CHAPTER 1
SECTION 2.1

# UNPROVEN DRUGS, DEVICES, MEDICAL TREATMENTS, AND PROCEDURES

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## I. POLICY

A. By law, TRICARE can only cost-share medically necessary supplies and services. TRICARE regulations and program policies restrict benefits to those drugs, devices, treatments, or procedures for which the safety and efficacy have been proven to be comparable or superior to conventional therapies. Any drug, device, medical treatment, or procedure whose safety and efficacy has not been established is unproven and is excluded from coverage.

B. A drug, device, medical treatment, or procedure is unproven:

1. If the drug or device cannot be lawfully marketed without the approval or clearance of the Food and Drug Administration (FDA) and approval or clearance for marketing has not been given at the time the drug or device is furnished to the patient.

2. If a medical device with an Investigational Device Exemption (IDE) approved by the FDA is categorized by the FDA as experimental/investigational (FDA Category A).

3. Unless reliable evidence shows that any medical treatment or procedure has been the subject of well-controlled studies of clinically meaningful endpoints, which have determined its maximum tolerated dose, its toxicity, its safety, and its efficacy as compared with standard means of treatment or diagnosis.

4. If the reliable evidence shows that the consensus among experts regarding the medical treatment or procedure is that further studies or clinical trials are necessary to determine its maximum tolerated dose, its toxicity, its safety, or its effectiveness as compared with the standard means of treatment or diagnosis.

C. This exclusion includes all services directly related to the unproven drug, device, medical treatment or procedure.

D. Cost-sharing may be allowed for services or supplies when there is no logical or causal relationship between the unproven drug, 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 drug, device, treatment, or procedure; e.g., medically necessary treatment the beneficiary would have received in the absence of the unproven drug, device, treatment, or procedure.

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

E. In making a determination that a drug, device, medical treatment, or procedure has moved from the status of unproven to the position of nationally accepted medical practice, TRICARE uses the following hierarchy of reliable evidence (see 32 CFR 199.2):

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.

F. The hierarchy of reliable evidence of proven medical effectiveness, established by paragraph I.E.1. through 5. above, is the order of the relative weight to be given to any particular source. 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 in the meaning of reliable evidence is the fact that a provider or a number of providers have elected to adopt a drug, device, medical treatment, or procedure as their personal treatment or procedure of choice or standard of practice.

G. 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.

H. The contractor(s) shall routinely review the hierarchy of reliable evidence, as defined in 32 CFR 199.2, and bring to TMA's attention drugs, devices, medical treatments, or procedures that they believe have moved from unproven to proven. This shall be done on a calendar quarterly basis in a written report to TMA. Accompanying this report will be the reliable evidence substantiating that the drugs, devices, medical treatments, or procedures have moved from unproven to proven. TMA will then apply the standards and procedures in TRICARE regulation and policy and if determined by TMA to have moved to proven, will notify all contractors that the drug, device, medical treatment, or procedure is proven and a part of the TRICARE benefit.

I. For drugs, devices, medical treatments, and procedures that TRICARE has determined have moved from the status of unproven to the status of proven in accordance with the procedure established in paragraph I.E., the effective date (or the date on which the particular drug, device, medical treatment, or procedure may be cost-shared) is the date published reliable evidence (as described in 32 CFR 199.2) shows proven medical effectiveness. For example, the effective date may be established as the date of publication of a well-controlled study of clinically meaningful endpoints published in refereed medical literature, or the publication date of a formal technology assessment.

J. The following is a partial list of drugs, devices, medical treatments, or procedures considered to be unproven. Other drugs, devices, medical treatments, or procedures also considered to be unproven are listed as specific exclusions in relevant sections of the TRICARE Policy Manual (TPM). For example, Cardiomyoplasty for treatment of heart failure is considered unproven and is listed as a specific exclusion in Chapter 4, Section 9.1 (Cardiovascular System). Neither the partial list below nor the exclusions cited in other sections of the TPM provide an all inclusive list of unproven drugs, devices, medical treatments, or procedures. Other unproven drugs, devices, medical treatments, or procedures are also excluded although they do not appear in the TPM.

1. Adoptive immunotherapy using either Tumor-Infiltrating Lymphocytes (TIL) or Lymphokine-Activated Killer (LAK) cells, activated in vitro by recombinant or natural IL-2 or other lymphokines, for the treatment of cancer.

2. Adrenal tissue transplant to brain.

3. Autolymphocyte Therapy (ALT).

4. 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.

5. Canaloplasty in the treatment of glaucoma is unproven.

6. 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 candidasis (ICD-9-CM 112.5) is a recognized diagnosis, and medically necessary treatment is covered.

7. Cellular therapy (HCPCS procedure code M0075).

8. Chelation therapy, except when using FDA-approved chelators for FDA-approved indications.

9. Diaphanography (Transillumination Light Scanning).

10. Dynamic Posturography (both static and computerized) (CPT[1] procedure code 92548).

11. Electric reflex salivary stimulation (Salitron® Electrostimulation System) in the treatment of xerostomia (dry mouth) secondary to Sjogren's syndrome (HCPCS procedure code E0755).

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

13. Hand transplant from a cadaver donor.

14. Histamine therapy.

15. 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.

16. Hyperosmotic blood-brain barrier disruption produced by infusion of Manitol to increase drug delivery to brain tumors.

17. Hyperventilation Provocation Test (HVPT) for diagnosing hyperventilation syndrome.

18. Immunotherapy for malignant disease except when using drugs approved by the FDA for this purpose.

19. Intracavitary administration of cisplatin for malignant disease is unproven, except for patients with optimally debulked Stage III ovarian cancer and pseudomyxoma peritonei resulting from appendiceal carcinoma.

20. Iridology (links flaws in eye coloration with disease elsewhere in the body).

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

22. Neurofeedback.

23. All organ transplants not listed as covered in the TPM or 32 CFR 199.4(e)(5).

24. Portable nocturnal hypoglycemia monitors.

25. Pupillometry.

26. Sensory Afferent Stimulation (SAS) devices for relief of nausea (e.g., Relief Band®).

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27. Spinoscopy. Use of a Spinoscope with skin markers to assess the function of the spine.

28. Synaptic 2000 for acute and chronic pain.

29. Tinnitus Masker.

30. Transdermal nicotine therapy used to treat ulcerative colitis.

31. 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.

NOTE: See Chapter 1, Section 3.1 for policy on Rare Diseases.

NOTE: See Chapter 7, Section 24.1 for policy on cancer clinical trials.

NOTE: See Chapter 8, Section 5.1 for policy on Medical Devices, including coverage of off-label uses of medical devices, Humanitarian Use Devices and a FDA-approved Investigational Device Exemption (IDE) categorized by the FDA as non-experimental/ investigational (FDA Category B).

NOTE: See Chapter 8, Section 9.1 for policy on off-label use of drugs.

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