

DEPARTMENT OF REGULATORY AGENCIES

Division of Insurance

3 CCR 702-4

LIFE, ACCIDENT AND HEALTH

New Regulation 4-2-100

CONCERNING REQUIREMENTS FOR PRESCRIPTION DRUG COVERAGE FOR SERIOUS MENTAL ILLNESSES

Section 1	Authority
Section 2	Scope and Purpose
Section 3	Applicability
Section 4	Definitions
Section 5	Rules
Section 6	Severability
Section 7	Enforcement
Section 8	Effective Date
Section 9	History

Section 1 Authority

This regulation is promulgated and adopted by the Commissioner of Insurance under the authority of §§ 10-1-109 and 10-16-145(6), C.R.S.

Section 2 Scope and Purpose

The purpose of this regulation is to implement sections 10-16-145(1)(f.5) and 10-16-145(4.5), C.R.S enacted in HB23-1130 and to establish the requirements, process, and form to be utilized by health benefit plans for step therapy utilization and exceptions for enrollees with serious mental illnesses.

Section 3 Applicability

This regulation applies to all carriers, private utilization review organizations, and pharmacy benefit managers ("PBM") marketing and issuing or renewing health benefit plans in the individual, small group and large group markets in Colorado, including non-grandfathered plans, short-term limited duration health insurance policies, and student health insurance coverage.

Section 4 Definitions

- A. "Carrier" shall have the same meaning as found at § 10-16-102(8), C.R.S.
- B. "Covered person" shall have the same meaning as found at § 10-16-105(15), C.R.S.
- C. "Health benefit plan" shall have the same meaning as found at § 10-16-102(32), C.R.S.
- D. "Provider" shall have the same meaning as found at § 10-16-102(56), C.R.S.
- E. "Private Utilization Review Organization" shall have the same meaning as found at § 10-16-112(1)(a), C.R.S.
- F. "Pharmacy benefit management firm," "pharmacy benefit manager," or "PBM" shall have the same meaning as found at § 10-16-102(49), C.R.S.

G. "Serious mental illness" shall have the same meaning as found at § 10-16-145(1)(f.5), C.R.S.

H. "Step therapy" shall have the same meaning as found at § 10-16-145(1)(g), C.R.S.

Section 5 Rules

A. If, under a health benefit plan, a carrier, private utilization review organization, or PBM requires step therapy for a prescription medication to treat a serious mental illness, it may only require a covered person to try one (1) prescription drug other than the drug prescribed by the provider prior to covering the drug prescribed by the covered person's provider.

B. A carrier, private utilization review organization, or PBM shall use the Serious Mental Illness Step Therapy Exception Form included in Appendix A and make such form available in paper and electronic format, including on the company website, to providers for use in exceptions to step therapy for a covered person with a serious mental illness if at least one of the following conditions is met:

- a. the provider attests that the required prescription drug is contraindicated or will likely cause an adverse reaction or harm to the covered person;
- b. the required prescription drug is ineffective based on the known clinical characteristics of the covered person and the known characteristics of the prescription drug regimen;
- c. the covered person has tried, while under the covered person's current or previous health benefit plan, the required prescription drug or another prescription drug in the same pharmacologic class or with the same mechanism of action, and the use of the prescription drug by the covered person was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event; or
- d. the covered person, while on the covered person's current or previous health benefit plan, is stable on a prescription drug selected by the prescribing provider for the medical condition under consideration after undergoing step therapy or after having sought and received a step-therapy exception.

C. A carrier, private utilization review organization, or PBM shall authorize coverage for a prescription drug prescribed by the covered person's provider when the Serious Mental Illness Step Therapy Exception Form in Appendix A is submitted and meets all necessary criteria for that drug. The provider's attestation shall be final, and a carrier must cover the prescription drug without additional step therapy requirements.

Section 6 Severability

If any provision of this regulation or the application of it to any person or circumstance is for any reason held to be invalid, the remainder of this regulation shall not be affected.

Section 7 Enforcement

Noncompliance with this regulation may result, after proper notice and hearing, in the imposition of any of the sanctions made available in the Colorado statutes pertaining to the business of insurance or other laws which include the imposition of fines, issuance of cease and desist orders, and/or suspensions or revocation of license. Among others, the penalties provided for in §10-3-1108, C.R.S., may be applied.

Section 8 Effective Date

This regulation shall be effective on January 1, 2025.

Section 9 History

New regulation effective January 1, 2025.

Appendix A: Serious Mental Illness Step Therapy Exception Form

Serious Mental Illness Step Therapy Exception Form

Plan/Medical Group Name: Optum Rx

Plan/Medical Group Fax#: (844) 403-1027

Plan/Medical Group Phone #: (800) 711-4555

Instructions: Please fill out all applicable sections completely and legibly. Information contained in this form is Protected Health Information under HIPAA.

Patient Information

First Name:	MI:	Last Name:	Date of Birth:
City:	State:	Zip Code:	Phone Number:
Patient's Authorized Representative (if applicable):		Authorized Representative Phone Number (if applicable):	

Insurance Information

Primary Insurance Name:	Patient ID Number:
Secondary Insurance Name:	Patient ID Number:

Prescriber Information

First Name:	Last Name:	Specialty:	
Address:	City:	State:	Zip Code:
NPI Number (individual):		Phone Number:	
DEA Number (if applicable):		Office Contact Person:	
Email Address:			

Medication:

Diagnosis:

Medication:

Attestation

- ☐ I attest the information provided is true and accurate to the best of my knowledge.
- ☐ I attest that any of the following criteria specified in subsections (4)(a)(I) –(IV) of § 10-16-145, C.R.S. have been met to exempt a step-therapy requirement for the prescription drug:
- (I) The provider attests that the required prescription drug is contraindicated or will likely cause an adverse reaction or harm to the covered person;
 - (II) The required prescription drug is ineffective based on the known clinical characteristics of the covered person and the known characteristics of the prescription drug regimen;
 - (III) The covered person has tried, while under the covered person's current or previous health benefit plan, the required prescription drug or another prescription drug in the same pharmacologic class or with the same mechanism of action, and the use of the prescription drug by the covered person was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
 - (IV) The covered person, while on the covered person's current or previous health benefit plan, is stable on a prescription drug selected by the prescribing provider for the medical condition under consideration after undergoing step therapy or after having sought and received a step-therapy exception.

Prescriber Signature or Electronic I.D. Verification: _____ Date: _____

Confidentiality Notice: The documents accompanying this transmission contain confidential health information that is legally privileged. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or action taken in reliance on the contents of these documents is strictly prohibited. If you have received this information in error, please notify the sender immediately (via return email or other electronic means) and arrange for the return or destruction of these documents.