Diabetic Foot and HBO Indication

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Hyperbaric oxygen treatment in chronic wounds in general, diabetic foot ulcers in particular, has been recommended by 7 independent evidenced-based reviews:

- BlueCross/BlueShield Technology Assessment 1999
- American Diabetes Association Foot Council 1999
- Wound Healing Society 1999
- Medical Services Advisory Committee, Australia
- AHRQ Report to CMS 2001
- CMS Coverage Decision for HBO in DFU 2002
CMS Decision  
Dept of Health & Human Services Program Memorandum

A National Coverage Decision expanded the use of HBO therapy to include coverage for the treatment of diabetic wounds of the lower extremities.

Centers for Medicare & Medicaid Services (CMS)  
Transmittal AB-02-183  
December 27, 2002  
Change Request 2388

• The effective date for this PM is April 1, 2003.  
• The implementation date for this PM is April 1, 2003.
CMS Decision

- A National Coverage Decision expanded the use of HBO therapy to include coverage for the treatment of diabetic wounds of the lower extremities in pts who meet the following criteria:

1. Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes
2. Patient has a wound classified as Wagner grade III or higher
3. Failure to respond to std wound care occurs when there are no measurable signs of healing for at least 30 consecutive days.
Step 1: General Requirements
Wagner Requirements
Defining Wound Care
Begin HBO
30 Day Re-evaluation
*Special Considerations
Step 1: General Requirements

- Type 1 or Type II Diabetes
- Lower Extremity Wound
- Wound class – Wagner Grade III or higher
- Documentation that patient has not responded to standard wound care for 30 days
**Step 2: Wagner Requirements**

"The dysvascular foot: a system for diagnosis & treatment" a system composed of 6 grades based on ulcer depth, infection and gangrene.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 0</td>
<td>Intact Skin</td>
</tr>
<tr>
<td>Grade I</td>
<td>Superficial without penetration deeper layers</td>
</tr>
<tr>
<td>Grade II</td>
<td>Deeper reaching tendon, bone, or joint capsule</td>
</tr>
<tr>
<td>Grade III</td>
<td>Deeper with abscess, osteomyelitis, or tendonitis</td>
</tr>
<tr>
<td>Grade IV</td>
<td>Gangrene of some portion of the toes or forefoot</td>
</tr>
<tr>
<td>Grade V</td>
<td>Gangrene involving the whole foot or enough of the foot that no local procedures are possible</td>
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</tbody>
</table>
**Step 2: Wagner Requirements**

**Wagner Grade III – working definitions**

A diabetic foot ulcer may be classified as a Grade III ulcer where one of more of the following elements is documented in the clinical record: **abcess, osteomyelitis, or tendonitis**

**Abcess**

**Clinical Translation – Notation in medical record**

The medical record should contain an entry noting the presence of some fluid release during the course of a surgical debridement or incision.

*Note: There are no restrictions on the size of the abscess e.g. big, little, or small. As such an abscess may range from a few drops of fluid to several cc’s.*
Wagner Grade III – working definitions

A diabetic foot ulcer may be classified as a Grade III ulcer where one of more of the following elements is documented in the clinical record: **abcess, osteomyelitis, or tendonitis**

**Osteomyelitis**

Clinical Translation – X-ray studies

The initial evaluation of a non-healing ulcer traditionally includes x-rays to evaluate the skeletal integrity of the foot. Special attention should be given to stress fractures, occult foreign bodies, and osteomyelitis. This study has special importance where neuropathy is present.
Step 2: Wagner Requirements

**Wagner Grade III – working definitions**

A diabetic foot ulcer may be classified as a Grade III ulcer where one of more of the following elements is documented in the clinical record: **abcess, osteomyelitis, or tendonitis**

**Tendonitis**

**Clinical Translation – Observations/Cultures**

The criteria for tendonitis may be met on either a clinical or laboratory basis. If the clinical findings cannot be documented (rubor, color, calor, discharge), the ulcer should be irrigated appropriately followed by swab cultures of the tendon. This should be done by pressing deeply into the tissue along the entry and exit points of the tendon inside the wound bed.

**Clinical Diagnosis**

Document appropriate findings of infection

**Laboratory Diagnosis**

Document positive cultures (moderate to large growth)
Step 2: Wagner Requirements

Wagner Grade IV – working scenarios

Clinical Translation

“Gangrene of the toes or some portion of the forefoot”

Certainly CMS did not intend or expect providers to leave tissue gangrenous tissue for 30 days so that the patient may receive HBO. In addition CMS has stipulated that HBO may not be used until the patient has received standard wound care which includes the removal of devitalized tissue.

Six clinical scenarios or pathways exist for these patients.
Step 2: Wagner Requirements

Wagner Grade IV – working scenarios

Scenario 1

Flow Augmentation/Amputation/Healing

For Wagner Grade IV patients, flow augmentation followed by local amputation represents the ideal strategy and is typically successful.

_HBO is not warranted._
Step 2: Wagner Requirements

Wagner Grade IV – working scenarios

Scenario 2

Flow Augmentation “Complicated”/Amputation

This scenario addresses the failed balloon angioplasty or bypass grafting. For these patients, the acute traumatic peripheral ischemia codes maybe employed on a limb salvage basis.

(902.53, 903.01, 903.1, 904.0, 904.41)

CMS views any manipulation of the vessel as inherently traumatic and permits HBO for purposes of limb salvage.
Wagner Grade IV – working scenarios

Scenario 3

Flow Augmentation/Amputation Failed

Patients in this group have received a technically adequate flow augmentation procedure yet fail to demonstrate measurable signs of healing 30 days post amputation.

Assuming all other aspects of “standard wound care” have been addressed, these patients would be HBO candidates on their 31st postoperative day.
Step 2: Wagner Requirements

Wagner Grade IV – working scenarios

Scenario 4

Flow Augmentation NA*/TcPO2 <40 mm Hg /Amputation

If augmentation is not achievable (*NA) transcutaneous oxygen mapping will provide valuable preoperative guidance in two areas.

1. As an aid for determining the most conservative surgical procedure to preserve limb length and function.

2. As a method for identifying those surgical sites that have marginal but salvageable amputation flaps.

Amputation sites which fit this profile have a room air values <40 mm Hg with a (+)O2 challenge. When the decision is made to minimize limb loss by selecting a marginal, but potentially viable amputation site, post-op HBO should be considered.
Scenario 5

Flow Augmentation NA*/TcPO2 >40 mm Hg
/Amputation

This scenario encompasses those patients for whom flow augmentation is not an option & the selected amputation site ahs room air values that approximate 40 mm Hg.

For these patients an uncomplicated post-op support is expected and post operative HBO is not warranted.
Step 2: Wagner Requirements

Wagner Grade IV – working scenarios

Scenario 6

Flow Augmentation NA*/Amputation Referral for Nonhealing Amputation site

Patients in this category have failed to recover from an amputation and have been referred to the Wound Healing Center.

HBO maybe applied immediately if a review of the records indicates no healing in the past 30 days & the basic elements of wound care as defined by CMS has been provided.
Wagner Grade V – working scenarios

By definition a Grade V foot is not salvageable – “no local procedures are possible” and requires amputation. As with Wagner Grade IV patients, pre-op TCOM’s will aid in the decision to operate below or above the knee and permit the early identification of the marginal amputation flap.

If a decision is made to maximize limb length by amputating at a level that appears marginal, immediate post-op HBO support will improve the outcome.
Step 3: Defining Wound Care

Translating the CMS elements of Standard Wound Care

Vascular Assessment (Clinical Translation)
  Perform Transcutaneous mapping

Correction of vascular problem (Clinical Translation)
  Document vascular opinion if TCOM is < 40 mm Hg

Nutritional Assessment (Clinical Translation)
  Document prealbumin, consider dietary consult

Debridement of Devitalized tissue (Clinical Translation)
  Document all debridements

Maintenance of clean moist wound bed (Clinical Translation)
  Document “clean moist bed w/appropriate dressing”

Appropriate off-loading (Clinical Translation)
  Document “appropriate foot wear” & any other interventions

Resolve any infection

Adequate Glycemic control
Step 4: Begin HBO

For wounds without signs of improvement following a 30 day trial of standard wound care, hyperbaric therapy may be started.

The treatment protocol is 2.0 ATA for 90 minutes on a QD basis Monday – Friday.
Step 5: 30 Day Reevaluation

Document wound status at the end of 30 days. Specifically note any signs of improvement. Repeat transcutaneous measurements.

If improved, this would constitute a “measurable sign of healing” & permit continuation of HBO for an additional 30 day period.
Special Considerations

Prior history of flap or graft.

Patients with a non-healing ulcer of any grade & a history of a failed flap or graft, would be a candidate for HBO.

For these individuals, CMS guidelines permit the use of HBO as a “prep for graft”. (ICD code 996.52)

The treatment protocol is 2.0 ATA x 90 min on QD basis.
Acute arterial insufficiency.

Sudden deterioration of an ulcer (necrosis) in the absence of traumatic injury or bacterial infection may be treated as an acute arterial insufficiency.

This is a historical diagnosis which points to a local occlusion of a branch artery.

The treatment protocol is 2.0 ATA x 90 min on QD basis.
Lower Extremity Diabetic Wounds

Is the wound the result of a failed graft?

- NO

A revascularization procedure was performed in the past 30 days & TcPO2 is < 40?

- NO

Determine Wagner Classification

- Wagner I or II
  - HBO Not Indicated
- Wagner III
  - Possible HBO
- Wagner IV or V
  - Possible HBO

Begin HBO
Lower Extremity Diabetic Wounds

Wagner III

Have the elements of Std Wound Care been met?

1 - Vascular Status?
2 - Correction of Vascular Problems?
3 - Nutritional Status?
4 - Glycemic Control?
5 - Debridement?
6 - Appropriate Dressing?
7 - Appropriate Off Loading?
8 - Resolution of Infection?

Decrease in Wound Volume in the past 30 days?

- YES
  - Cont Standard Wound Care*
- NO
  - Begin HBO 2.0 ATA QD

*Management Options
Lower Extremity Diabetic Wounds

Wagner IV or V

Is this condition sudden in onset AND TcPO$_2$ < 40 mm Hg?

YES

TCOM’s for level of amputation – If the selected amputation site is partially compromised, but highly desirable (eg BKA vs AKA), postoperative HBO may be given to support the compromised flap.

NO

Continue Std Wound Care*

*See Management Options
Lower Extremity Diabetic Wounds

Management Options

**Revascularization** –
If unsuccessful & TcPO\textsubscript{2} < 40 mm Hg, may use HBO under the label of acute (post surgical / angioplasty) ischemia.

**TCOM’s for level of amputation** –
If the selected amputation site is partially compromised, but highly desirable (eg BKA vs AKA), postop HBO may be given to support the compromised flap.
SUMMARY

- The General CMS Requirements
- The Wagner Requirements
- Defining Wound Care
- Operational Definitions
- Operational Scenarios Wagner Grade IV and V
- Starting & Evaluation of Progress
- Special Considerations
- Supporting Studies