THE INSURANCE CODE OF 1956 (EXCERPT)
Act 218 of 1956

500.3406q Off-label use of approved drug; coverage; conditions; compliance; use of copayment, deductible, sanction, or utilization control; limitation; definitions.

Sec. 3406q. (1) An insurer that delivers, issues for delivery, or renews in this state a health insurance policy that provides pharmaceutical coverage shall provide coverage for an off-label use of a United States Food and Drug Administration approved drug and the reasonable cost of supplies medically necessary to administer the drug.

(2) Coverage for a drug under subsection (1) applies if all of the following conditions are met:

(a) The drug is approved by the United States Food and Drug Administration.

(b) The drug is prescribed by an allopathic or osteopathic physician for the treatment of either of the following:

(*i*) A life-threatening condition if the drug is medically necessary to treat the condition and the drug is on the plan formulary or accessible through the insurer's formulary procedures.

(*ii*) A chronic and seriously debilitating condition if the drug is medically necessary to treat the condition and the drug is on the plan formulary or accessible through the insurer's formulary procedures.

(c) The drug has been recognized for treatment for the condition for which it is prescribed by 1 of the following:

(*i*) The American Medical Association drug evaluations.

(*ii*) The American Hospital Formulary Service drug information.

(*iii*) The United States Pharmacopoeia Dispensing Information, Volume 1, "Drug Information for the Health Care Professional".

(*iv*) Two articles from major peer-reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal.

(3) Upon request, the prescribing allopathic or osteopathic physician shall supply to the insurer documentation supporting compliance with subsection (2).

(4) This section does not prohibit the use of a copayment, deductible, sanction, or mechanism for appropriately controlling the utilization of a drug that is prescribed for a use different from the use for which the drug has been approved by the United States Food and Drug Administration. This may include prior approval or a drug utilization review program. Any copayment, deductible, sanction, prior approval, drug utilization review program, or mechanism described in this subsection must not be more restrictive than for prescription coverage generally.

(5) As used in this section:

(a) "Chronic and seriously debilitating" means a disease or condition that requires ongoing treatment to maintain remission or prevent deterioration and that causes significant long-term morbidity.

(b) "Life-threatening" means a disease or condition as to which the likelihood of death is high unless the course of the disease is interrupted or that has a potentially fatal outcome and as to which the end point of clinical intervention is survival.

(c) "Off-label" means the use of a drug for clinical indications other than those stated in the labeling approved by the United States Food and Drug Administration.

History: Add. 2002, Act 538, Eff. Jan. 22, 2003;—Am. 2003, Act 88, Eff. Jan. 23, 2004;—Am. 2016, Act 276, Imd. Eff. July 1, 2016
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