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?** Yes

    A. **What is the rule's five year review date?** 5/29/2020

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?**

    Pursuant to R.C. 119.032, state agencies are required to review all agency rules every five years to determine whether to amend the rules, rescind the rules, or continue the rules without change. Due to such review, the Bureau is proposing to amend this rule for the purposes explained below.

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 the formulary rule are to:
Add language clarifying that, except as indicated in the rule, the appendix is the complete list of medication approved for reimbursement by BWC "when dispensed to an injured worker by a registered pharmacist from an enrolled outpatient pharmacy provider".
Condense and rephrase language related to revisions to the formulary.
Revise language requiring BWC to develop policies related to expedited review processes to state BWC will provide an expedited review, when necessary.
Remove language requiring BWC to develop policies to address timely review of new drug products.
Add language providing for the reimbursement of antineoplastic drugs not listed in the appendix when prescribed for treatment of an allowed cancer condition.
Revise the appendix to add the following medications:
o Lidocaine 4% topical spray
o Diclofenac epolamine 1.3% patches with the following restrictions:
This drug may be reimbursed with prior authorization when medical documentation shows contraindication, intolerance, or clinical failure to at least 2 other non-steroidal anti inflammatory drugs on the formulary. Reimbursement is limited to the first 12 weeks following the date of injury and may not exceed 2 patches per day. BWC will not reimburse for concurrent use with other non-steroidal anti-inflammatory drugs.
o Erenumab-aooe, fremanezumab-vfrm, and galcanezumab-gnlm with the following limitations:
Migraine Products - Monoclonal Antibodies Class Restrictions: These drugs may be reimbursed with prior authorization when migraine is an allowed condition in the claim and medical documentation shows a systemic allergic reaction, consistent with known symptoms or clinical findings of a medication allergy, or a clinical failure to at least three of the following:
Topiramate, sodium valproate, divalproex sodium, amitriptyline, venlafaxine, atenolol, metoprolol, nadolol, propranolol, timolol. The initial reimbursement may be for up to 3 months. Subsequent approvals may be granted if there is a documented positive response to therapy demonstrated by a reduction in migraines AND there is documented improvement in function. A maximum of two pens for the initial fill, followed by 1 pen per month is allowed.

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.**

    BWC is revise filing this rule to update the effective date in paragraph (A) (and in the footer on the appendix) of this rule, from June 1, 2020 to September 1, 2020.

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?** Yes

    A. **How many new regulatory restrictions do you propose adding?** 0

    B. **How many existing regulatory restrictions do you propose removing?** 2

       4123-6-21.3(D) removes a mandate that the bureau's pharmacy and therapeutic committee shall evaluate and make recommendations regarding formulary medications.

       4123-6-21.3(E) removes a mandate that the bureau shall develop policies to address the timely review of new drug products.