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

Contact: Aniko Nagy **Phone:** 614-466-3293

Email: aniko.n.1@bwc.state.oh.us

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.

This rule establishes the outpatient medication formulary list of drugs approved for reimbursement when prescribed to treat conditions allowed in a claim filed by an injured worker.
The proposed changes to OAC 4123-6-21.3 listed below are contained in the Appendix to the rule, which is the formulary drug list. This proposed revision shall make the following changes in coverage:
MEDICATIONS TO BE DELETED FROM THE FORMULARY
• A total of 100 discontinued drugs will be removed from the outpatient formulary. Deletions are indicated in the proposed Appendix to OAC 4123-6-21.3.

MEDICATIONS TO BE ADDED TO THE FORMULARY
Restrictions for the following proposed formulary additions are outlined in the proposed Appendix to OAC 4123-6-21.3:
• Certolizumab (Cimzia®)
• Golimumab (Simponi®)
• Tofacitinib (Xeljanz®)
• Upadacitinib (Rinvoq®)
• Baricitinib (Olumiant®)
• Abatacept (Orencia®)
• Dupilumab (Dupixent®)
• Lansoprazole 15 mg and 30 mg capsules
• Pantoprazole 20 mg and 40 mg tablets
• Esomeprazole 20 mg tablets
• Buprenorphine-Naloxone sublingual tablets
• Naltrexone (Vivitrol®) long-acting injection
• Ticagrelor (Brilinta®)
• Liquid glycerin suppository
• Mycophenolate mofetil oral suspension
• Cyanocobalamin sublingual tablet

MEDICATIONS WITH CHANGES IN COVERAGE
Coverage changes for the following drugs and drug classes are outlined in the proposed Appendix to OAC 4123-6-21.3:
• Non-Barbiturate Hypnotics
• Ondansetron 4 mg and 8 mg orally disintegrating tablets
• Ulcer Drugs- Proton Pump Inhibitors
• Topical Corticosteroids
• Buprenorphine-Naloxone Buccal Film

OTHER CHANGES
Restrictions for the following drug classes were updated to remove redundant language and to add clarifying language:
- Opioid Agonists- Immediate Release
- Opioid Agonists- Sustained release
- Opioid Combinations
- Opioid Partial Agonists- Sustained Release

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.

    0.00

    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?** No

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

Not Applicable

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

Not Applicable