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Off- Label Use of Medications, Treatments, Procedures

Off-label use is defined as the use of medications, treatments, procedures, etc. for a condition other than those approved by the Federal Food and Drug Administration (FDA). Off-label use of medications, treatments or procedures require preauthorization by the Division. Preauthorization may include review of the evidence by a physician or pharmacist as determined by the Division. Use of medications for diagnoses listed in the drug labeling, considered standard of care or included in treatment guidelines will not require prior authorization unless otherwise indicated in policy.

Rules and Regulations Section 19. Off-Label Use of Medical Services.

Medications, treatments, procedures or other medical services used for other than the approved Food and Drug Administration (FDA) indications. These services should be medically necessary, i.e., have a reasonable expectation of cure or significant relief of a condition consistent with any applicable treatment parameter (Rules and Regulations Chapter (1), Section (4), Subsection (am)). The Health Care Provider must document in the medical record the off-label use is medically necessary, and will submit to the Division a comprehensive review of the medical literature. This review will include at least two good prospective, randomized, placebo-controlled, double-blind trial. The Division will consider the quality of the evidence and determine medical necessity.

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