Medicare Coverage Issues Manual

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

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REFER TO: CHANGE REQUEST 1005

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
Table of Contents	2 pp.	2 pp.
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NEW/REVISED MATERIAL--*EFFECTIVE DATE:* January 1, 2001
***IMPLEMENTATION DATE:* January 1, 2001**

Section 35-90, Extracorporeal Immunoadsorption (ECI) Using Protein A Columns, is revised to provide coverage of this treatment for patients with severe active rheumatoid arthritis.

For this service use the recently issued national code:

CPT 36521 Therapeutic apheresis; plasma and/or cell exchange with extracorporeal affinity column adsorption and plasma reinfusion.

The corresponding ICD-9-CM codes are:

287.3 -- Primary thrombocytopenia
714.0 -- Rheumatoid arthritis
714.1 -- Felty's syndrome
714.2 -- Other rheumatoid arthritis with visceral or systemic involvement
714.30, 714.31, 714.32, and 714.33 -- Types of juvenile rheumatoid arthritis

These instructions should be implemented within your current operating budget.

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.

This section of the Coverage Issues Manual is a national coverage decision made under §1862(a)(1) of the Social Security Act (the Act). National coverage determinations (NCDs) are binding on all Medicare carriers, fiscal intermediaries, Peer Review Organizations, and other contractors. 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 disregard, set aside, or otherwise review a national coverage decision issued under §1862(a)(1) of the Act. (42 CFR 405.732, 405.860.)

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COVERAGE ISSUES

Diagnostic Services

35-89 SPEECH PATHOLOGY SERVICES FOR THE TREATMENT OF DYSPHAGIA (Effective for services performed on and after 08/28/89)

Dysphagia is a swallowing disorder that may be due to various neurological, structural, and cognitive deficits. Dysphagia may be the result of head trauma, cerebrovascular accident, neuromuscular degenerative diseases, head and neck cancer, and encephalopathies. While dysphagia can afflict any age group, it most often appears among the elderly. Speech pathology services are covered under Medicare for the treatment of dysphagia, regardless of the presence of a communication disability.

Patients who are motivated, moderately alert, and have some degree of deglutition and swallowing functions are appropriate candidates for dysphagia therapy. Elements of the therapy program can include thermal stimulation to heighten the sensitivity of the swallowing reflex, exercises to improve oral-motor control, training in laryngeal adduction and compensatory swallowing techniques, and positioning and dietary modifications. Design all programs to ensure swallowing safety of the patient during oral feedings and maintain adequate nutrition.

Cross-refer: Intermediary Manual, §3101.l0A; Carriers Manual, §2216; Hospital Manual, §210.11; Home Health Agency Manual, §205.2C.; Skilled Nursing Facility Manual, §230.3B.; Outpatient Physical Therapy and Comprehensive Outpatient Rehabilitation Facility Manual, §205.6.

35-90 EXTRACORPOREAL IMMUNOADSORPTION (ECI) USING PROTEIN A COLUMNS

Extracorporeal immunoadsorption (ECI), using Protein A columns, has been developed for the purpose of selectively removing circulating immune complexes (CIC) and immunoglobulins (IgG) from patients in whom these substances are associated with their diseases. The technique involves pumping the patient's anticoagulated venous blood through a cell separator from which 1-3 liters of plasma are collected and perfused over adsorbent columns, after which the plasma rejoins the separated, unprocessed cells and is retransfused to the patient.

For claims with dates of service on or after January 1, 2001, Medicare covers the use of Protein A columns for the treatment of ITP. In addition, Medicare will cover Protein A columns for the treatment of rheumatoid arthritis (RA) under the following conditions:

1. Patient has severe RA. Patient disease is active, having > 5 swollen joints, > 20 tender joints, and morning stiffness > 60 minutes.

2. Patient has failed an adequate course of a minimum of 3 Disease Modifying Anti-Rheumatic Drugs (DMARDs). Failure does not include intolerance.

Other uses of these columns are currently considered to be investigational and, therefore, not reasonable and necessary under the Medicare law. (See §1862(a)(1)(A) of the Act.)

35-91 LAPAROSCOPIC CHOLECYSTECTOMY (Effective for services performed on and after November 18, 1991)

Laparoscopic cholecystectomy is a covered surgical procedure in which a diseased gall bladder is removed through the use of instruments introduced via cannulae, with vision of the operative field maintained by use of a high-resolution television camera-monitor system (video laparoscope). For inpatient claims, use ICD-9-CM code 51.23, Laparoscopic cholecystectomy. For all other claims, use CPT codes 49310 for laparoscopy, surgical; cholecystectomy (any method), and 49311 for laparoscopy, surgical: cholecystectomy with cholangiography.

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35-92 TRANSCENDENTAL MEDITATION - NOT COVERED

Transcendental meditation (TM) is a skill that is claimed to produce a state of rest and relaxation when practiced effectively. Typically, patients are taught TM techniques over the course of several sessions by persons trained in TM. The patient then uses the TM technique on his or her own to induce the relaxed state. Proponents of TM have urged that Medicare cover the training of patients to practice TM when it is medically prescribed as treatment for mild hypertension, as adjunctive therapy in the treatment of essential hypertension, or as the sole or adjunctive treatment of anxiety and other psychological stress-related disorders.

After review of this issue, HCFA has concluded that the evidence concerning the medical efficacy of TM is incomplete at best and does not demonstrate effectiveness and that a professional level of skill is not required for the training of patients to engage in TM.

Although many articles have been written about application of TM for patients with certain forms of hypertension and anxiety, there are no rigorous scientific studies that demonstrate the effectiveness of TM for use as an adjunct medical therapy for such conditions. Accordingly, neither TM nor the training of patients for its use are covered under the Medicare program.

35-93 LUNG VOLUME REDUCTION SURGERY (REDUCTION PNEUMOPLASTY, ALSO CALLED LUNG SHAVING OR LUNG CONTOURING) UNILATERAL OR BILATERAL BY OPEN OR THORACOSCOPIC APPROACH FOR TREATMENT OF EMPHYSEMA OR CHRONIC OBSTRUCTIVE PULMONARY DISEASE - NOT GENERALLY COVERED

Lung volume reduction surgery (LVRS) or reduction pneumoplasty, also referred to as lung shaving or lung contouring, is performed on patients with emphysema and chronic obstructive pulmonary disease (COPD) in order to allow the underlying compressed lung to expand, and thus, establish improved respiratory function. The goal of this procedure is to offer a better quality of life for patients with emphysema and COPD. In addition, LVRS may be offered as a "bridge to transplant" for patients who otherwise may not have been considered candidates for lung transplantation.

Unilateral or bilateral LVRS by open or thoracoscopic approach is not generally covered, because there is insufficient medical evidence available to base a determination that this procedure is generally safe and effective. Therefore, LVRS generally cannot be considered reasonable and necessary under §1862(a)(1)(A) of the Act in most cases.

When this policy was first established in December 1995, HCFA committed Medicare to reviewing the scientific literature as it was published in order to modify coverage policy as clinical data were developed. HCFA has reviewed data that suggest the need for a randomized clinical trial regarding the safety and effectiveness of LVRS. On April 24, 1996, the Health Care Financing Administration (HCFA) and the National Heart, Lung and Blood Institute (NHLBI) of the National Institutes of Health announced their intention to collaborate on a multi-center, randomized clinical study evaluating the effectiveness of LVRS. On December 20, 1996, HCFA and NHLBI announced the clinical centers and the data coordinating center that will be participating in the study. HCFA has determined that LVRS is reasonable and necessary when it is provided under the conditions detailed by the protocol of the HCFA/NHLBI clinical study. Therefore, Medicare will cover LVRS in those limited circumstances when it is provided to a Medicare beneficiary under the protocols established for the study. Coverage will be provided where the care is furnished in facilities that are approved as meeting the criteria established by HCFA and NHLBI for this study.

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