# Rule Summary and Fiscal Analysis
## Part A - General Questions

**Rule Number:** 4123-6-21.3

**Rule Type:** Amendment

**Rule Title/Tagline:** Outpatient medication formulary.

**Agency Name:** Bureau of Workers' Compensation

**Division:**

**Address:** 30 W. Spring St. Columbus OH 43215

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## I. Rule Summary

1. **Is this a five year rule review?** No

    A. **What is the rule's five year review date?** 5/1/2025

2. **Is this rule the result of recent legislation?** No

3. **What statute is this rule being promulgated under?** 119.03

4. **What statute(s) grant rule writing authority?** 4121.12, 4121.121, 4121.30, 4121.31, 4121.44, 4121.441, 4123.05, 4123.66

5. **What statute(s) does the rule implement or amplify?** 4121.12, 4121.121, 4121.44, 4121.441, 4123.66

6. **What are the reasons for proposing the rule?**

    The Bureau proposes to revise the formulary appendix to this rule by amending coverage to the drug products listed in the formulary. These proposed changes are the result of recommendations from the Bureau's Pharmacy & Therapeutics Committee (P&T). These revisions reflect the Bureau's dedication to providing for appropriate care while ensuring the safety of our injured workers. The committee's recommendations resulted from consideration of current medical literature, accepted treatment guidelines and best clinical practices.

**7. Summarize the rule's content, and if this is an amended rule, also summarize the rule's changes.**

The proposed changes to this rule are to:
* Add language to provide for the reimbursement of antiretroviral drugs prescribed for an allowed condition of human immunodeficiency virus (HIV); an exposure to HIV in an allowed claim ; or pursuant to R.C. 4123.026, which provides for payment of post exposure medical diagnostic services consistent with the standards of medical care existing at the time of the exposure for a peace officer, firefighter, emergency medical worker, or detention facility employee exposed to blood or other body fluid.
The proposed changes to the Appendix to this rule are:
Medications to be deleted:
* Tolmetin Sodium cap. 400 MG and tab. 200 and 600 MG
* Ketoprofen cap. 50, 75, and ER 24 HR 200 MG
* Fenoprofen Calcium cap. 200, 400, and tab. 600 MG
* Meclofenamate Sodium cap. 50 and 100 MG

Medications and drug classes to be added are:
* Brivaracetam 10, 25, 50 and 75 MG, with prior authorization. Reimbursement limited to claims with an allowed condition of seizure disorder and the injured worker has tried and failed at least one anticonvulsant.
* Fluticasone-umeclidinium-vilanterol AEPB 200-62.5-25 MCG/INH
* Glycopyrrolate oral solution 1 MG/5ML
* Isavuconazonium 186 MG, with prior authorization. Reimbursement considered for individuals who are being treated for a fungal infection related to an allowed condition in the claim who have tried and failed at least one antifungal.
* Lanthanum carbonate 500mg chewable tab
* Lasmiditan 50 and 100 MG, with prior authorization. Reimbursement considered for individuals who have not received an adequate response from use of at least one triptan medication, or if the injured worker has a contraindication for triptans. Reimbursement limited to claims in which migraine headaches are related to an allowed condition in the claim. Reimbursement will not be approved for duplicate therapy with a triptan or CGRP antagonist. Maximum reimbursement of 4 tablets per 30 days.
* Migraine Products - calcitonin gene-related peptide (CGRP) receptor antagonists - All drugs within this class may be reimbursed with prior authorization. Reimbursement limited to claims in which migraine headaches are related to an allowed condition in the claim. Reimbursement will not be approved for duplicate therapy with a triptan or other
CGRP antagonists.
* Rimegepant 75 MG ODT, in addition to the restrictions for this drug class:

When the request is for treatment of migraine: reimbursement considered for individuals who have not received an adequate response from use of at least one triptan medication, or if the injured worker has a contraindication for triptans.
When the request is for prevention of migraine: reimbursement considered for individuals who have not received an adequate response from use of at least three of the following: topiramate, valproic acid, divalproex, amitriptyline, venlafaxine, atenolol, metoprolol, nadolol, propranolol, and timolol.
Maximum reimbursement of 18 tablets per 30 days.
* Ubrogepant 50 and 100 MG, in addition to the restriction for this drug class, reimbursement considered for individuals who have not received an adequate response from use of at least one triptan medication, or if the injured worker has a contraindication for triptans.
Maximum reimbursement of 16 tablets per 30 days.
Drug class with changes in coverage:
* Anticoagulants - Direct Factor Xa Inhibitors: after 30 days of use, prior authorization is required if treatment is not directly for an allowed condition in the claim
* Hypnotics - Non-Barbiturate: reimbursement for eszopiclone, zaleplon, zolpidem, zolpidem ER within this drug class is restricted to a total of a 30 day supply without prior authorization. Prior authorization is required beyond 30 days. Reimbursement for these drugs considered for acute care only and not in combination with opioids or stimulants.

8. **Does the rule incorporate material by reference?** No

9. **If the rule incorporates material by reference and the agency claims the material is exempt pursuant to R.C. 121.75, please explain the basis for the exemption and how an individual can find the referenced material.**

   *Not Applicable*

10. **If revising or re-filing the rule, please indicate the changes made in the revised or re-filed version of the rule.**

    *Not Applicable*

## II. Fiscal Analysis

11. **Please estimate the increase / decrease in the agency's revenues or expenditures in the current biennium due to this rule.**

    This will have no impact on revenues or expenditures.

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Not Applicable.

12. **What are the estimated costs of compliance for all persons and/or organizations directly affected by the rule?**

    The prescriber and pharmacy business communities are the only two business communities involved with medication prescribing and dispensing and affected by this rule. There should be no negative financial impact on the prescriber community as any necessary changes to the injured worker's drug regimen should be done in the context of routine office visits. Any prescriptions that result from the changes in the drug regimen would continue to be processed by a pharmacy.

13. **Does the rule increase local government costs? (If yes, you must complete an RSFA Part B).** No

14. **Does the rule regulate environmental protection? (If yes, you must complete an RSFA Part C).** No

15. **If the rule imposes a regulation fee, explain how the fee directly relates to your agency's cost in regulating the individual or business.**

    Not Applicable.

## III. Common Sense Initiative (CSI) Questions

16. **Was this rule filed with the Common Sense Initiative Office?** Yes

17. **Does this rule have an adverse impact on business?** Yes

    A. **Does this rule require a license, permit, or any other prior authorization to engage in or operate a line of business?** No

    B. **Does this rule impose a criminal penalty, a civil penalty, or another sanction, or create a cause of action, for failure to comply with its terms?** No

    C. **Does this rule require specific expenditures or the report of information as a condition of compliance?** Yes

       The proposed rule requires that clinical documentation and evidence of medical necessity be provided to the BWC for short term reimbursement of

new drugs or new dosage forms or strengths of existing drugs approved for use in the United Sates by the FDA on or after the effective date of the rule.

**D. Is it likely that the rule will directly reduce the revenue or increase the expenses of the lines of business of which it will apply or applies?** No

## IV. Regulatory Restrictions (This section only applies to agencies indicated in R.C. 121.95 (A))

**18. Are you adding a new or removing an existing regulatory restriction as defined in R.C. 121.95?** Yes

**A. How many new regulatory restrictions do you propose adding?** 2

4123-6-21.3 Appendix Anticoagulants - Direct Factor Xa Inhibitors "After 30 days of use, prior authorization will be required if treatment is not directly for an allowed condition in the claim"

4123-6-21.3 Appendix Hypnotics - Non-Barbiturate "Prior authorization is required beyond 30 days. "

**B. How many existing regulatory restrictions do you propose removing?** 0