



Blue Cross
Blue Shield
of Michigan

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Blue Cross Blue Shield of Michigan Medical Policy

These documents are not used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information.

Enterprise: Blue Cross Blue Shield of Michigan
Department: Medical Affairs
Effective Date: July 1, 2016
Next Review Date: 3rd Quarter 2027
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Approved Off-Label Drug Usage

Background:

Off-label drug use is the use of a drug approved by the U.S. Food and Drug Administration (FDA) for other uses or in treatment regimens of patient populations that are not included in approved labeling.

The FDA approves drugs for specific indications that are included in the drug's labeling. When a drug is used for an indication other than those specifically included in the labeling, it is referred to as an off-label use. Many off-label uses are effective and well documented in the literature. Additionally, much of the off-label use recognized today was derived outside of strict clinical research corridors.

The State of Michigan passed legislation in 2002, (Public Acts 538 and 539), to allow coverage of medications for use other than FDA approved indications when specific criteria are met.

Medical Policy Statement:

In accordance with Public Acts 538 and 539, Blue Cross Blue Shield of Michigan (BCBSM) will allow coverage of medications for use other than FDA approved

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indications if specified criteria are met. The criteria as set forth in the PA 538 and 539 include:

- (a) The drug is approved by the Federal Food and Drug Administration (FDA).
- (b) The drug is prescribed by an allopathic or osteopathic physician for the treatment of either of the following:
 - (i) A life-threatening condition so long as the drug is medically necessary to treat that condition and the drug is on the plan formulary or accessible through the health plan's formulary procedures.
 - (ii) A chronic and seriously debilitating condition so long as the drug is medically necessary to treat that condition and the drug is on the plan formulary or accessible through the health plan'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 (AMA) Drug Evaluations.
 - (ii) The American Hospital Formulary Service (AHFS) 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.

* The prescribing allopathic or osteopathic physician shall supply documentation supporting compliance with the aforementioned criteria detailed in the PA 538 and 539.

Definitions:

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

(b) **“Life-threatening”** - a disease or condition where the likelihood of death is high unless the course of the disease is interrupted or that has a potentially fatal outcome where the end point of clinical intervention is survival.

(c) **“Off-label”** - the use of a drug for clinical indications other than those stated in the labeling approved by the federal Food and Drug Administration.

Scope:

This policy applies to all underwritten contracts; and, self-funded or ASC contracts, pending customer approval.

BCBSM Policy History

Policy Effective Date	BCBSM Signature/Review Date	Comments
1/22/2003	6/16/15	Routine review- no changes
7/1/2016	8/9/16	Routine review – minor formatting changes.
7/1/2016	9/27/2017	Routine maintenance
7/1/2016	7/19/2018	Routine maintenance
7/1/2016	9/24/2019	Routine maintenance
7/1/2016	7/9/2020	Routine maintenance
7/1/2016	7/15/2021	Routine maintenance
7/1/2016	7/7/2022	Routine maintenance
7/1/2016	7/13/2023	Routine maintenance

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7/1/2016	7/11/2024	Routine maintenance
7/1/2016	7/10/2025	Routine maintenance
7/1/2016	7/14/2026	Routine maintenance