COMPLETE GUIDE TO
MEDICARE COVERAGE ISSUES

A REFERENCE TO COVERED AND NONCOVERED SERVICES
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Final Decision Made Regarding Coverage of Autologous Platelet-rich Plasma

After the third reconsideration of section 270.3 of the National Coverage Determination Manual, CMS announced the agency’s final decision pertaining to the coverage of autologous platelet-rich plasma (PRP) for patients with chronic non-healing diabetic, pressure, and venous wounds—but only when the patient is enrolled in a clinical research study meeting strict requirements.

Autologous PRP is comprised of blood from the patient who will receive the PRP. The patient donates blood, which is then centrifuged to produce an autologous gel to treat chronic, non-healing wounds that fail to heal after 30 or more days. It contains whole cells including white cells, red cells, plasma, platelets, fibrinogen, stem cells, macrophages, and fibroblasts.

After the extensive review, the agency has made the decision to cover the treatment when the patient is enrolled in a clinical research study that addresses the following questions using validated and reliable methods of evaluation. Applications for a clinical study must be received by August 2, 2014. The clinical research study must address:

Prospectively, do Medicare beneficiaries with chronic non-healing diabetic, pressure, and/or venous wounds receiving well-defined optimal usual care along with PRP therapy experience clinically significant health outcomes as compared to patients receiving well-defined optimal usual care for chronic non-healing diabetic, pressure, and/or venous wounds as indicated by addressing at least one of the following:

– Complete healing of the wound  
– Ability to resume normal functions and activities  
– Reduction of wound size or healing trajectory resulting in the patient being able to resume normal functions and activities

PRP studies are required to comply with the following standards of scientific integrity and relevance to the Medicare population:

– The principal purpose of the study is to test whether PRP improves the participants’ health outcomes.  
– The study is well supported by available scientific and medical information or intended to clarify or establish the health outcomes of interventions already in use.  
– The study does not duplicate existing studies.  
– The study design is appropriate for the research question being asked.  
  – The study is sponsored by an organization or individual capable of performing it successfully.  
  – The study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46.  
  – All aspects of the study are conducted according to appropriate standards of scientific integrity set by the International Committee of Medical Journal Editors (http://www.icmje.org).  
  – The study has a written protocol addressing or incorporating by reference, the standards listed here as Medicare requirements for coverage with evidence development (CED).  
  – The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.  
  – The study is registered on the ClinicalTrials.gov website by the principal sponsor/investigator before the first study subject is enrolled.
Thoracic electrical bioimpedance (TEB) devices, a form of plethysmography, monitor cardiac output by noninvasively measuring hemodynamic parameters, including stroke volume, systemic vascular resistance, and thoracic fluid status. Under a previous coverage determination, effective for services performed on and after July 1, 1999, use of TEB was covered for the "noninvasive diagnosis or monitoring of hemodynamics in patients with suspected or known cardiovascular disease." In reconsidering this policy, the Centers for Medicare and Medicaid Services (CMS) concluded that this use was neither sufficiently defined nor supported by available clinical literature to offer the guidance necessary for practitioners to determine when TEB would be covered for patient management. Therefore, CMS revised its coverage policy language in response to a request for reconsideration to offer more explicit guidance and clarity for coverage of TEB based on complete updated literature review.

1. Differentiation of cardiogenic from pulmonary causes of acute dyspnea when medical history, physical examination, and standard assessment tools provide insufficient information, and the treating physician has determined that TEB hemodynamic data are necessary for appropriate management of the patient.
2. Optimization of atrioventricular (A/V) interval for patients with A/V sequential cardiac pacemakers when medical history, physical examination, and standard assessment tools provide insufficient information, and the treating physician has determined that TEB hemodynamic data are necessary for appropriate management of the patient.
3. Monitoring of continuous inotropic therapy for patients with terminal congestive heart failure, when those patients have chosen to die with comfort at home, or for patients waiting at home for a heart transplant.
4. Evaluation for rejection in patients with a heart transplant as a predetermined alternative to a myocardial biopsy. Medical necessity must be documented should a biopsy be performed after TEB.
5. Optimization of fluid management in patients with congestive heart failure when medical history, physical examination, and standard assessment tools provide insufficient information, and the treating physician has determined that TEB hemodynamic data are necessary for appropriate management of the patient.

NCD 20.16—Cardiac Output Monitoring by Thoracic Electrical Bioimpedance (TEB) (formerly CIM 50-54)

93701

Effective Date: November 24, 2006
Implementation Date: January 16, 2007
Benefit Category: Diagnostic Tests (other)
Lab Services

Item/Service Description

A. General
Thoracic electrical bioimpedance (TEB) devices, a form of plethysmography, monitor cardiac output by noninvasively measuring hemodynamic parameters, including stroke volume, systemic vascular resistance, and thoracic fluid status. Under a previous coverage determination, effective for services performed on and after July 1, 1999, use of TEB was covered for the "noninvasive diagnosis or monitoring of hemodynamics in patients with suspected or known cardiovascular disease." In reconsidering this policy, the Centers for Medicare and Medicaid Services (CMS) concluded that this use was neither sufficiently defined nor supported by available clinical literature to offer the guidance necessary for practitioners to determine when TEB would be covered for patient management. Therefore, CMS revised its coverage policy language in response to a request for reconsideration to offer more explicit guidance and clarity for coverage of TEB based on complete updated literature review.

Indications and Limitations of Coverage

1. Nationally Covered Indications
Effective for services performed on and after January 23, 2004, TEB is covered for the following uses:

   a. With proven or suspected disease in the aorta;
   b. With minute ventilation (MV) sensor function pacemakers, since the device may adversely affect the functioning of that type of pacemaker;
   c. During cardiac bypass surgery; or
   d. In the management of all forms of hypertension (with the exception of drug-resistant hypertension as outlined above).

2. All other uses of TEB not otherwise specified remain noncovered.

D. Other

Contractors have discretion to determine whether the use of TEB for the management of drug-resistant hypertension is reasonable and necessary. Drug resistant hypertension is defined as failure to achieve goal blood pressure in patients who are adhering to full doses of an appropriate 3-drug regimen that includes a diuretic. Effective November 24, 2006, after reconsideration of Medicare policy, CMS will continue current Medicare policy for TEB.

Revision History
08/1989—Excluded from coverage. Effective date 08/25/1989. (TN 38)
04/1999—Limited coverage for six uses. Contractors may cover additional uses when they believe there is sufficient evidence of medical effectiveness of such uses. Effective date 07/01/1999. (TN 109) (CR 827)
However, the CP must be legally authorized to perform the services under applicable licensure laws of the State in which they are furnished.

C. Types of Clinical Psychologist Services That May Be Covered

The CPs may provide the following services:

- Diagnostic and therapeutic services that the CP is legally authorized to perform in accordance with State law and/or regulation. Carriers pay all qualified CPs based on the physician fee schedule for the diagnostic and therapeutic services. (Psychological tests by practitioners who do not meet the requirements for a CP may be covered under the provisions for diagnostic tests as described in sec. 80.2.

Services and supplies furnished incident to a CP’s services are covered if the requirements that apply to services incident to a physician’s services, as described in sec. 60 are met. These services must be:

- Mental health services that are commonly furnished in CPs’ offices;
- An integral, although incidental, part of professional services performed by the CP;
- Performed under the direct personal supervision of the CP; i.e., the CP must be physically present and immediately available;
- Furnished without charge or included in the CP’s bill;
- Performed by an employee of the CP (or an employee of the legal entity that employs the supervising CP) under the common law control test of the Act, as set forth in 20 CFR 404.1007 and sec. RS 2101.020 of the Retirement and Survivors Insurance part of the Social Security Program Operations Manual System; and
- Diagnostic psychological testing services when furnished under the general supervision of a CP.

Carriers are required to familiarize themselves with appropriate State laws and/or regulations governing a CP’s scope of practice.

D. Noncovered Services

The services of CPs are not covered if the service is otherwise excluded from Medicare coverage even though a clinical psychologist is authorized by State law to perform them. For example, sec. 1862(a)(1)(A) of the Act excludes from coverage services that are not “reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member.” Therefore, even though the services are authorized by State law, the services of a CP that are determined to be not reasonable and necessary are not covered. Additionally, any therapeutic services that are billed by CPs under CPT psychotherapy codes that include medical evaluation and management services are not covered.

E. Requirement for Consultation

When applying for a Medicare provider number, a CP must submit to the carrier a signed Medicare provider/supplier enrollment form that indicates an agreement to the effect that, contingent upon the patient’s consent, the CP will attempt to consult with the patient’s attending or primary care physician in accordance with accepted professional ethical norms, taking into consideration patient confidentiality.

If the patient assents to the consultation, the CP must attempt to consult with the patient’s physician within a reasonable time after receiving the consent. If the CP’s attempts to consult directly with the physician are not successful, the CP must notify the physician within a reasonable time that he or she is furnishing services to the patient. Additionally, the CP must document, in the patient’s medical record, the date the patient consented or declined consent to consultations, the date of consultation, or, if attempts to consult did not succeed, that date and manner of notification to the physician.

The only exception to the consultation requirement for CPs is in cases where the patient’s primary care or attending physician refers the patient to the CP. Also, neither a CP nor a primary care nor attending physician may bill Medicare or the patient for this required consultation.

F. Outpatient Mental Health Services Limitation

All covered therapeutic services furnished by qualified CPs are subject to the outpatient mental health services limitation in Pub. 100-1, Medicare General Information, Eligibility, and Entitlement Manual, Chapter 3, “Deductibles, Coinsurance Amounts, and Payment Limitations,” sec. 30, (i.e., only 62 1/2 percent of expenses for these services are considered incurred expenses for Medicare purposes). The limitation does not apply to diagnostic services.

G. Assignment Requirement

Assignment is required.

170—Clinical Social Worker (CSW) Services

(Rev. 1, 10-01-03)

Cross-reference: Medicare Carriers Manual 2152

See the Medicare Claims Processing Manual Chapter 12, Physician/Nonphysician Practitioners, sec. 150, “Clinical Social Worker Services,” for payment requirements.

A. Clinical Social Worker Defined

Section 1861(hh) of the Act defines a “clinical social worker” as an individual who:

- Possesses a master’s or doctor’s degree in social work;
- Has performed at least two years of supervised clinical social work; and
- Is licensed or certified as a clinical social worker by the State in which the services are performed; or
- In the case of an individual in a State that does not provide for licensure or certification, has completed at least 2 years or 3,000 hours of post master’s degree supervised clinical social work practice under the supervision of a master’s level social worker in an appropriate setting such as a hospital, SNF, or clinic.

B. Clinical Social Worker Services Defined

Section 1861(hh)(2) of the Act defines “clinical social worker services” as those services that the CSW is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are performed for the diagnosis and treatment of mental illnesses.

Services furnished to an inpatient of a hospital or an inpatient of a SNF that the SNF is required to provide as a requirement for participation are not included. The services that are covered are those that are otherwise covered if furnished by a physician or as incident to a physician’s professional service.

C. Covered Services

Coverage is limited to the services a CSW is legally authorized to perform in accordance with State law (or State regulatory mechanism established by State law). The services of a CSW may be covered under Part B if they are:

- The type of services that are otherwise covered if furnished by a physician, or as incident to a physician’s service. (See sec. 30 for a description of physicians’ services and sec. 70 of Pub. 100-1, the Medicare General Information, Eligibility, and Entitlement Manual, Chapter 5, for the definition of a physician.);
- Performed by a person who meets the definition of a CSW (See subsection A.); and
- Not otherwise excluded from coverage.