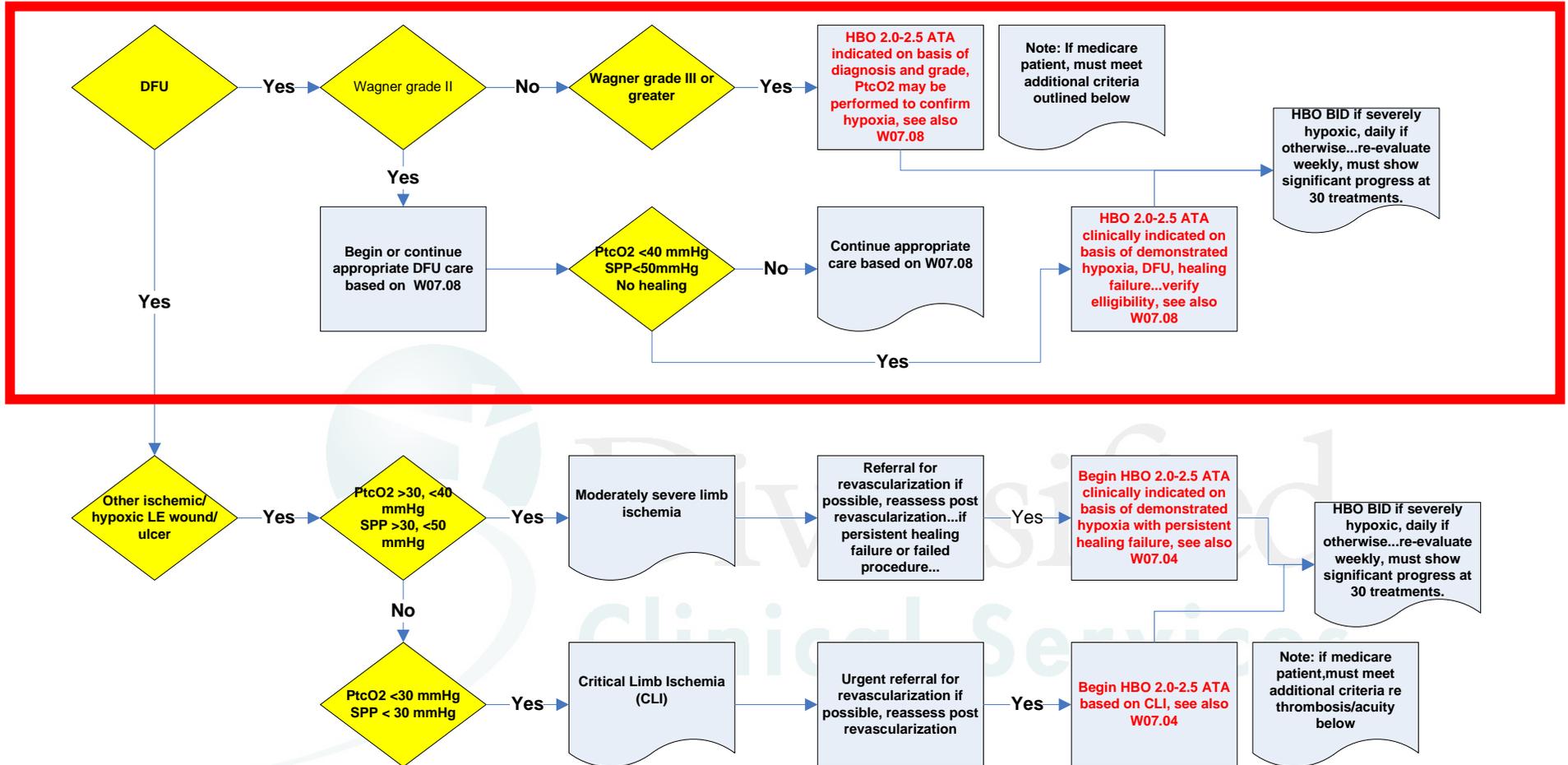


DCS CPG: H02.01A HYPOXIC WOUNDS...DIABETIC LOWER EXTREMITY



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ENTRY CRITERIA:	HYPERBARIC KEY THERAPEUTIC OBJECTIVES:	CONTRAINDICATIONS: ABSOLUTE/RELATIVE:
<p><input type="checkbox"/> Wound*</p> <p><input type="checkbox"/> Demonstrated periwound hypoxia by PtcO₂ measurement when technically possible:</p> <p>PtcO₂ >40mmHg required for spontaneous healing in diabetic patients PtcO₂ >30mmHg required for spontaneous in non diabetic patients See H02.01C Transcutaneous PO₂ Interpretation</p> <p>* May be used following treatment with another Clinical Practice Guideline such as a wound previously treated as a traumatic wound, crush injury, or necrotizing soft tissue infection, refractory osteomyelitis when the intent is to support local wound healing without coverage by a graft or flap by reversing tissue hypoxia.</p> <p><u>For CMS beneficiaries:</u> Diabetic wounds of the lower extremities (250.7, 250.8, 707, 707.1, 707.10, 707.12, 707.13, 707.14, 707.19)</p> <ol style="list-style-type: none"> 1. Patient has type I or type II diabetes and a lower extremity wound that is due to diabetes 2. Patient has a wound classified as a Wagner grade III or higher; and 3. Patient has failed an adequate course of standard wound therapy (30 days of standard care) 4. Continued HBO will not be covered if there are no measurable signs of healing during the 30 day period <p>See details of CMS requirements for coverage for HBO for Wagner grade III and higher diabetic lower extremity wounds below.</p>	<p><input type="checkbox"/> Treatment of hypoxia</p> <p><input type="checkbox"/> Bacteriostatic/cidal effects</p> <p>The goal of adjunctive hyperbaric oxygen treatment is to provide an adequate granulation to support spontaneous or surgically supported wound healing. Hyperbaric oxygen therapy for difficult wounds should be undertaken with the clear understanding that it must be part of a vigorous and coordinated team approach to total patient and wound management.</p> <p>Remember that there are two physiological justifications for the application of HBO in diabetic wound healing:</p> <ol style="list-style-type: none"> 1. Wound predicted not to heal based on critical ischemia/hypoxia without addition of HBO (PtcO₂ < 30 mmHg) 2. Wound might heal without HBO but will take > 12 weeks (PtcO₂ 30-50 mmHg) <p>The earlier HBO is applied in these situations the greater the likelihood of providing benefit to the patient in question. The more consistently HBO treatment is applied (i.e., adequate treatment pressure based on achieving an in chamber PtcO₂ value of at least 200-200mmHg and avoiding interruptions in treatment.</p> <p>There is data to suggest that patients with extremely low baseline PtcO₂ values may achieve better outcomes if treatment is initially administered BID (perhaps the first 5 days or so).</p>	<p>Absolute Contraindications to Hyperbaric Therapy</p> <ul style="list-style-type: none"> <input type="checkbox"/> Untreated pneumothorax <input type="checkbox"/> Concomitant administration of doxorubicin, cisplatin, other chemotherapeutics (esp antiangiogenic), amiodarone <input type="checkbox"/> Bleomycin administration within 12 months (caution re pulmonary oxygen toxicity if > 12 months) <input type="checkbox"/> Pregnancy in non-life threatening circumstances <input type="checkbox"/> Terminal patient with irreversible disease <p>Relative Contraindications to Hyperbaric Therapy</p> <ul style="list-style-type: none"> <input type="checkbox"/> Upper respiratory infections <input type="checkbox"/> Chronic sinusitis <input type="checkbox"/> History of reconstructive ear surgery <input type="checkbox"/> Auditory impairment <input type="checkbox"/> Visual impairment <input type="checkbox"/> Cognitive impairment <input type="checkbox"/> Uncontrolled high fever <input type="checkbox"/> Congenital spherocytosis <input type="checkbox"/> Sickle cell anemia <input type="checkbox"/> History of optic neuritis (may be associated with increased risk of recurrence but only limited case report experience) <input type="checkbox"/> History of seizure disorder <input type="checkbox"/> Congestive heart failure <input type="checkbox"/> Pacemaker or AICD <input type="checkbox"/> Uncontrolled bronchospasm <input type="checkbox"/> History of previous thoracic surgery <input type="checkbox"/> Non-communicating air trapping lesions on x-ray or CT scan <input type="checkbox"/> History of spontaneous pneumothorax <input type="checkbox"/> Emphysema with CO₂ retention <input type="checkbox"/> Pregnancy in life threatening circumstances <input type="checkbox"/> Concomitant administration of medications that lower threshold for CNS oxygen toxicity

Level of Evidence...The available evidence supports the use of adjunctive hyperbaric oxygen treatment for diabetic foot ulcers. Its application meets the requirements for AHA category I definitely recommended based on level 1 evidence consisting of positive randomized controlled trials with statistically significant results. **WHS CPG 2006...**Guideline #6.B.1a: In patients with non-reconstructable anatomy or whose ulcer is not healing despite revascularization, hyperbaric oxygen therapy (HBOT) should be considered as an adjuvant therapy. Selection criteria include ulcers that are hypoxic (due to ischemia) and the hypoxia is reversible by

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hyperbaric oxygenation. Tissue hypoxia, reversibility, and responsiveness to oxygen challenge are currently measured by transcutaneous oximetry (PtcO₂), although other methods are under investigation. The majority of data have been collected in patients with diabetes and arterial ulcers. Studies are required to determine whether these results can be generalized to all ischemic ulcers and whether post revascularization treatment is of benefit.

Cost Impact...Hyperbaric oxygen therapy as an adjunct to medical and surgical treatment of difficult problem, chronic wounds, particularly diabetic lower extremity wounds, has been shown to be cost effective in limited reviews, especially when compared to major lower extremity amputation. Preventing a below the knee amputation by salvaging a ray resection or transmetatarsal amputation of the foot or preventing an above the knee amputation by preserving a below the knee amputation represents a satisfactory outcome in these high risk patients. Wounds healed with adjunctive hyperbaric oxygen treatment have also demonstrated excellent durability.

TREATMENT GUIDELINES	Treatment Table	Pressure ATA	Oxygen Breathing Minutes	Air Breaks	Air Break intervals
Limb threatening wound:	Wound Healing 1	2.0	90	No	NA
<ul style="list-style-type: none"> Wound healing treatment table at 2.0 or 2.4/5 ATA BID, usually 1-5 days When wound stabilizes or is no longer limb threatening, treatments should be decreased to once daily 	Wound Healing 2	2.0	90	Yes	30-5-30-5-30 ¹ 20-5-20-5-20-5-20 ²
Chronic wounds or non urgent (diabetic, amputations, traumatic, surgical):	Wound Healing 3	2.0	120	No	NA
<ul style="list-style-type: none"> Wound healing treatment table at 2.0 or 2.4/5 ATA: daily until healed, normalized or ready for graft, flap, or closure 	Wound Healing 4	2.0	120	Yes	30-5-30-5-30-5-30 ¹ 20-5-20-5-20-5-20-5-20-5-20 ²
<p>In-chamber PtcO₂: Evidence is strongest in DFU patients that a minimum in-chamber PtcO₂ must be achieved in order for healing to occur, Fife Warriner (2002). A PtcO₂ >200mmHg should be achieved for HBO to be continued (see H01.03 Treatment Profile Decisions). The treatment profile should be selected to provide that level of tissue oxygenation during HBO.</p> <p>Based on the ORN and other data, it probably requires 15-20 treatments to produce a clinically significant angiogenic effect in most hypoxic problem wounds.</p> <p>The wound should be evaluated at least weekly for evidence of therapeutic response and improvement.</p> <p>Utilization review Hyperbaric oxygen treatments are performed at 2.0 to 2.4/5 ATA for 90 to 120 minutes of oxygen breathing. The initial treatment schedule is dictated by the severity of the disease process. In the presence of limb-threatening infection after debridement or incompletely corrected peripheral arterial occlusive disease, patients may require twice daily treatments. Once stabilized, treatment frequency may decrease to once daily. Utilization review is required after the initial 30 days of treatment and at every 10 treatments thereafter.</p>	Wound Healing 5	2.4 or 2.55	90	Yes	30-5-30-5-30 ¹ 20-5-20-5-20-5-20 ²

¹ Standard air breaks are given for 5 minutes at 30 minute intervals.

² Air breaks are given for 5 minutes at 20 minute intervals in patients who are at increased risk for CNS oxygen toxicity or who have had a previous oxygen toxicity seizure during HBO. Compression and decompression are on 100% oxygen in monoplace chamber, air in multiplace chamber.

DCS CPG: H02.01A HYPOXIC WOUNDS...DIABETIC LOWER EXTREMITY

TIME REFERENCE FOR INTERVENTION AND PROGRESS (This time line can be compressed based on patient condition and wound severity but not expanded.)									
HBO #5	HBO #10	HBO #15	HBO #20	HBO #25	HBO #30	HBO #35	HBO #40	HBO#45	HBO #50
Initial PtcO2 measurement under hyperbaric conditions, routine surveillance	Documentation of progress to continue, may repeat 1 ATA air PtcO2, routine surveillance	Documentation of progress to continue	Scheduled reevaluation for satisfactory progress, may repeat 1 ATA air PtcO2, documentation of progress to continue	Documentation of progress to continue	Scheduled reevaluation for satisfactory progress, may repeat 1 ATA air PtcO2, documentation of progress to continue CMS mandated review at 30!	Documentation of progress to continue	Scheduled reevaluation for satisfactory progress, may repeat 1 ATA air PtcO2, documentation of progress to continue	Documentation of progress to continue	Scheduled reevaluation for satisfactory progress, may repeat 1 ATA air PtcO2, documentation of progress to continue

Follow the **KTO...Essentials for Wound Management (W05.XX)** and/or the specific **Wound Treatment by Diagnosis Guidelines (W07.08)** for all non-hyperbaric oxygen treatment related wound and patient management issues.

Documentation: At a minimum, documentation should include diagnosis of diabetes, degree of glycemic control, other metabolic risk factors, lower extremity vascular assessment and appropriate interventions, location and extent of the ulcer, Wagner and/or UTHSCSA DFU grade, results of ancillary testing including cultures or histopathology establishing the diagnosis of osteomyelitis if present, results of prior therapy, documentation of hypoxia and transcutaneous PO2 response to HBO.

Additional notes concerning Medicare beneficiaries and coverage for diabetic wounds of the lower extremities (250.7, 250.8, 707, 707.1, 707.10, 707.12, 707.13, 707.14, 707.19)

1. Patient has type I or type II diabetes and a lower extremity wound that is due to diabetes
2. Patient has a wound classified as a Wagner grade III or higher (**Wagner FW, 1981**); and
 - Grade 0:** Intact skin
 - Grade I:** Superficial ulcer without penetration deeper layers
 - Grade II:** Deeper ulcer reaching tendon, bone, or joint capsule (*if bone is exposed, based upon the preponderance of evidence of the association of osteitis and osteomyelitis, the ulcer should be reclassified as a Wagner grade III ulcer*)
 - Grade III:** Deeper tissues involved and there is abscess, osteomyelitis, or tendonitis usually with extension along the midfoot compartments of tendon sheaths (Wagner in his original article refers to "abscess or osteitis"...remember that anatomically Wagner grade II and III are the same...it is the presence or absence of infection that defines the transition to Wagner grade III from II, so aggressively look for evidence of infection; any ischemic necrosis will move the grade to Wagner IV)
 - Grade IV:** Gangrene of some portion of the toe, toes, and/or forefoot
 - Grade V:** Gangrene involving the whole foot or enough of the foot that no local procedures are possible
3. Patient has failed an adequate course of standard wound therapy (30 days of standard care)
 - Assessment of vascular status
 - Optimization of nutrition/glucose control
 - Debridement
 - Moist dressings
 - Off loading
 - Treatment of Infection

CMS gives little guidance here, so apply community standard of care rather than the wound care center standard of care which is much higher.

DCS CPG: **H02.01A HYPOXIC WOUNDS...DIABETIC LOWER EXTREMITY**

How should failure to respond to standard care be defined...CMS refers to failure but gives little objective guidance here. I believe it is reasonable to apply a standard for meaningful response to intervention as a **50% reduction in wound volume or surface area within 4 weeks** based on the work by **Sheehan, et al (2006)**.

4. Continued HBO will not be covered if there are no measurable signs of healing during the 30 day period (apply the same 30% in 4 week standard referenced above).

Refer to your Medicare Carrier and Intermediary LCD for hyperbaric oxygen treatment for additional documentation requirements or other essential information.

References:

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