

4. American Heart Association (AHA). 2016 AHA/ACC guideline on the management of patients with lower extremity peripheral artery disease. https://www.heart.org. Published March 21, 2017. Accessed April 20, 2023.

5. American Heart Association (AHA). AHA/ASA guideline for the early management of patients with acute ischemic stroke: 2019 update. https://www.heart.org. Published October 30, 2019. Accessed April 20, 2023.

6. Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA). Billing and Coding: Topical HBO and Physician Related Service Billing and Coding Guidelines. (A56025). https://www.cms.gov. Published April 3, 2017. Updated January 1, 2023. Accessed August 30, 2023.

7. Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA). Billing and Coding: Topical HBO and Physician Related Service Billing and Coding Guidelines. (A56026). https://www.cms.gov. Published April 3, 2017. Updated January 1, 2023. Accessed August 30, 2023.

8. Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA). Billing and Coding: Topical Oxygen Therapy. (A56431). https://www.cms.gov. Published May 6, 20197. Updated March 4, 2021. Accessed August 30, 2023.

9. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Topical Oxygen Therapy. (L37873). https://www.heart.org. Published May 6, 2019. Updated May 4, 2023. Accessed August 30, 2023.

10. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Hyperbaric oxygen therapy (20.29). https://www.cms.gov. Published October 19, 2000. Updated April 3, 2017. Accessed April 20, 2023.

11. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Treatment of decubitus ulcers (270.4). https://www.cms.gov. Accessed April 20, 2023.

12. ECRI Institute. Clinical Evidence Assessment. Hyperbaric oxygen therapy for chronic diabetic ulcers. https://www.ecri.org. Published August 17, 2021. Accessed April 18, 2023.

13. ECRI Institute. Clinical Evidence Assessment. Hyperbaric oxygen therapy for delayed radiation injury. https://www.ecri.org. Published August 12, 2021. Accessed April 18, 2023.

14. ECRI Institute. Clinical Evidence Assessment. Standard-of-care practices for managing diabetic foot ulcers. https://www.ecri.org. Published January 28, 2020. Updated December 31, 2021. Accessed April 18, 2023.

15. ECRI Institute. Clinical Evidence Assessment. Topical oxygen therapy for diabetic foot ulcers. https://www.ecri.org. Published April 19, 2019. Updated August 19, 2021. Accessed April 18, 2023.

16. ECRI Institute. Hotline Response (ARCHIVED). Hyperbaric oxygen therapy for postconcussion syndrome. https://www.ecri.org. Published May 11, 2016. Accessed April 18, 2023.

17. ECRI Institute. Hotline Response (ARCHIVED). Topical oxygen therapy for pressure ulcers. https://www.ecri.org. Published April 19, 2019. Accessed April 18, 2023.

18. ECRI Institute. Hotline Response (ARCHIVED). Topical oxygen therapy for venous leg ulcers. https://www.ecri.org. Published April 19, 2019. Accessed April 18, 2023.

19. Hayes, Inc. Evidence Analysis Research Brief. Hyperbaric oxygen therapy for arterial ulcers. https://evidence.hayesinc.com. Published December 15, 2022. Accessed April 18, 2023.

20. Hayes, Inc. Evidence Analysis Research Brief. Hyperbaric oxygen therapy for treatment of post-COVID conditions. https://evidence.hayesinc.com. Published July 18, 2022. Accessed April 18, 2023.

21. Hayes, Inc. Evidence Analysis Research Brief. Hyperbaric oxygen therapy for treatment of venous ulcers. https://evidence.hayesinc.com. Published December 6, 2022. Accessed April 18, 2023.

22. Hayes, Inc. Evidence Analysis Research Brief (ARCHIVED). Hyperbaric oxygen therapy for post-concussive syndrome in children. https://evidence.hayesinc.com. Published October 12, 2021. Accessed April 18, 2023.

23. Hayes, Inc. Health Technology Assessment. Systemic hyperbaric oxygen therapy for post-concussive syndrome in adults. https://evidence.hayesinc.com. Published September 14, 2022. Accessed April 18, 2023.

24. Hayes, Inc. Health Technology Brief (ARCHIVED). Hyperbaric oxygen (HBO) for treatment of cerebral palsy. https://evidence.hayesinc.com. Published January 30, 2007. Updated January 26, 2009. Accessed April 18, 2023.

25. Hayes, Inc. Medical Technology Directory (ARCHIVED). Hyperbaric oxygen therapy for autistic disorder. https://evidence.hayesinc.com. Published July 16, 2009. Updated July 11, 2013. Accessed April 18, 2023.

26. Hayes, Inc. Medical Technology Directory (ARCHIVED). Hyperbaric oxygen therapy for burns, infections and nondiabetic wounds. https://evidence.hayesinc.com. Published September 15, 2008. Updated August 7, 2012. Accessed April 18, 2023.

27. Hayes, Inc. Medical Technology Directory (ARCHIVED). Hyperbaric oxygen therapy for carbon monoxide poisoning. https://evidence.hayesinc.com. Published December 22, 2008. Updated January 26, 2012. Accessed April 18, 2023.

28. Hayes, Inc. Medical Technology Directory (ARCHIVED). Hyperbaric oxygen therapy for diabetes-related foot ulcers: a review of reviews. https://evidence.hayesinc.com. Published October 5, 2017. Updated November 19, 2021. Accessed April 18, 2023.

29. Hayes, Inc. Medical Technology Directory (ARCHIVED). Hyperbaric oxygen therapy for osteoradionecrosis. https://evidence.hayesinc.com. Published March 12, 2009. Updated March 1, 2013. Accessed April 18, 2023.

30. Hayes, Inc. Medical Technology Directory (ARCHIVED). Hyperbaric oxygen therapy for soft tissue radiation injuries. https://evidence.hayesinc.com. Published May 5, 2010. Updated March 6, 2014. Accessed April 18, 2023.

31. Hayes, Inc. Medical Technology Directory (ARCHIVED). Hyperbaric oxygen therapy for sudden sensorineural hearing loss. https://evidence.hayesinc.com. Published September 29, 2016. Updated January 29, 2021. Accessed April 18, 2023.

32. Hayes, Inc. Medical Technology Directory (ARCHIVED). Topical oxygen therapy for chronic wound healing. https://evidence.hayesinc.com. Published November 21, 2017. Updated January 6, 2022. Accessed April 18, 2023.

33. Marx R. A new concept in the treatment of osteoradionecrosis. *J Oral Maxillofacial Surg.* 1983;41:351-357.

34. MCG Health. Hyperbaric oxygen. 26th edition. https://www.mcg.com. Accessed April 6, 2023.

35. Society for Vascular Surgery (SVS). The management of diabetic foot: a clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. https://www.jvascsurg.org. Published February 2016. Accessed May 1, 2023.

36. Undersea & Hyperbaric Medical Society, Inc. (UHMS). A clinical practice guideline for the use of hyperbaric oxygen therapy in the treatment of diabetic foot ulcers. https://www.uhms.org. Published June 2015. Updated 2018. Accessed May 1, 2023.

37. Undersea & Hyperbaric Medical Society, Inc. (UHMS). Hyperbaric oxygen therapy indications 14th edition. https://www.uhms.org. Published 2019. Accessed May 1, 2023.

38. Undersea & Hyperbaric Medical Society, Inc. (UHMS). Position Statement. Topical oxygen for chronic wounds. https://www.uhms.org. Published 2005. Updated May 23, 2018. Accessed May 1, 2023.

39. UpToDate, Inc. Abdominal actinomycosis. https://www.uptodate.com. Updated October 2023. Accessed November 2, 2023.

40. UpToDate, Inc. Air embolism. https://www.uptodate.com. Updated March 2023. Accessed April 18, 2023.

41. UpToDate, Inc. Approach to the patient who declines blood transfusion. https://www.uptodate.com. Updated March 7, 2023. Accessed April 18, 2023.

42. UpToDate, Inc. Autism spectrum disorder in children and adolescents: complementary and alternative therapies. https://www.uptodate.com. Updated March 2023. Accessed April 18, 2023.

43. UpToDate, Inc. Basic principles of wound management. https://www.uptodate.com. Updated March 2023. Accessed April 18, 2023.

44. UpToDate, Inc. Calciphylaxis (calcific uremic arteriolopathy). https://www.uptodate.com. Updated March 2023. Accessed April 18, 2023.

45. UpToDate, Inc. Carbon monoxide poisoning. https://www.uptodate.com. Updated March 2, 2023. Accessed April 18, 2023.

46. UpToDate, Inc. Central and branch retinal artery occlusion. https://www.uptodate.com. Updated March 2023. Accessed April 18, 2023.

47. UpToDate, Inc. Chemotherapy and radiation-related hemorrhagic cystitis in cancer patients. https://www.uptodate.com. Updated March 2023. Accessed April 18, 2023.

48. UpToDate, Inc. Clinical manifestations, prevention, and treatment of radiation-induced fibrosis. https://www.uptodate.com. Updated March 2023. Accessed April 18, 2023.

49. UpToDate, Inc. Clinical staging and general management of pressure-induced skin and soft tissue injury. https://www.uptodate.com. Updated March 2023. Accessed April 18, 2023.

50. UpToDate, Inc. Clostridial myonecrosis. https://www.uptodate.com. Updated March 2023. Accessed April 18, 2023.

51. UpToDate, Inc. Complications of SCUBA diving. https://www.uptodate.com. Updated March 2023. Accessed April 18, 2023.

52. UpToDate, Inc. Cyanide poisoning. https://www.uptodate.com. Updated March 2023. Accessed April 18, 2023.

53. UpToDate, Inc. Diagnosis and management of chronic radiation enteritis. https://www.uptodate.com. Updated March 2023. Accessed April 18, 2023.

54. UpToDate, Inc. Hyperbaric oxygen therapy. https://www.uptodate.com. Updated March 29, 2023. Accessed April 18, 2023.

55. UpToDate, Inc. Management of diabetic foot ulcers. https://www.uptodate.com. Updated March 2023. Accessed April 18, 2023.

56. UpToDate, Inc. Management of late complications of head and neck cancer and its treatment. https://www.uptodate.com. Updated March 2023. Accessed April 18, 2023.

57. UpToDate, Inc. Medical management of lower extremity chronic venous disease. https://www.uptodate.com. Updated March 2023. Accessed April 18, 2023.

58. UpToDate, Inc. Nonvertebral osteomyelitis in adults: treatment. https://www.uptodate.com. Updated March 17, 2023. Accessed April 18, 2023.

59. UpToDate, Inc. Overview of treatment of chronic wounds. https://www.uptodate.com. Updated March 2023. Accessed April 18, 2023.

60. UpToDate, Inc. Radiation proctitis: clinical manifestations, diagnosis, and management. https://www.uptodate.com. Updated March 2023. Accessed April 18, 2023.

61. UpToDate, Inc. Sudden sensorineural hearing loss in adults: evaluation and management. https://www.uptodate.com. Updated March 2023. Accessed April 18, 2023.

62. UpToDate, Inc. Treatment of nontraumatic hip osteonecrosis (avascular necrosis of the femoral head) in adults. https://www.uptodate.com. Updated March 2023. Accessed April 18, 2023.

63. US Food & Drug Administration (FDA). 510(k) summary: EPIFLO. https://www.fda.gov. Published April 27, 2012. Accessed February 18, 2019.

64. US Food & Drug Administration (FDA). 510(k) summary: Hyper-Box topical wound oxygen system. https://www.fda.gov. Published August 6, 2008. Accessed April 19, 2023.

65. US Food & Drug Administration (FDA). 510(k) summary: TransCu O2. https://www.fda.gov. Published August 12, 2009. Accessed February 18, 2019.

66. US Food & Drug Administration (FDA). 510(k) summary: VHT-200 wound treatment system. https://www.fda.gov. Published March 23, 2023. Accessed April 10, 2023.

67. US Food & Drug Administration (FDA). Medical devices. Hyperbaric oxygen therapy: get the facts. https://www.fda.gov. Published July 26, 2021. Accessed March 21, 2022.

68. Wagner F. The diabetic foot. *Orthopedics.* 1987;10(1):163-172.

Appendix

Appendix A
Standard care of diabetic wounds include:

- Appropriate offloading; **AND**
- Assessment of an individual's vascular status and correction of any amenable vascular problems; **AND**
- Debridement by any means to remove devitalized tissue and infected bone; **AND**
- Improvement of glucose control with glycosylated hemoglobin level (HbA1c) ideally less than 9.0% or blood glucose records demonstrating efforts to sustain blood sugar less than 200 mg/dL as clinically indicated; **AND**
- Maintenance of a clean, moist wound bed with appropriate dressings (eg, alginate, films, foams, hydrocolloid, hydrogels that provide a moist wound environment); **AND**
- Necessary treatment to resolve any infection that may be present, including surgical management of osteomyelitis; **AND**
- Optimization of nutritional status as wound healing best occurs when pre-albumin level is greater than 20 mg/dL or albumin level is greater than 3.4 g/dL)

Appendix B
Wagner Grading System[66]

Grade 1	Superficial ulcer without penetration of deep layers
Grade 2	Deeper ulcer, reaching tendon, bone or joint capsule
Grade 3	Deeper tissues are involved and there is abscess, osteomyelitis or tendonitis
Grade 4	There is gangrene of some part of the toe(s) and/or forefoot
Grade 5	Gangrene involves the whole foot or enough of the foot that no local procedures are possible and below knee amputation (BKA) is indicated

Appendix C
Treatment for established ORN:

- **Stage I:** 30 HBOT sessions prior to bony debridement, followed by 10 sessions immediately postoperatively; OR
- **Stage II** (failure of treatment for stage I or newly diagnosed stage II): 30 HBOT sessions prior to radical surgical debridement (maintaining mandibular continuity), followed by 10 sessions immediately postoperative; OR
- **Stage III** (failure of treatment for stages I and/or II or newly diagnosed stage III): 30 HBOT sessions prior to mandibular resection, followed by 10 sessions immediately postoperative. May need an additional 10 sessions to support initial tissue metabolic demands if reconstruction of the mandible occurs;

Change Summary

- 01/01/2024 New Policy.