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CHAMPVA POLICY MANUAL

CHAPTER: 2
SECTION: 16.5
TITLE: **EXPERIMENTAL/INVESTIGATIONAL (UNPROVEN) PROCEDURES**

AUTHORITY: 38 CFR 17.270(a) and 17.272 (a)(14)

RELATED AUTHORITY: 32 CFR 199.4(g)(15)

I. EFFECTIVE DATE

November 1, 1983

II. POLICY

A. Benefits are restricted 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, supply or procedure whose safety and efficacy has not been established and proven is considered experimental/investigational (unproven) and is excluded from coverage.

B. Exclusions include all services directly related to the experimental/investigational (unproven) device, medical treatment, or procedure.

C. 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 a necessary follow-up to the unproven device, treatment, or procedure, which may have been necessary in the absence of the unproven treatment.

3. When it is questionable whether or not certain services or supplies are related to experimental/investigational (unproven) device, treatment, or procedures, claims will be sent for a medical review determination.

D. In making the determination that a device, medical treatment, or procedure has moved from the status of experimental/investigational (unproven) to the position of nationally accepted medical practice, the following hierarchy of reliable evidence is used.

1. Well-controlled studies of clinically meaningful endpoints, published in referenced 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.

E. With respect to clinical studies, only those reports and articles containing scientifically valid data and published in the referred medical and scientific literature shall be considered 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.

III. POLICY CONSIDERATIONS

A. The following is a partial list of devices, medical treatment, and procedures considered to be experimental/investigational (unproven). These are excluded benefits. The list is not all-inclusive and there are many other experimental/investigational (unproven) devices, medical treatments, and procedures that do not appear on this partial list. The codes listed in this policy are associated with the respective experimental/investigational (unproven) devices, medical treatments, and procedures but may also be used for other applications that are not investigational/experimental (unproven). The listing of procedure codes is for claims processors to use in screening for experimental/investigational (unproven) as opposed to proven applications. The date listed with each device, medical treatment, or procedure indicates the date the most recent literature was reviewed to determine whether the device, medical treatment, or procedure should remain on the experimental/investigational (unproven) list.

B. 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.

C. 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 it is determined that based on reliable evidence such devices, medical treatment, or procedure has proven medical effectiveness, action will be initiated to remove the device, medical treatment, or procedure from this partial list of experimental/investigational (unproven) devices, medical treatments, or procedures. From the date established as the date of 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, CHAMPVA will suspend treatment of the device, medical treatment, or procedure as experimental/investigational (unproven). Following is the partial list of experimental/investigational (unproven) devices, medical treatments, or procedures, all of which are excluded from benefits.

1. Adrenal-to-brain transplantation for Parkinson's disease. [January 1997]
2. Balloon dilatation of the prostate. [June 1996]
3. Calcium epiallopregnanolone (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, and multiple sclerosis – considered experimental/investigational (unproven) treatment for any indication. [June 1999]
4. Candidiasis Hypersensitivity Syndrome. Services related to the candidiasis hypersensitivity syndrome, yeast syndrome or gastrointestinal candidiasis is experimental/investigational (unproven) (i.e., allergenic extracts of candida albicans for immunotherapy and/or provocation/neutralization). Disseminated systemic candidiasis (International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) 112.5) is a recognized diagnosis, and medically necessary treatment is covered. [December 5, 1996]
5. Carotid Body Resection, both unilateral and bilateral, when done solely to relieve the symptoms of pulmonary dyspnea, including chronic obstructive pulmonary disease, is considered investigational/experimental (unproven). [October 1996]
6. Cellular therapy. [June 1999]
7. Cerebellar stimulators/pacemakers. Use of cerebellar stimulators/pacemakers for the treatment of neurologic disorders. [October 1996]

8. Cryosurgery for prostate metastases. [November 1996]
9. Electrostimulation of salivary production in the treatment of xerostomia secondary to Sjogren's syndrome. [October 1996]
10. Endoscopic third ventriculostomy. [June 1996]
11. Enterra implant for gastroparesis. [April 2000]
12. Eye movement desensitization reprocessing therapy for treatment of anxiety-related disorders. [February 1998]
13. Gastric electrical stimulation for gastroparesis. [May 2004]
14. GDC endovascular treatment of wide-necked aneurysms and ruptured aneurysms. [September 1998]
15. Growth factor, including platelet-derived growth factors, for treating non-healing wounds. This includes Procuren®, a platelet-derived wound-healing formula. [January 1997]
16. Hair analysis to identify mineral deficiencies from the chemical composition of hair is experimental/investigational (unproven). Hair analysis testing may be reimbursed when necessary to determine lead poisoning. [January 1997]
17. Hand transplant from a cadaver donor. [February 1999]
18. High-dose lymphoablative therapy with or without stem cell rescue for treatments of severe autoimmune diseases. [April 2000]
19. Histamine therapy. [June 1996]
20. 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]
21. Human papillomavirus DNA testing in the management of cervical neoplasia. [October 1995]
22. Hyperosmolar blood-brain barrier disruption produced by infusion of Mannitol to increase drug delivery to brain tumors. [August 1998]
23. Hyperventilation Provocation Test (HVPT) for diagnosing hyperventilation syndrome. [February 1997]
24. Intracavitary administration of cisplatin for malignant disease. [July 1996]

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25. Intradiscal electro thermal therapy (IDET) for back pain. [December 2002]
 26. Intraoperative Radiation Therapy. [April 1996]
 27. **In utero** fetal surgery. [June 1996]
 28. Iridology (links flaws in eye coloration with diseases elsewhere in the body). [January 1997]
 29. Ligament replacement with absorbable copolymer carbon fiber scaffold. [July 1996]
 30. Light Therapy for Seasonal Depression (also known as seasonal affective disorder (SAD) - this therapy uses varying degrees of light to treat depression. [July 1996]
 31. Meniscal transplant (allograft) for meniscal injury. [July 1998]
 32. MosaicPlasty. [August 1998]
 33. Neurofeedback. [February 1998]
 - || 34. **Oncotype DX™ breast cancer assay. [July 2004]** ||
 35. Pancreatic islet cell transplantation. [October 1998]
 36. Percutaneous interstitial thermal ablation in the treatment of hepatic cancer. [May 1998]
 37. Portable nocturnal hypoglycemia detectors. [August 1996]
 38. Pupillometry. [August 1995]
 39. Radioimmunoguided surgery in the detection of cancer. [November 1996]
 40. Sensory afferent stimulation (SAS) devices for relief of nausea (e.g., Relief Band®). [August 1996]
 41. Serologic assays for the diagnosis and management of inflammatory bowel disease. [October 2003]
 42. Spinoscopy. Use of a spinoscope with skin markers to assess the function of the spine. [August 1996]

43. Stereotactic cingulotomy. [August 1996]
44. Synaptic 2000 for acute and chronic pain. [June 1998]
45. 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 experimental/investigational (unproven). [December 1989]
46. Transurethral needle ablation (TUNA) of the prostate. [October 1997]
47. Uterine artery embolization for the treatment of fibroids. [March 2003]
48. Vascularized omental transfer procedure for Raynaud's disease. [October 1999]
49. Vestibular rehabilitation therapy for bilateral paresis; for Meniere's disease; and for acoustic neuroma patients recovering from vestibular ablative surgery. [October 1999]

END OF POLICY