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:

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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.

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
Nitroglycerin capsule ER 9 MG
Pseudoephedrine, codeine, and guaifenesin solution 30-10-100 MG/5ML
Hyoscyamine sulfate tablet 0.125 MG
Phenobarbital-Hyoscyamine-Atropine-Scopolamine tablet 16.2-0.1037-0.0194-0.0065 MG
Methenamine-Hyoscyamine-Methylene Blue-Sodium Phosphate-Phenyl Salicylate Tab 81 MG
Potassium Citrate & Citric Acid Solution 1100-334 MG/5ML
Isometheptene-Dichloralphenazone-Acetaminophen Cap 65-100-325 MG
Pramoxine-HC-Chloroxylenol Otic Soln 10-10-1 MG/ML
Hydrocortisone Acetate Suppository 25 MG
Hydrocortisone Acetate Suppository 30 MG
Hydrocortisone Acetate w/ Pramoxine Rectal Cream 1-1%
Hydrocortisone Acetate w/ Pramoxine Rectal Cream 2.5-1%
Iodoquinol-HC Cream 1%
Iodoquinol-Hydrocortisone-Aloe Polysaccharide Gel 1-2-1%
Pramoxine-HC Cream 1-1%
Pramoxine-HC Lotion 1-2.5%
Pramoxine-HC Ointment 1-2.5%
Trypsin w/ Castor Oil & Peruvian Balsam Spray
Butamben-Tetracaine-Benzocaine Aerosol Spray 2-2-14%

MEDICATIONS TO BE ADDED TO THE FORMULARY
Ketorolac Tromethamine IM Inj 60 MG/2ML
Ketorolac Tromethamine Inj 15 MG/ML
Ketorolac Tromethamine Inj 30 MG/ML
Midazolam HCl Inj 5 MG/ML
Midazolam Nasal Spray Soln 5 MG/0.1 ML
Prior authorization required. Reimbursement is limited to claims in which all of the following are documented: frequent seizure activity that is related to allowed conditions in the claim, the injured worker is concurrently receiving maintenance anticonvulsant medication, and the injured worker is unable to administer generic

injectable midazolam intranasally. Reimbursement is limited to one package every 30 days.
Rivaroxaban Tab 2.5 MG
Benralizumab Subcutaneous Soln Prefilled Syringe 30 MG/ML and Benralizumab Subcutaneous Soln Auto-injector 30 MG/ML
Prior authorization is required. Reimbursement is limited to claims in which all of the following are documented: diagnosis of asthma allowed in the claim, inadequate control of asthma after at least three months of use of an inhaled corticosteroid plus a long acting beta-agonist OR an inhaled corticosteroid plus a long acting muscarinic antagonist, and a peripheral eosinophil count greater than or equal to 300 cells/mcL within the past 12 months. Initial approval will be
granted for six months, and subsequent requests may be considered if there is a documented decrease in exacerbations, improvement in symptoms, or decrease in utilization of rescue medications.
Glecaprevir-Pibrentasvir Tab 100-40 MG
Sodium Chloride Soln Nebu 3%

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