



NATIONAL BAROMEDICAL SERVICES, INC.

August 25, 2008

James W. Cope, MD
Medical Director, Medicare Part A
National Government Services, Inc.
6775 W. Washington St.
Milwaukee, WI 53214-5644

Dear Dr. Cope:

I write to seek coding clarification related to your Local Coverage Determination for Hyperbaric Oxygen Therapy (HBO) (L25204).

Under 'Utilization Guidelines' #5(c) the last sentence reads '*Arterial insufficiency ulcers may be treated by HBO therapy if they are persistent after reconstructive surgery has restored large vessel function*'. In searching through the accompanying CPT/HCPCS codes listing I was unable to find ICD-9 code 440.23 'Atherosclerosis of the extremities with ulceration'.

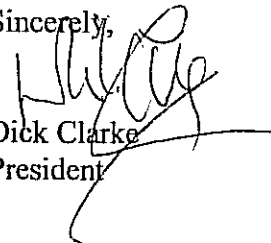
This may represent an oversight by NGS when this new indication (arterial insufficiency ulcer) was added to the 'Utilization Guidelines'. The nearest thing that I can find in your LCD is 444.22 'Arterial embolism and thrombosis of lower extremity'.

I fully recognize that using this latter code when submitting a claim for a refractory arterial insufficiency may lead to a denial. I respectfully request, therefore, that you add code 440.23, or advice how we might otherwise meet your coding expectations.

Enclosure

c. Sentara HBO MD Team
Sentara HBO Managers
Marcia Moore
Stacy Handley, ACHRN

Sincerely,



Dick Clarke
President



6775 West Washington Street
Milwaukee, Wisconsin 53214-5644
www.NGSMedicare.com

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October 29, 2008

Dick Clark
President
National Baromedical Services, Inc..
Five Richland Medical Park
Columbia, South Carolina 29203

Dear Mr. Clark,

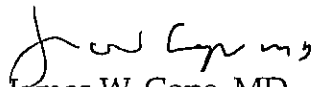
Thank you for your inquiry of August 25, 2008 regarding out LCD on Hyperbaric Oxygen (HBO) Therapy. I apologize for the delay in my response. Your letter requests the addition of the ICD-9-CM code 440.23, *Atherosclerosis of the extremities with ulceration*, to the list of covered diagnoses.

We will add the requested code to the LCD's list of covered diagnoses. Please note that the use of this code also requires the use of an additional code for any associated ulceration.

Please also be aware that the nationally covered indications have not changed. HBO is not indicated for ulcers / wounds that are the result of chronic peripheral vascular disease.

I hope I have adequately answered your question.

Sincerely,


James W. Cope, MD
Medical Director



Original Determination Effective Date

For services performed on or after 12/01/2007

Original Determination Ending Date**Revision Effective Date****Revision Ending Date****Indications and Limitations of Coverage and/or Medical Necessity****1. Abstract:**

This LCD is a clarification of the NCD as published in CMS Pub 100-3, *Medicare National Coverage Determinations Manual, Section 20.29*.

For purposes of coverage under Medicare, hyperbaric oxygen (HBO) therapy is a modality in which the entire body is exposed to oxygen under increased atmospheric pressure. The patient is entirely enclosed in a pressure chamber breathing 100% oxygen (O₂) at greater than one atmosphere (atm) pressure. Either a monoplace chamber pressurized with pure O₂ or a larger multiplace chamber pressurized with compressed air where the patient receives pure O₂ by mask, head tent, or endotracheal tube may be used.)

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.*

Developed as treatment for decompression illness, this modality is an established therapy for treating medical disorders such as carbon monoxide poisoning and gas gangrene. HBO is also considered acceptable in treating acute vascular compromise and as adjuvant therapy in the management of disorders that are refractory to standard medical and surgical care.

For outpatient settings other than Comprehensive Outpatient Rehabilitation Facilities

presents with severe and sudden pain at the infected area. The skin overlying the wound progresses from shiny and tense, to dusky, then bronze in color. The infection can progress as rapidly as six inches per hour. Hemorrhagic vesicles may be noted. A thin, sweet-odored exudate is present. Swelling and edema occur. The noncontractile muscles progress to dark red to black in color. The goal of HBO therapy is to stop alpha-toxin production thereby inhibiting further bacterial growth at which point the body can use its own host defense mechanisms. HBO treatment starts as soon as the clinical picture presents and is supported by a positive gram-stained smear. A treatment approach utilizing HBO, is adjunct to antibiotic therapy and surgery. Initial surgery may be limited to opening the wound. Debridement of necrotic tissue can be performed between HBO treatments when clear demarcation between dead and viable tissue is evident. The usual treatment consists of oxygen administered at 3.0 ATA pressure for 90 minutes three times in the first 24 hours. Over the next four to five days, treatment sessions twice a day are usual. The sooner HBO treatment is initiated, the better the outcome in terms of life, limb and tissue saving.

5. Crush injuries and suturing of severed limbs, acute traumatic peripheral ischemia (ATI), and acute peripheral arterial insufficiency associated with arterial embolism and thrombosis: Acute traumatic ischemia is the result of injury by external force or violence compromising circulation to an extremity. The extremity is then at risk for necrosis or amputation. Secondary complications are frequently seen: infection, non-healing wounds, and non-united fractures. The goal of HBO therapy is to enhance oxygen at the tissue level to support viability. When tissue oxygen tensions fall below 30mm Hg., the body's ability to respond to infection and wound repair is compromised. Using HBO at 2-2.4 ATA, the tissue oxygen tension is raised to a level such that the body's responses can become functional again. The benefits of HBO therapy for this indication are:
 - a. increased oxygen delivery per unit of blood flow or enhanced tissue oxygenation,
 - b. edema reduction and
 - c. reduction in the complication rates for infection, nonunion and amputation. The usual treatment schedule is three 1.5 hour treatment periods daily for the first 48 hours. Additionally, two 1.5 hour treatment sessions daily for the next 48 hours may be required. On the fifth and sixth days of treatment, one 1.5 hour session would typically be utilized. At this point in treatment, outcomes of restored perfusion, edema reduction and either demarcation or recovery would be sufficient to guide discontinuing further treatments. For acute traumatic peripheral ischemia, crush injuries and suturing of severed limbs, Hyperbaric Oxygen 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. Arterial insufficiency ulcers may be treated by HBO therapy if they are persistent after reconstructive surgery has restored large vessel function.
6. The principal treatment for progressive necrotizing infections (necrotizing fasciitis) is surgical debridement and systemic antibiotics. HBO therapy is recommended as an adjunct only in those settings where mortality and morbidity are expected to be high despite aggressive standard treatment. Progressive necrotizing fasciitis is a relatively rare infection. It is usually a