AMA Drug Evaluations Added As Alternative in Absence of FDA Guidelines

Information posted April 22, 2011

This is an update to the 2011 Texas Medicaid Provider Procedures Manual, Medical and Nursing Specialists, Physicians, and Physician Assistants Handbook, subsection 8.2.37, “Medications-Injectable.”

The American Medical Association Drug Evaluations (AMA-DE) has been added to the list of alternatives that can be used in the absence of drug guidelines that are approved by the Food and Drug Administration (FDA).

The following is the complete, updated text that is affected by this change:

Providers are responsible for administering drugs based on the FDA-approved guidelines. In the absence of FDA indications, a drug needs to meet the following criteria:

- The drug is recognized by the American Medical Association Drug Evaluations (AMA-DE), American Hospital Formulary Service Drug Information, the U.S. Pharmacopoeia Dispensing Information, Volume I, or two articles from major peer-reviewed journals that have validated and uncontested data supporting the proposed use for the specific medical condition as safe and effective.

- It is medically necessary to treat the specific medical condition, including life-threatening conditions or chronic and seriously debilitating conditions.

- The off-label use of the drug is not investigational or experimental.

Retrospective review may be performed to ensure documentation supports the medical necessity of the service.

For more information, call the TMHP Contact Center at 1-800-925-9126.