
Medicare Coverage Issues Manual

Department of Health &
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<u>HEADER SECTION NUMBERS</u>	<u>PAGES TO INSERT</u>	<u>PAGES TO DELETE</u>
35-10 – 35-13	4 pp.	4 pp.

NEW/REVISED MATERIAL--*EFFECTIVE DATE:* *April 1, 2003*
IMPLEMENTATION DATE: *April 1, 2003*

Section 35-10, Hyperbaric Oxygen Therapy. Hyperbaric oxygen therapy (HBO) is a modality in which the entire body is exposed to oxygen under increased atmospheric pressure. Based on evidence that we have reviewed, we are expanding coverage for the treatment of diabetic wounds of the lower extremities in patients who meet all of 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.

These instructions should be implemented within your current operating budget.

This revision to the Coverage Issues Manual is a national coverage decision (NCD). NCDs are binding on all Medicare carriers, intermediaries, peer review organization, Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans. Under 42 CFR 422.256 (b), an NCD that expands coverage is also binding on a Medicare+Choice Organization. In addition, an administrative law judge may not review an NCD. (See §1869 (f)(1)(A)(i) of the Social Security Act.)

DISCLAIMER: The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.

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in those areas of the world where it has been widely used, its mechanism is not known. Three units of the National Institutes of Health, the National Institute of General Medical Sciences, National Institute of Neurological Diseases and Stroke, and Fogarty International Center have been designed to assess and identify specific opportunities and needs for research attending the use of acupuncture for surgical anesthesia and relief of chronic pain. Until the pending scientific assessment of the technique has been completed and its efficacy has been established, Medicare reimbursement for acupuncture, as an anesthetic or as an analgesic or for other therapeutic purposes, may not be made. Accordingly, acupuncture is not considered reasonable and necessary within the meaning of §1862(a)(1) of the Act.

35-9 PHACO-EMULSIFICATION PROCEDURE - CATARACT EXTRACTION

In view of recommendations of authoritative sources in the field of ophthalmology, the subject technique is viewed as an accepted procedure for removal of cataracts. Accordingly, program reimbursement may be made for necessary services furnished in connection with cataract extraction utilizing the phaco-emulsification procedure.

35-10 HYPERBARIC OXYGEN THERAPY

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.

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:

1. Acute carbon monoxide intoxication, (ICD-9 -CM diagnosis 986).
2. Decompression illness, (ICD-9-CM diagnosis 993.2, 993.3).
3. Gas embolism, (ICD-9-CM diagnosis 958.0, 999.1).
4. Gas gangrene, (ICD-9-CM diagnosis 0400).
5. Acute traumatic peripheral ischemia. HBO therapy is an adjunctive treatment to be used in combination with accepted standard therapeutic measures when loss of function, limb, or life is threatened. (ICD-9-CM diagnosis 902.53, 903.01, 903.1, 904.0, 904.41.)
6. 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. (ICD-9-CM diagnosis 927.00- 927.03, 927.09-927.11, 927.20-927.21, 927.8-927.9, 928.00-928.01, 928.10-928.11, 928.20-928.21, 928.3, 928.8-928.9, 929.0, 929.9, 996.90- 996.99.)
7. Progressive necrotizing infections (necrotizing fasciitis), (ICD-9-CM diagnosis 728.86).
8. Acute peripheral arterial insufficiency, (ICD-9-CM diagnosis 444.21, 444.22, 444.81).
9. Preparation and preservation of compromised skin grafts (not for primary management of wounds), (ICD-9CM diagnosis 996.52; excludes artificial skin graft).
10. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management, (ICD-9-CM diagnosis 730.10-730.19).
11. Osteoradionecrosis as an adjunct to conventional treatment, (ICD-9-CM diagnosis 526.89).

12. Soft tissue radionecrosis as an adjunct to conventional treatment, (ICD-9-CM diagnosis 990).

13. Cyanide poisoning, (ICD-9-CM diagnosis 987.7, 989.0).

14. Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment, (ICD-9-CM diagnosis 039.0-039.4, 039.8, 039.9).

15. Diabetic wounds of the lower extremities in patients who meet the following three criteria:

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

b. Patient has a wound classified as Wagner grade III or higher; and

c. Patient has failed an adequate course of standard wound therapy.

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. Standard wound care in patients with diabetic wounds includes: assessment of a patient’s vascular status and correction of any vascular problems in the affected limb if possible, optimization of nutritional status, optimization of glucose control, debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, appropriate off-loading, and necessary treatment to resolve any infection that might be present. 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.

B. Noncovered Conditions.--All other indications not specified under §35-10 (A) are not covered under the Medicare program. No program payment may be made for any conditions other than those listed in §35-10(A).

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 disease, Alzheimer’s disease, 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. (Cross refer: §35-31.)

35-11 STERILIZATION

A. Covered Conditions.--

- o Payment may be made only where sterilization is a necessary part of the treatment of an illness or injury, e.g., removal of a uterus because of a tumor, removal of diseased ovaries
- o Sterilization of a mentally retarded beneficiary is covered if it is a necessary part of the treatment of an illness or injury. (bilateral oophorectomy), or bilateral orchidectomy in a case of cancer of the prostate. Deny claims when the pathological evidence of the necessity to perform any such procedures to treat an illness or injury is absent; and .

Monitor such surgeries closely and obtain the information needed to determine whether in fact the surgery was performed as a means of treating an illness or injury or only to achieve sterilization.

B. Noncovered Conditions.--

- o Elective hysterectomy, tubal ligation, and vasectomy, if the stated reason for these procedures is sterilization;
- o A sterilization that is performed because a physician believes another pregnancy would endanger the overall general health of the woman is not considered to be reasonable and necessary for the diagnosis or treatment of illness or injury within the meaning of §1862(a)(1) of the law. The same conclusion would apply where the sterilization is performed only as a measure to prevent the possible development of, or effect on, a mental condition should the individual become pregnant; and
- o Sterilization of a mentally retarded person where the purpose is to prevent conception, rather than the treatment of an illness or injury.

35-12 PLASTIC SURGERY TO CORRECT "MOON FACE"--NOT COVERED

The cosmetic surgery exclusion precludes payment for any surgical procedure directed at improving appearance. The condition giving rise to the patient's preoperative appearance is generally not a consideration. The only exception to the exclusion is surgery for the prompt repair of an accidental injury or for the improvement of a malformed body member which coincidentally serves some cosmetic purpose. Since surgery to correct a condition of "moon face" which developed as a side effect of cortisone therapy does not meet the exception to the exclusion, it is not covered under Medicare (§1862(a)(10) of the Act).

Cross refer: Intermediary Manual, §3160; Carriers Manual, §2329; Hospital Manual, §260.11.

35-13 PROLOTHERAPY, JOINT SCLEROTHERAPY, AND LIGAMENTOUS INJECTIONS WITH SCLEROSING AGENTS--NOT COVERED

The medical effectiveness of the above therapies has not been verified by scientifically controlled studies. Accordingly, reimbursement for these modalities should be denied on the ground that they are not reasonable and necessary as required by §1862(a)(1) of the law.

35-14 CONSULTATIONS WITH A BENEFICIARY'S FAMILY AND ASSOCIATES

In certain types of medical conditions, including when a patient is withdrawn and uncommunicative due to a mental disorder or comatose, the physician may contact relatives and close associates to secure background information to assist in diagnosis and treatment planning. When a physician contacts his patient's relatives or associates for this purpose, expenses of such interviews are properly chargeable as physician's services to the patient on whose behalf the information was secured. If the beneficiary is not an inpatient of a hospital, Part B reimbursement for such an interview is subject to the special limitation on payments for physicians' services in connection with mental, psychoneurotic, and personality disorders.

A physician may also have contacts with a patient's family and associates for purposes other than securing background information. In some cases, the physician will provide counseling to members of the household. Family counseling services are covered only where the primary purpose of such counseling is the treatment of the patient's condition. For example, two situations where family counseling services would be appropriate are as follows: (1) where there is a need to observe the patient's interaction with family members; and/or (2) where there is a need to assess the capability of and assist the family members in aiding in the management of the patient. Counseling principally concerned with the effects of the patient's condition on the individual being interviewed would not be reimbursable as part of the physician's personal services to the patient. While to a limited degree, the counseling described in the second situation may be used to modify the behavior of the family members, such services nevertheless are covered because they relate primarily to the management of the patient's problems and not to the treatment of the family member's problems.