UNPROVEN DEVICES, MEDICAL TREATMENT, AND PROCEDURES

I. POLICY

A. TRICARE/CHAMPUS regulations and program policies restrict benefits to those devices, treatments, or procedures for which the safety and efficacy have been proven to be comparable or superior to conventional therapies. Any device, medical treatment, or procedure whose safety and efficacy has not been established is unproven. Services and supplies considered to be unproven are excluded from coverage.

B. This exclusion includes all services directly related to the unproven device, medical treatment, or procedure. Treatment that is related to an unproven device, medical treatment, or procedure can be divided into three categories:

1. Treatment that is specifically related to the unproven device, medical treatment, or procedure because it is an integral part of it;

2. Treatment that is not related to the unproven device, medical treatment, or procedure; e.g., medically necessary in the absence of the unproven treatment;

3. Treatment which is a necessary follow-up to the unproven device, medical treatment, or procedure, but which might have been necessary in the absence of the unproven treatment.

II. POLICY CONSIDERATIONS

A. The following is a partial list of devices, medical treatments, and procedures considered to be unproven. These are excluded from benefits. The list is not all inclusive. Other unproven devices, medical treatments, and procedures are similarly excluded, although they do not appear on this partial list. The codes listed have been associated with the respective unproven device, medical treatment, or procedure but may also be used for other applications which are not unproven. The listing of the procedure codes is for contractors to use in screening for unproven as opposed to proven application. The date listed with each device, medical treatment, or procedure indicates the date TRICARE Management Activity (TMA) reviewed the most recent literature to determine whether the device, medical treatment, or procedure should remain on the unproven list.
B. In making the determination that a device, medical treatment, or procedure has moved from the status of unproven to the position of nationally accepted medical practice, TMA uses the following hierarchy of reliable evidence:

1. Well controlled studies of clinically meaningful endpoints, published in refereed medical literature.

2. Published formal technology assessments.

3. The published reports of national professional medical associations.

4. Published national medical policy organization positions.

5. The published reports of national expert opinion organizations.

C. With respect to clinical studies, only those reports and articles containing scientifically valid data and published in the refereed medical and scientific literature shall be considered as meeting the requirements of reliable evidence. Specifically not included in the meaning of reliable evidence are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence or personal professional opinions. Also not included is the fact that a provider or a number of providers have elected to adopt a device, medical treatment or procedure as their personal treatment or procedure of choice or standard of practice.

D. TRICARE Policy and benefit structure are never based solely on coverage offered by other third party payers, including Medicare, since each operates under different rules and requirements.

E. This partial list will be reviewed and updated periodically as new information becomes available. With respect to any device, medical treatment or procedure included on this partial list, if and when TMA determines that based on reliable evidence such device, medical treatment or procedure has proven medical effectiveness, TMA will initiate action to remove the device, medical treatment or procedure from this partial list of unproven devices, medical treatments or procedures. From the date established by TMA as the date the device, medical treatment or procedure has established proven medical effectiveness until the date the regulatory change is made to remove the device, medical treatment or procedure from the partial list, TMA will suspend treatment of the device, medical treatment or procedure as unproven. Following is the partial list of unproven devices, medical treatments or procedures, all of which are excluded from benefits:


3. Allogeneic bone marrow transplantation for:

d. Hodgkin’s disease. This does not include syngeneic stem cell transplantation which is considered proven for the treatment of Hodgkin’s disease. May 1998.

4. Allogeneic donor bone marrow transplantation (infusion) performed with or after organ transplants for the purpose of increasing tolerance of the organ transplant. (See Chapter 3, Section 6.1.) December 1996.


7. Amniocentesis performed for ISO immunization to the ABO blood antigens. (See Chapter 3, Section 13.3.) June 1996.


17. Calcium EAP/calcium orotate and selenium (also known as Nieper therapy) - Involves inpatient care and use of calcium compounds and other non-FDA approved drugs and special diets. Used for cancer, heart disease, diabetes, multiple sclerosis -- Not a proven treatment for any indication. June 1996.

18. Services related to the candidiasis hypersensitivity syndrome, yeast syndrome, or gastrointestinal candidiasis are unproven (i.e., allergenic extracts of Candida albicans for immunotherapy and/or provocation/neutralization). Disseminated systemic candidiasis (ICD-9-CM 112.5) is a recognized diagnosis, and medically necessary treatment is covered. December 5, 1996.

20. Carotid Body Resection, both unilateral and bilateral, when done solely to relieve the symptoms of pulmonary dyspnea, including chronic obstructive pulmonary disease, is considered unproven. October 1996.


23. Cervicography. While it shows promise as a screening procedure when used in conjunction with the pap smear, additional studies are needed before it’s considered beyond the unproven state.

24. Chelation therapy, except under specific conditions. (See Chapter 1, Section 11.3.) August 1996.


27. Cognitive rehabilitation services that are prescribed specifically and uniquely to teach compensatory methods to accomplish tasks which rely upon cognitive processes.


31. Dorsal column and deep brain electrical stimulation for treatment of motor function disorders. (See Chapter 3, Section 15.5.) August 1996.

32. Dorsal root entry zone (DREZ) thermocoagulation or microcoagulation neurosurgical procedure. August 1996.


39. Extracorporeal immunoabsorption using Protein A Columns is investigational in the treatment of disease process other than idiopathic thrombocytopenic purpura (ITP). See Chapter 3, Section 5.8 June 1996.

40. Extraoperative electrocorticography for stimulation and recording in order to determine electrical thresholds of neurons as an indicator of seizure focus. (See also Chapter 1, Section 22.4.) December 1996.


42. Fetal tissue transplantation for movement disorders (including Parkinson’s disease). July 1996.

43. Gait analysis (also known as a walk study or electrodynogram). (See Chapter 1, Section 25.1.) May 1995.

44. Gastric bubble or balloon. July 1996.

45. Gastric wrapping/gastric banding. October 1996.

46. Growth factor, including platelet-derived growth factors, for treating non-healing wounds. This includes Procuren®, a platelet-derived wound-healing formula. January 1997.

47. Hair analysis to identify mineral deficiencies from the chemical composition of hair is unproven. Hair analysis testing may be reimbursed when necessary to determine lead poisoning. January 1997.


49. High dose chemotherapy with stem cell rescue (HDC/SCR) for any of the following malignancies:
   
   
   
   
   
   

51. Holding therapy - Involves holding the patient in an attempt to achieve interpersonal contact, and to improve the patient's ability to concentrate on learning tasks. June 1996.

52. Home uterine activity monitoring for the purpose of preventing pre-term labor and/or delivery. Please reference Chapter 3, Section 13.2, Maternity Care. February 1997.


54. Hyperbaric oxygen therapy for treatment or complications of peripheral vascular disease. October 1996.


57. Immunotherapy for malignant disease except when using drugs approved by the FDA for this purpose. July 1996.

58. Implantable infusion pumps, except as authorized in Chapter 3, Section 5.5. See Chapter 7, Section 3.10 for policy concerning external infusion pumps. August 1996.


61. Intraoperative monitoring of sensory evoked potentials (SEP) to define conceptional or gestational age in pre-term infants. October 1996.


67. Light therapy for Seasonal Depression (also known as seasonal affective disorder (SAD)). - This therapy uses varying degrees of light to treat depression. July 1996.

69. Magnetic Resonance Angiography for indications other than those specifically listed in Chapter 4, Section 2.1, paragraph III.C. October 1995.


71. Muscle resection for severe Parkinsonian tremor, intention tremor, or dystonia.


75. All organ transplants except heart, heart-lung, lung, kidney, some bone marrow, liver, liver-kidney, pancreas-kidney, small intestine, small intestine-liver, multivisceral, heart-kidney, corneal, and heart-valve (subject to the provisions of 32 CFR 199.4(e)(5)). February 1998.

76. Orthoptics, also known as eye exercises, eye therapy, training, vision therapy, vision training. January 1996.

   NOTE: Orthoptics are excluded by 32 CFR 199.4(g)(46).


79. Peri-urethral Teflon injections to manage urinary incontinence.

80. Photopheresis for indications other than for treatment of skin manifestations of cutaneous T-cell lymphoma (CTCL) (see Chapter 3, Section 5.7) in persons who have not been responsive to other forms of treatment. May 1998.


82. Portable nocturnal hypoglycemia detectors. August 1996.


86. Pulmonary rehabilitation, except as authorized in Chapter 3, Section 1.6B. See Chapter 1, Section 20.1 for policy concerning pulmonary services. September 1996.


90. Rhizotomy for Parkinsonian tremor, intention tremor, or dystonia.

91. Selective peripheral denervation for severe Parkinsonian tremor, intention tremor, or dystonia.

92. Sensory afferent stimulation (SAS) devices for relief of nausea (e.g., Relief Band®). August 1996.

93. Sensory evoked potentials (SEP) monitoring of the sciatic nerve during total hip replacement. SEP for monitoring simple laminectomies or other spinal procedures which are not considered to be a significant risk to the spinal cord. Recording SEPs in unconscious head injured patients to assess the status of the somatosensory system. The use of SEPs to define conceptional or gestational age in pre-term infants. April 1997.


96. Small intestinal bypass (jejunoileal bypass) for treatment of morbid obesity - (CPT 44131).

97. Sperm evaluation, Hamster penetration test (CPT-4 code 89329).

98. Spinoscopy. Use of a Spinoscope with skin markers to assess the function of the spine. CPT codes 95999 and 97799 have been used. August 1996.

99. Stem Cell Assay, Differential Staining Cytoxicity (Disc) Assay and Thymidine Incorporation Assay. Laboratory procedures to predict the type and dose of cancer chemotherapy drugs to be used, based on in vitro analysis of their effects on cancer cells taken from an individual. The efficacy of these tests is not established by scientific data and does not reflect standard laboratory procedures provided in the United States. July 1996.
100. Stereotactic Cingulotomy. August 1996.


103. Test of Variable of Attention (TOVA®) for diagnosing Attention Deficit Hyperactivity disorder and titrating pharmacotherapy levels. September 1997.


106. Topical Application of Oxygen. The clinical efficacy of oxygen by topical application has not been established and is considered unproven. August 1996.

107. Topographic brain mapping (TBM) procedure. "Brain mapping" performed from the surface of the scalp rather than from the surface of the brain or from deeper structures in the brain using indwelling electrodes. (For information concerning functional cortical mapping (CPT 95961-95962) see Chapter 1, Section 22.7). February 1997.

108. Transcatheter hepatic arterial embolization for the treatment of cancers that have metastasized to the liver, unresectable hepatocellular carcinoma and resectable hepatocellular carcinoma. June 1997.

109. Transcervical block silicone plug. (See Chapter 7, Section 4.2.) June 1996.


111. Transfer factor (TF). This is a dialyzable leukocyte extract (DLE) used to transfer delayed hypersensitivity from an immune to a nonimmune subject and is considered unproven. December 1989.

112. Transjugular Intrahepatic Portosystemic Shunt (TIPS) as initial therapy for acute or recurrent esophageal variceal bleeding, as treatment of refractory ascites, Budd-Chiari syndrome, hepatorenal syndrome, gastric variceal bleeding and preoperative portal decompression to facilitate liver transplantation. July 1997.


118. Vestibular rehabilitation therapy used to treat benign paroxysmal positional vertigo. February 1997.

119. Videofluoroscopy evaluation in speech pathology.


III. EXCEPTIONS

A. Cost-sharing may be allowed for services or supplies when there is no logical or casual relationship between the unproven device, treatment, or procedure and the treatment at issue or where such a logical or causal relationship cannot be established with a sufficient degree of certainty. This cost-sharing is authorized in the following circumstances:

1. Treatment that is not related to the unproven device, treatment, or procedure: e.g., medically necessary treatment the beneficiary would have received in the absence of the unproven device, treatment, or procedure.

2. Treatment which is necessary follow-on to the unproven device, treatment, or procedure but which might have been necessary in the absence of the unproven treatment.

B. When it is questionable whether or not certain services or supplies are related to unproven devices, treatments, or procedures, claims will be sent to Medical Review for determination.

C. Currently, high dose chemotherapy with stem cell rescue (HDC/SCR) is considered to be unproven for the treatment of ovarian and testicular cancer. A demonstration project is being conducted wherein the DoD will participate in breast cancer treatment clinical trials under approved National Cancer Institute (NCI) protocols for high dose chemotherapy with stem cell rescue (HDC/SCR). Refer to the OPM Part Two, Chapter 20, Section II.D., for additional information regarding the demonstration project.

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