Chapter 1 Section 2.1

Unproven Drugs, Devices, Medical Treatments, And Procedures

Issue Date: November 1, 1983
Authority: 32 CFR 199.2 and 32 CFR 199.4(g)(15)
Revision:

1.0 POLICY

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.

2.0 A drug, device, medical treatment, or procedure is unproven:

2.1 If the drug or device cannot be lawfully marketed without the approval or clearance of the U.S. 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.

2.2 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).

2.3 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.

2.4 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.

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

4.0 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:

4.1 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.

4.2 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.

5.0 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):

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

5.2 Published formal technology assessments.

5.3 The published reports of national professional medical associations.

5.4 Published national medical policy organization positions.

5.5 The published reports of national expert opinion organizations.

6.0 The hierarchy of reliable evidence of proven medical effectiveness, established by paragraph 5.1 through 5.5, 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.

7.0 TRICARE policy and benefit structure is never based solely on that of other Government medical programs, including Medicare, because each operates under its own statutes and regulations. Furthermore, while TRICARE may examine the policies of private third party payers, TRICARE coverage may only be based on governing statutes and regulations.

8.0 The contractor(s) shall routinely review the hierarchy of reliable evidence, as defined in 32 CFR 199.2, and provide a report to the Defense Health Agency (DHA) when the contractor identifies drugs, devices, medical treatments, or procedures that they believe have moved from unproven to proven. DHA will apply the standards and procedures in TRICARE regulation and policy and if determined by DHA 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.

9.0 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 5.0, 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.

Note: See 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 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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