

WORKING DRAFT OF FORMULARY RULES

RULE I. DEFINITIONS As used in these formulary rules, the following definitions apply:

- (1) "Department" means the Department of Labor and Industry, Employment Relations Division.
- (2) "Formulary" means the list of drugs for which prior authorization is generally not needed, as adopted and automatically updated pursuant to [NEW RULE III].
- (3) "Formulary rules" means:
 - (a) [NEW RULE I];
 - (b) [NEW RULE II];
 - (c) [NEW RULE III];
 - (d) [NEW RULE IV];
 - (e) [NEW RULE V];
 - (f) [NEW RULE VI];
 - (g) [NEW RULE VII]; and
 - (h) [NEW RULE VIII].
- (4) "Insurer" means compensation plan No. 1, plan No. 2, plan No. 3.
- (5) "Legacy claim" means a workers' compensation or occupational disease claim with an occurrence date before April 1, 2019.
- (6) "Montana Guidelines" are the Montana utilization and treatment guidelines adopted by the department in [ARM 24.29.1591].
- (7) "ODG drug formulary" means the ODG Workers' Compensation Drug Formulary, established as Appendix A to the ODG Treatment in Workers' Comp publication, published by MCG Health, LLC.
- (8) "PBM" mean the pharmacy benefits manager used by an insurer to help the insurer implement the formulary's use in the insurer's claims handling processes.
- (9) "Primary medical services" has the same meaning as provided by 39-71-116, MCA.
- (10) "Refill" means the dispensing of additional medications after the initial number of doses authorized by a written prescription have been dispensed, where the prescription expressly indicates that a certain number of refills are allowed without the need for another written prescription.
- (11) "Supportive services" means those treatments, therapies, and related services that are designed to safely, effectively, and compassionately assist an injured worker transition from an existing medication regimen.
- (12) "Treating physician" has the same meaning as provided by ARM 24.29.1401A.

AUTH: 39-71-203, 39-71-704, MCA

IMP: 39-71-704, MCA

RULE II APPLICABILITY OF FORMULARY RULES TO OUT-PATIENT

SERVICES (1) The provisions of these formulary rules apply to all claims arising on or after **[April 1, 2019]**, but only with respect to outpatient services.

(2) For claims arising before **[April 1, 2019]**, which are referred to as "legacy claims", the rules in [this subchapter] will apply to prescriptions written on or after **[April 1, 2020]**, or 90 days after the insurer gives notice as provided in [NEW RULE VI], whichever is later.

(3) The provisions of [this subchapter], including formulary adopted and automatically updated as provided in [NEW RULE III] apply as they are in effect on the date the prescription is written.

(4) Nothing in [this subchapter] excuses an insurer from providing medications that constitute primary medical services required to be furnished by 39-71-704, MCA.

(5) Nothing in [this subchapter] requires an insurer to use the services of a PBM.

AUTH: 39-71-203, 39-71-704, MCA

IMP: 39-71-704, MCA

RULE III INCORPORATION BY REFERENCE AND UPDATES TO THE

FORMULARY (1) The department will annually undertake formal rulemaking to select a formulary. The formulary may be any one of the following:

(a) a formulary published by a commercial vendor;

(b) a formulary published by another state for use in workers' compensation and occupational disease claims; or

(c) a formulary specially developed by the department.

(2) The department adopts and incorporates by reference the **[date]** edition of the ODG Drug Formulary as its formulary.

(3) Pursuant to 2-4-307, MCA, the automatic monthly updates of the annually adopted edition of the formulary are incorporated by reference without additional rulemaking, and are applicable as of the [date the update is posted on the department's website].

(4) The formulary is available from:

(a) the department's website **[web address]**, at no charge;

(b) the department **[mailing address]**, at the costs of reproduction and postage for a printed .pdf version; and

(c) the vendor, via electronic access, at a subscription rate charged by vendor, which may include supplemental information or materials that are not incorporated by reference. The vendor may be contacted via the internet at www.mcg.com/odg, and at ODG by MCG Health, 3006 Bee Caves Road, Suite A250, Austin, TX 78746.

(5) Archived versions of the formulary will be maintained by the department for five years from the date of the adoption of the formulary.

AUTH: 39-71-203, 39-71-704, MCA

IMP: 39-71-704, MCA

RULE IV INTEGRATION OF FORMULARY WITH MONTANA UTILIZATION AND TREATMENT GUIDELINES – WHEN PRIOR AUTHORIZATION IS REQUIRED

- (1) The formulary is considered to be a part of the Montana Guidelines established by the department.
- (2) A medical provider is expected to write a prescription for medication in accordance with the Montana Guidelines, as adopted by **[ARM 24.29.1591]**, and in accordance with the formulary adopted by **[NEW RULE III]**.
- (3) Because the formulary is part of the Montana Guidelines, medical providers are required to prescribe in accordance with the provisions of the formulary unless the provider can sufficiently articulate sound medical reasoning to vary from the formulary.
- (4) Although insurers are obligated to pay for medications that are prescribed in a manner consistent with the formulary, the insurer must consider whether the medical provider has furnished sufficiently supported reasoning as required by **[ARM 24.29.1593]**.
- (5) Pursuant to the formulary, prior authorization for medication is required as follows:
 - (a) A medical provider does not need prior authorization to prescribe an injury-appropriate medication that is listed as "Y" on the formulary.
 - (b) Except as provided in **[NEW RULE V]**, a medical provider shall seek prior authorization whenever prescribing a medication that is not listed as a "Y" on the formulary.
 - (c) A medical provider shall seek prior authorization whenever prescribing a medication that is a compound, even if all the components of the compound are listed as "Y" medications on the formulary.
- (6) The prior authorization process described in **[ARM 24.29.1593]** applies to formulary matters, except that:
 - (a) the insurer shall respond within three business days of a request for prior authorization being made to the insurer or the insurer's designee, by either approving or denying the request; and
 - (b) If the insurer fails to respond within three business days to a request for prior authorization, the prescription is deemed to be approved. An approval for a prescription medication made due to the lack a timely response by the insurer does not apply to any refill that may be ordered.
- (7) An insurer may delegate prior authorization decisions pertaining to the formulary to a PBM or other agent with which it contracts. An insurer has the legal responsibility for the decisions made by the PBM on behalf of the insurer.
- (8) The delegation by an insurer of prior authorization decisions pertaining to the formulary to a PBM or other agent does not, in and of itself, violate the requirement of 39-71-107, MCA, that all claims be examined by a claims examiner in Montana.

AUTH: 39-71-203, 39-71-704, MCA
IMP: 39-71-107, 39-71-704, MCA

NEW RULE V FIRST FILL PROCEDURES (1) As used in these formulary rules the term "first fill" means:

(a) any prescription medication is dispensed to or prescribed for an injured worker by an out-patient medical provider;

(b) when the out-patient medical care first occurs; and

(c) it is written within 7 days of the occurrence of the workplace injury.

(2) Prior authorization is not needed for first fill medications listed as "N" status on the formulary, provided that the medication is injury- appropriate for the injured worker at the time the worker seeks medical care.

(a) A brand-name drug listed as "N" status on the formulary is subject to the provisions of 39-71-727, MCA, regarding generic-name drugs and brand-name drugs.

(3) A first fill for a prescription is limited to a maximum of a seven-day supply. A prescription for more than a seven-day supply of a medication is not guaranteed for payment beyond the seven-day supply.

(4) Drugs not eligible to be filled as a first fill are:

(a) experimental;

(b) investigational;

(c) compounds; or

(d) drugs not listed on the formulary.

(5) The generic drug requirements of 39-71-727, MCA, are applicable to first fills.

AUTH: 39-71-203, 39-71-704, MCA

IMP: 39-71-107, 39-71-704, 39-71-721, 39-71-727, MCA

RULE VI SPECIAL PROVISIONS FOR TRANSITION OF LEGACY CLAIMS –

WHEN APPLICABLE (1) The insurer shall notify in writing the injured worker and the treating physician (who, for the purposes of this rule, also includes any other prescribing medical provider) that a claim constitutes a legacy claim in which the insurer will enforce the applicability of these formulary rules.

(2) This rule applies to a legacy claim on the latter of:

(a) **[April 1, 2020]**; or

(b) 90 days after the insurer provides notice as provided by (1).

(3) By not later than the applicability date of this rule pursuant to (2), the treating physician shall determine whether a transition plan is needed for an injured worker who is receiving:

(a) one or more drugs for which prior authorization is otherwise required; or

(b) drugs at a dosage level greater than recommended by the Montana Guidelines.

(4) The treating physician must state in writing whether the injured worker:

(a) should transition to "Y" status drugs or to medication dosages which are consistent with the recommendations of the Montana Guidelines; or

(b) such a transition is not medically appropriate.

(5) The treating physician must provide the basis for the medical provider's decision as required by **[ARM 24.29.1593]**. The explanation, and development of a transition plan as appropriate, constitutes a "by report" service (CPT code 99080).

(6) If the treating physician fails to provide the determination required in (4), by the date this rule becomes applicable to the claim pursuant to (2), these formulary rules will apply to prescriptions written for the injured worker.

(7) If the treating physician determines a transition from one or more drugs for which prior authorization required to a "Y" status drug is appropriate, or that a reduction in dosage is appropriate, the treating physician shall include in the worker's treatment plan a specific plan, including a projected time table or schedule, for transitioning the injured worker to care that is consistent with the Montana Guidelines.

(8) The treatment plan may, when determined by the treating physician to be medically necessary, include the provision of supportive services to the injured worker during the transition.

(9) Supportive services may be delivered in an out-patient or an in-patient setting, as appropriate, based upon the treating provider's transition plan. Supportive services that are reasonable and medically necessary constitute part of the primary medical services to which an injured worker with a legacy claim is entitled.

(10) Nothing in this rule prohibits the treating physician from proposing a treatment plan for transition prior to an insurer's authorization as provided in (1).

AUTH: 39-71-203, 39-71-704, MCA

IMP: 39-71-704, MCA

NEW RULE VII EXPEDITED CASE REVIEW FOR PRESCRIPTION

MEDICATIONS BY DLI MEDICAL DIRECTOR (1) Expedited case review is available only when insurer declines to authorize further dispensing of an already prescribed medication.

(2) Expedited case review is only applicable in cases of medical emergency. A medical emergency is defined for the purposes of this rule as meaning:

- (a) the sudden onset;
- (b) of a medical condition manifested by acute symptoms of sufficient severity, including severe pain;
- (c) that in the absence of immediate medical attention could reasonably be expected to result in:
 - (i) placing the injured worker's health or bodily functions in serious jeopardy; or
 - (ii) a serious dysfunction of any body organ or part of the injured worker.

(3) An expedited case review may be requested concurrently with a demand for mediation on the dispute concerning the medication.

(4) An expedited case review may only be requested within 14 business days of the insurer's denial of, or refusal to authorize further dispensing of an already prescribed medication.

(5) A request for an expedited case review must be supported by such written information as the treating physician considers pertinent to the treating physician's opinion that a medical emergency is likely to occur as a result of the denial of the medication.

(6) The expedited medical review will be conducted within of three business days of receipt by the department of a written request for an expedited medical review. The findings of the expedited medical review must be in writing and be based on the information provided by the treating physician, along with the reasoning given by the insurer or its agent for the denial.

(7) If the findings of the medical director determine that a medical emergency is likely to occur as the result of not providing the further dispensing of medication as prescribed by the treating physician, those findings may be offered in evidence in mediation or the Workers' Compensation Court.

(8) If the findings of the medical director are that no medical emergency is likely to occur as a result of the insurer's denial, then the medical director shall further consider the matter of the denial under the independent medical review procedures provided for by **[ARM 24.29.1595]**.

AUTH: 39-71-203, 39-71-704, MCA

IMP: 39-71-704, MCA

RULE VIII DISPUTE RESOLUTION (1) Disputes between the treating physician and the insurer regarding the formulary are subject to the same process available for other with disputes regarding the Montana Guidelines, except as provided in [NEW RULE VII].

(2) A dispute between the injured worker and the insurer regarding the use or application of the formulary constitutes a dispute concerning benefits, and may be resolved as provided by 39-71-2905, MCA.

AUTH: 39-71-203, 39-71-704, MCA

IMP: 39-71-704, 39-71-2905, MCA

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