COLORADO DEPARTMENT OF REGULATORY AGENCIES

Division of Insurance

3 CCR 702-4

LIFE ACCIDENT AND HEALTH

New Regulation 4-2-49

CONCERNING THE DEVELOPMENT AND IMPLEMENTATION OF A UNIFORM DRUG BENEFIT PRIOR AUTHORIZATION PROCESS

Section 1 Authority

This regulation is promulgated and adopted by the Commissioner of Insurance under the authority of §§ 10-1-109, 10-16-124.5(3)(a), and 10-16-124.5(3)(c), C.R.S.

Section 2 Scope and Purpose

The purpose of this regulation is to establish the requirements, process, and form to be utilized by carriers and contracted pharmacy benefit management firms for the prior authorization process for prescription drug benefits.

Section 3 Applicability

Except as noted, the provisions of this regulation shall apply to all carriers that market health benefit plans in the state of Colorado which provide prescription drug benefits. The provisions of this regulation do not apply to non-profit health maintenance organizations with respect to managed care plans that provide a majority of covered professional services through a single contracted medical group.

Section 4 Definitions

A. "Adverse determination" shall have the same meaning as found at § 10-16-113(1)(b), C.R.S.

B. "Carrier" shall have the same meaning as found at § 10-16-102(8), C.R.S., and shall, for the purposes of this regulation, include a pharmacy benefit management firm contracted by a carrier.

C. "Drug benefit" means, for the purposes of this regulation, the provision of a drug used to treat a covered medical condition of a covered person.

D. "Health benefit plan" shall have the same meaning as found at § 10-16-102(32), C.R.S.

E. "Health Maintenance Organization" shall have the same meaning as found at § 10-16-102(35), C.R.S.

F. "Pharmacy benefit management firm" shall have the same meaning as found at § 10-16-102(49), C.R.S.

G. "Prescribing provider" shall have the same meaning as found at § 10-16-124.5(8)(a), C.R.S.

H. "Urgent prior authorization request" shall have the same meaning as found at § 10-16-124.5(8)(b), C.R.S.

Section 5 Rules

A. Beginning on January 1, 2015, all carriers shall utilize the uniform prior authorization process established by this regulation.

B. A prior authorization process for a drug benefit, as developed by a carrier, shall:

1. Be made available electronically to the prescribing provider;

2. Make the following information available and accessible in a centralized location on the carrier's or its designated pharmacy benefit management firm's website:

a. The prior authorization requirements and restrictions, including, but not limited to:

(1) The prescribing provider's obligation to respond to requests for additional information; and

(2) When requests will be deemed "approved" or "denied";

b. An alphabetical list of drugs, including both brand name and scientific name, that require prior authorization, including the clinical criteria and supporting references that will be used in making a prior authorization determination;

c. Written clinical criteria that include the criteria for reauthorization of a previously approved drug, if applicable, after the previous approval period has expired; and

d. The standard form for prior authorization for a drug benefit, provided in Appendix A of this regulation.

3. Include evidence-based guidelines to be used by the carrier when making prior authorization determinations;

4. Allow for, but not require, the electronic submission of prior authorization requests for a drug benefit to the carrier.

C. Urgent prior authorization requests.

1. A carrier shall process and provide notification of approval or denial to the patient, prescribing provider, and dispensing pharmacy within one (1) business day of receiving an urgent prior authorization request. Carriers shall include appropriate information on the expedited appeals process related to urgent care situations, as found in § 10-16-113,

C.R.S., and associated regulations, with any denial of an urgent prior authorization request.

a. If additional information is required to process an urgent prior authorization request, the carrier must advise the prescribing provider of any and all information needed within one (1) business day of receiving the request.

b. If additional information is required to process an urgent prior authorization request, the prescribing provider shall submit the information requested by the carrier within two (2) business days of receiving such a request from the carrier.

c. If the additional information requested from the prescribing provider is not received within two (2) business days of the prescribing provider receiving such a request, the request shall be deemed denied. The carrier shall provide the patient, prescribing provider, and the dispensing pharmacy with a confirmation of the denial within one (1) business day of the date the request was deemed denied.

d. Once the requested additional information is received, the carrier shall make a determination in accordance with Section 5.C.1., of this regulation.

2. If a carrier does not request additional information or provide notification of approval or denial, as required by Section 5.C.1., the request shall be deemed approved. The carrier shall provide the patient, prescribing provider, and the dispensing pharmacy with a confirmation of the deemed approval within one (1) business day of date the request was deemed approved.

D. Non-urgent prior authorization requests.

1. A carrier shall process and provide notification of approval or denial to the patient, prescribing provider, and dispensing pharmacy within two (2) business days of receiving a non-urgent prior authorization request that has been submitted through the carrier's electronic pre-authorization system.

a. If additional information is required, the carrier must advise the prescribing provider of any and all information needed within two (2) business days of receiving the non-urgent prior authorization request.

b. If additional information is required to process a non-urgent prior authorization request, the prescribing provider shall submit the information requested by the carrier within two (2) business days of receiving such a request from the carrier.

c. If the additional information requested from the prescribing provider is not received within two (2) business days of the prescribing provider receiving such a request, the request shall be deemed denied. The carrier shall provide the patient, prescribing provider, and the dispensing pharmacy with a confirmation of the denial within two (2) business days of the date the request was deemed denied.

d. Once the requested additional information is received, the carrier shall make a determination in accordance with Section 5.D.1. or Section 5.D.2., of this regulation, as applicable

2. A carrier shall process and provide notification of approval or denial to the patient, prescribing provider, and dispensing pharmacy within three (3) business days of receiving

a non-urgent prior authorization request that has been submitted via facsimile, electronic mail, or verbally with associated written confirmation.

3. If a carrier does not request additional information or provide notification of approval or denial within:

   a. Two (2) business days of the receipt of an electronically filed non-urgent prior authorization request, as required by Section 5.D.1., the request shall be deemed approved. The carrier shall provide the patient, prescribing provider, and the dispensing pharmacy with a confirmation of the deemed approval within two (2) business days of the date the request was deemed approved; or

   b. Three (3) business days of the receipt of a non-urgent prior authorization request that has been submitted via facsimile, electronic mail, or verbally with associated written confirmation, as required by Section 5.D.2., the request shall be deemed approved. The carrier shall provide the patient, prescribing provider, and the dispensing pharmacy with a confirmation of the deemed approval within two (2) business days of the date the request was deemed approved.

E. When notifying a prescribing provider of a prior authorization approval, a carrier shall include:

   1. A unique prior authorization number attributable only to that drug benefit approval request;

   2. Specifications for the particular approved drug benefit, and the source and date of the clinical criteria used to make the determination for each particular drug;

   3. The next date for review of the approved drug benefit; and

   4. A link to the current criteria that will need to be submitted in order to reapprove the current prior authorization.

F. When notifying a prescribing provider of a prior authorization denial, a carrier shall include a notice to the prescribing provider, and dispensing pharmacy, if provided, that the covered person has the right to appeal the adverse determination pursuant to §§ 10-16-113 and 10-16-113.5, C.R.S.

G. A prior authorization approval is valid for at least one hundred eighty (180) days after the date of approval.

H. If a prior authorization request is submitted electronically, verbally, via facsimile, or electronic mail, the response to that request shall be made through the same medium, or in a manner specifically requested by the provider.

Section 6 Form

Beginning on January 1, 2015, all carriers shall utilize the uniform prior authorization form found in Appendix A of this regulation.

Section 7 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 8 Enforcement

Noncompliance with this regulation may result 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 civil penalties, issuance of cease and desist orders, and/or suspensions or revocation of license, subject to the requirements of due process.

Section 9 Effective Date

This regulation shall become effective on July 15, 2014.

Section 10 History

New regulation effective July 15, 2014.

APPENDIX A

[CARRIER LOGO]
[CARRIER NAME]

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to:
[CARRIER OR PHARMACY BENEFIT MANAGEMENT FIRM CONTACT INFORMATION]

☐ **Urgent** [1]	☐ **Non-Urgent**
Requested Drug Name:	

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit:	☐ New Request ☐ Reauthorization
Patient Diagnosis and ICD Diagnostic Code(s):	
Drug(s) Requested (with J-Code, if applicable):	
Strength/Route/Frequency:	
Unit/Volume of Named Drug(s):	
Start Date and Length of Therapy:	
Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:	
Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response: [ADD ADDITIONAL LINES AS NEEDED SO AS TO CONTAIN ALL APPROVAL CRITERIA]	
For use in clinical trial? (If yes, provide trial name and registration number):	
Drug Name (Brand Name and Scientific Name)/Strength:	

Dose:	Route:	Frequency:
Quantity:	Number of Refills:	

Product will be delivered to:	☐ Patient's Home	☐ Physician Office	☐ Other:
Prescriber or Authorized Signature:			Date:
Dispensing Pharmacy Name and Phone Number:			

☐ **Approved**	☐ **Denied**
If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:	

1. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request