Definitions:

**Hyperbaric oxygen therapy (HBOT)**
Systemic treatment in which the patient is entirely enclosed in an air-tight chamber that is pressurized to 1.4 to 3.0 atmospheres absolute (atm abs or ATA) and breathing 100% oxygen. It is used to treat certain diseases and conditions which may improve when an increased partial pressure of oxygen is delivered and present in perfused tissues.

Hyperbaric oxygen therapy serves four primary functions:
1. It increases the concentration of dissolved oxygen in the blood, which enhances perfusion;
2. It stimulates the formation of a collagen matrix so that new blood vessels may develop;
3. It replaces inert gas in the bloodstream with oxygen, which is then metabolized by the body; and
4. It works as a bactericide.

Policy:
To ensure that corporate authorization processes are consistent, this policy shall apply to all states where MHP operates, except insofar as this policy is found to inadvertently conflict with any previously established or new state laws/policies.

Procedure:
MHP considers Topical Hyperbaric Oxygen (THBO) experimental, investigational or unproven and is not covered because its efficacy has not been established through controlled clinical trials.
Covered Conditions:
Systemic hyperbaric oxygen therapy (HBOT) may be appropriate and can be approved for the following conditions, within the limits outlined.

1. **Emergent Conditions:**
   a. Acute arterial Air or Gas Embolism – *Usual treatment involves 1-2 sessions, but may require 5-10*
   b. Acute carbon monoxide poisoning- *Less than/equal to 5 sessions should be needed, until there is no longer evidence of progression and infection is considered under control.*
   c. Clostridial myositis or myonecrosis (gas gangrene) with documentation of a Gram stain consistent with a Clostridial species
   d. Acute cyanide poisoning, after antidote administration has been given (with co-existing carbon monoxide poisoning) - *No more than 10 sessions should be needed.*
   e. Decompression sickness or illness (“The Bends”)—Complete resolution of symptoms or lack of improvement on two consecutive treatments establishes the end point. *No more than 5-10 treatments per individual is considered the norm.*
   f. Progressive necrotizing soft tissue infections, including mixed aerobic and anaerobic infections (necrotizing fasciitis, Meleney's ulcer)-*Treatment until there is no longer evidence of progression and infection is considered controlled*
   g. Compromised skin grafts or flaps (i.e. preexisting grafts or flaps that are showing signs of failure or necrosis)-*20 treatments with the potential for additional short term once daily treatments*
   h. Crush injuries, compartment syndrome and other acute traumatic ischemia in a salvageable area when loss of function, limb, or life is threatened and HBOT is used in combination with standard therapy—*Up to three treatments a day, up to 6 days.*
   i. Acute peripheral arterial insufficiency.
   j. Anemia resulting from overwhelming blood loss IF one of the two circumstances below apply:
      a. No suitable blood products are available for transfusion within reasonable time frame
      b. The patient/legal guardian refuses transfusion on religious/philosophical grounds.

2. **Non-Emergent Conditions:**
   Prefacing Note: HBOT may be approved as an *adjunct* to standard wound care when there are no measurable signs of wound healing following at least 30 days of standard treatments. HBOT can only be approved when it is being used in conjunction with standard wound care, not as a substitute. Standard wound care in patients with diabetic wounds includes but is not limited to:
   a. Assessment of a patient’s vascular status and appropriate correction of any vascular problems in the affected limb whenever medically appropriate,
   b. Optimization of nutritional status and glucose control,
   c. Appropriate debridement to remove devitalized tissue,
   d. Maintenance of a clean, moist bed of granulation tissue with appropriate dressings,
   e. Appropriate treatments for resolving active infection. When there are no measurable signs of healing after 30 consecutive days of wound care, the therapy can be considered to have failed. There must be documentation of wound evaluation at least every 30 days during administration of HBOT. If wounds fail to show measurable signs of healing within 30 days of initiating HBOT, MHP considers continuation of HBOT treatments not *medically necessary.*
   f. Diabetic wounds/ulcers of the lower extremities, Wagner grade III or higher that have failed standard wound therapy (See Appendix B for Wagner scale)
   g. Osteomyelitis refractory to standard medical management—*Patients with refractory Cierny-Mader stage 3B and 4B osteomyelitis should be considered candidates for*
HBOT. Approximately 20-40 postoperative treatments should be delivered over a 4-6 week period. **Patients with Cierny-Mader stage 1 and 2 are not recommended for HBOT as these patients should be treated primarily with antibiotics and limited surgical debridement.** (See Appendix A for Cierny-Mader scale.)

- Radiation tissue injury, chronic (e.g., osteoradionecrosis, soft tissue radiation necrosis, and related conditions except for those investigational indications listed in exclusions)
- Radiation tissue damage (non-neurologic tissue), delayed (osteoradionecrosis and soft tissue radionecrosis)
- Radiation-induced cystitis or hemorrhagic cystitis (i.e., resulting from chemolytic response, graft-versus-host disease [GVHD])
- Radiation-induced enterocolitis
- Pre- and post-treatment for patients undergoing dental surgery (non-implant related) of an irradiated jaw
- Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment

3. MHP does not cover systemic hyperbaric oxygen therapy in single or multiple chambers for the treatment of any condition considered experimental, investigational or unproven in that there is insufficient evidence in the medical literature establishing that systemic HBOT is more effective than conventional therapies. **See special instructions for a list of non-covered conditions (not an all-inclusive list):**

4. MHP considers HBOT experimental and investigational for members with any of the following contraindications to systemic HBOT, as the safety of systemic HBOT for persons with these contraindications to HBOT has not been established:
   - Concurrent administration of doxorubicin, cisplatin, or disulfiram
   - Premature infants (birth prior to 37 weeks gestation)

5. Untreated pneumothorax is an absolute contraindication to HBOT.

**Special Instructions:**

**Medicaid/All:**

**Non-Covered Conditions:**

MHP considers the use of systemic HBOT experimental and investigational for conditions for which there is insufficient evidence in the medical literature that systemic HBOT is any more effective than conventional therapies. Below is a partial (but not all inclusive) list of these conditions:

1. Actinic skin damage
2. Acute cerebral edema
3. Acute coronary syndrome (ACS)/myocardial ischemia/infarction (MI), cardiogenic shock
4. Acute or chronic cerebrovascular insufficiency/accident (including thrombotic or embolic stroke)
5. Acute renal arterial insufficiency
6. Acute thermal and chemical pulmonary damage secondary to smoke inhalation (e.g., carbon tetrachloride, hydrogen sulfide) which results in pulmonary insufficiency
7. Acute thermal skin burns not meeting above criteria
8. Aerobic septicemia and systemic aerobic infection
9. Anaerobic septicemia and infection other than clostridial
10. Anorectal disorders (e.g., chronic anal fissure, internal hemorrhoids, infectious proctitis)
11. Arthritic diseases
12. As an adjunct to coronary interventions, including but not limited to percutaneous coronary interventions and cardiopulmonary bypass

Medical Management
Policy: B.04
Page 3 of 9
13. Aseptic necrosis of the femoral head and neck
14. Autism
15. Avascular necrosis
16. Bell's palsy
17. Bone grafts or fracture healing (e.g., nonunion fractures)
18. Brain injury, closed head injury, traumatic brain injury (TBI), anoxic encephalopathy
19. Cancer
20. Carbon tetrachloride poisoning
21. Cerebellar hypoperfusion
22. Cerebral palsy
23. Cerebral radionecrosis
24. Chronic fatigue syndrome
25. Chronic peripheral vascular insufficiency
26. Closed head and/or spinal cord injury
27. Cognitive impairment (e.g., senility, dementia)
28. Crohn's disease, Severe or refractory
29. Cutaneous, decubitus/pressure ulcers
30. Cystic acne
31. Delayed onset muscle soreness
32. Demyelinating diseases, e.g., multiple sclerosis, amyotrophic lateral sclerosis
33. Epilepsy
34. Facial neuritis
35. Fractures, acute, delayed union or nonunion
36. Headaches (e.g., cluster, migraine)
37. Hepatic necrosis
38. HIV infection
39. Hydrogen sulfide poisoning
40. Idiopathic sudden sensorineural hearing loss (ISSHL)
41. In vitro fertilization
42. Interstitial cystitis
43. Intra-abdominal abscess, pseudomembranous colitis (antibiotic-induced colitis)
44. Intracranial abscesses
45. In-vitro fertilization
46. Ischemia due to lupus vasculitis
47. Legg-Calve Perthes disease
48. Lepromatous leprosy
49. Lyme disease
50. Lymphedema
51. Malignant otitis externa (e.g., necrotizing external otitis)
52. Melasma
53. Meningitis
54. Necrotizing arachnidism (e.g. Brown Recluse envenomation)
55. Non-diabetic cutaneous, decubitus, pressure and venous stasis ulcers
56. Non-vascular causes of chronic brain syndrome (e.g., Pick's disease, Alzheimer's disease, Korsakoff's disease)
57. Ophthalmologic diseases (including diabetic retinopathy, retinal detachment, central retinal artery occlusion, central retinal vein occlusion, optic neuropathy, radiation injury to the optic nerve, glaucoma, keratoconjunctivitis)
58. Organ storage
59. Organ transplantation
60. Osteoporosis
61. Pseudomembranous colitis (antimicrobial agent-induced colitis)
62. Pulmonary emphysema
63. Pyoderma gangrenosum
64. Radiation-induced brachial plexopathy, radiation myelitis
65. Radiation-induced cystitis, myelitis, enteritis
66. Reflex sympathetic dystrophy (complex regional pain syndrome)
67. Retinopathy, adjunct to scleral buckling procedures in patients with sickle cell peripheral retinopathy and retinal detachment
68. Sepsis – aerobic and anaerobic with the exception of clostridial
69. Severe or refractory Crohn's disease
70. Sickle cell crisis or hematuria
71. Soft tissue injury (e.g., delayed onset muscle soreness, sprains, strains)
72. Spinal cord injury
73. Stroke
74. Superficial and/or non-infected diabetic ulcers
75. Surgical wound dehiscence.
76. Tetanus
77. Tinnitus
78. Tumor sensitization for cancer treatments including but not limited to, radiotherapy and/or chemotherapy
79. Venous stasis ulcers
80. Viral encephalitis or viral encephalopathy

Medicare/All:

A. Covered Conditions:
Program reimbursement for HBO therapy will be limited to that which is administered in a chamber (including the one man unit) and is limited to the following conditions:

a. Acute carbon monoxide intoxication
b. Decompression illness
c. Gas embolism
d. Gas gangrene
e. Acute traumatic peripheral ischemia. 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
f. 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
g. Progressive necrotizing infections (necrotizing fasciitis)
h. Acute peripheral arterial insufficiency
i. Preparation and preservation of compromised skin grafts (not for primary management of wounds),
j. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management,
k. Osteoradionecrosis as an adjunct to conventional treatment
l. Soft tissue radionecrosis as an adjunct to conventional treatment
m. Cyanide poisoning
n. Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment
o. Diabetic wounds of the lower extremities in patients who meet the following three 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; and
   3. Patient has failed an adequate course of standard wound therapy

B. Non-covered Conditions
Any and all other indications for HBOT not specified in the preceding section are not covered under the Medicare program and no program payment may be made. Specifically, no program payment may be made for HBO in the treatment of the following conditions:
1. Cutaneous, decubitus, and stasis ulcers
2. Chronic peripheral vascular insufficiency
3. Anaerobic septicemia and infection other than clostridial
4. Skin burns (thermal)
5. Senility
6. Myocardial infarction
7. Cardiogenic shock
8. Sickle cell anemia
9. Acute thermal and chemical pulmonary damage, i.e., smoke inhalation with pulmonary insufficiency
10. Acute or chronic cerebral vascular insufficiency
11. Hepatic necrosis
12. Aerobic septicemia
13. Nonvascular causes of chronic brain syndrome (Pick’s, Alzheimer’s, or Korsakoff’s disease)
14. Tetanus
15. Systemic aerobic infection
16. Organ transplantation
17. Organ storage
18. Pulmonary emphysema
19. Exceptional blood loss anemia
20. Multiple Sclerosis
21. Arthritic Diseases
22. Acute cerebral edema

C. Topical Application of Oxygen
This method of administering oxygen does not meet the definition of HBO therapy as stated above. Also, its clinical efficacy has not been established. Therefore, no Medicare reimbursement may be made for the topical application of oxygen.

Line of Business Applicability:
For Medicaid/Medicaid Expansion Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the codes being submitted and considered for review being included on either the Michigan Medicaid Fee Schedule (located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--00.html), the Illinois Medicaid Fee Schedule (located at: http://www.illinois.gov/hfs/MedicalProviders/MedicaidReimbursement/Pages/default.aspx), or the Iowa Medicaid Fee Schedule (located at: http://dhs.iowa.gov/ime/providers/csrp/fee-schedule). If there is a discrepancy between this policy and either the Michigan Medicaid Provider Manual (located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--00.html), the Illinois Medicaid Provider Manual (located at: http://www.illinois.gov/hfs/MedicalProviders/Handbooks/Pages/default.aspx), or the Iowa Medicaid Provider Manual (located at: http://dhs.iowa.gov/policy-manuals/medicaid-provider) the applicable Medicaid Provider Manual will govern.

For Medicare members, coverage is determined by the Centers for Medicare and Medicaid Services (CMS). If a coverage determination has not been adopted by CMS, this policy applies. Medicare Fee Schedules can be found on the CMS website (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FeeScheduleGenInfo/index.html).

For Exchange members, please refer to the Meridian Choice Certificate of Coverage located here: https://share13.mhplan.com/sites/communications/Bronson%20Healthcare/MCH%20Certificate%20of%20Coverage%202016.pdf. If there is a discrepancy between this policy and the Certificate of Coverage for Meridian Choice, the Certificate will govern.

| Approved by: |
|-----------------------------------------------|------------------|
| Corporate Chief Operating Officer: |
| Date: 04/21/2016 |

| Reviewed and approved by Medical Policy and Procedures Committee: |
|---------------------------------------------------------------|------------------|
| Date: 03/04/2016 |

| Reviewed and approved by Medical Policy Operations Committee: |
|---------------------------------------------------------------|------------------|
| Date: 03/11/2016 |

| Reviewed and approved by Physician Advisory Committee: |
|--------------------------------------------------------|------------------|
| Date: 03/25/2016 |

| Reviewed and approved by Corporate Compliance Committee: |
|----------------------------------------------------------|------------------|
| Date: 04/21/2016 |

References:

### State Letters/Bulletins

<table>
<thead>
<tr>
<th>CMS National/Local Coverage Determination (NCD/LCD)</th>
<th>NCD 20.29 Hyperbaric Oxygen Therapy (v.3, 06/2006)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare Managed Care Manual:</td>
<td></td>
</tr>
<tr>
<td>Medicaid CFR:</td>
<td>§270.4(A)</td>
</tr>
<tr>
<td>§270.5</td>
<td></td>
</tr>
<tr>
<td>State Administrative Codes:</td>
<td></td>
</tr>
<tr>
<td>Contract Requirements:</td>
<td></td>
</tr>
<tr>
<td>Related Policies:</td>
<td></td>
</tr>
</tbody>
</table>

### Appendix A

#### Cierny-Mader Staging System for Osteomyelitis

**Anatomic type**
- Stage 1: medullary osteomyelitis
- Stage 2: superficial osteomyelitis
- Stage 3: localized osteomyelitis
- Stage 4: diffuse osteomyelitis

**Physiologic class**
- A host: healthy
- B host:
  - Bs: systemic compromise
  - Bl: local compromise
  - Bls: local and systemic compromise
- C host: treatment worse than the disease

**Factors affecting immune surveillance, metabolism and local vascularity**
- Systemic factors (Bs): malnutrition, renal or hepatic failure, diabetes mellitus, chronic hypoxia, immune disease, extremes of age, immunosuppression or immune deficiency
- Local factors (Bl): chronic lymphedema, venous stasis, major vessel compromise, arteritis, extensive scarring, radiation fibrosis, small-vessel disease, neuropathy, tobacco abuse

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### Wagner Ulcer Classification System:

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<tr>
<th>Grade</th>
<th>Lesion</th>
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<tr>
<td>0</td>
<td>No open lesions; may have deformity or cellulitis</td>
</tr>
<tr>
<td>1</td>
<td>Superficial diabetic ulcer (partial or full thickness)</td>
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<tr>
<td>2</td>
<td>Ulcer extension to ligament, tendon, joint capsule, or deep fascia</td>
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<tr>
<td></td>
<td>without abscess or osteomyelitis</td>
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<tr>
<td>3</td>
<td>Deep ulcer with abscess, osteomyelitis, or joint sepsis</td>
</tr>
<tr>
<td>4</td>
<td>Gangrene localized to portion of forefoot or heel</td>
</tr>
<tr>
<td>5</td>
<td>Extensive gangrenous involvement of the entire foot</td>
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