Rule Summary and Fiscal Analysis (Part A)

Bureau of Workers' Compensation
Agency Name

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4123-6-21.3 **AMENDMENT**
Rule Number TYPE of rule filing

Rule Title/Tag Line **Outpatient medication formulary.**

RULE SUMMARY

1. Is the rule being filed for five year review (FYR)? **No**

2. Are you proposing this rule as a result of recent legislation? **No**

3. Statute prescribing the procedure in accordance with the agency is required to adopt the rule: **119.03**

4. Statute(s) authorizing agency to adopt the rule: **4121.12, 4121.121, 4121.30, 4121.31, 4121.44, 4121.441, 4123.05, 4123.66**

5. Statute(s) the rule, as filed, amplifies or implements: **4121.12, 4121.121, 4121.44, 4121.441, 4123.66**

6. State the reason(s) for proposing (i.e., why are you filing,) this rule:

The Bureau proposes to revise the formulary appendix to this rule by amending coverage to the opioid drug class and drug products listed in the formulary.

These recommended changes are the result of recommendations from the Bureau's Pharmacy & Therapeutics Committee (P&T) as well as a general clean up of the formulary appendix. 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 literature, accepted treatment guidelines and best clinical practice as well as FDA and information published by the drug manufactures.

7. If the rule is an AMENDMENT, then summarize the changes and the content of the proposed rule; If the rule type is RESCISSION, NEW or NO CHANGE, then summarize the content of the rule:

This rule is a list of drugs approved for reimbursement when prescribed to treat conditions allowed in the claim. The formulary is maintained by the Bureau with input from the Bureau's P&T Committee.

The proposed changes are contained in the Appendix to the rule, which is the formulary drug list. These proposed revisions are effective October 1, 2017:

MEDICATIONS TO BE DELETED FROM THE FORMULARY:

a. All dosage forms of alprazolam;

1. In claims where alprazolam has not been previously covered, reimbursement will be denied for all prescriptions for any dosage form of alprazolam.

2. In claims where alprazolam was covered prior to October, 2017, the coverage of alprazolam will be limited to the daily dose and dosage form that was last covered prior to October 1, 2017.

b. Fluoxetine tablets; all doses of fluoxetine capsules will continue to be covered products.

1. In claims where fluoxetine tablets have not been previously covered, reimbursement will be denied for all prescriptions for fluoxetine tablets.

2. In claims where fluoxetine tablets was covered prior to October 1, 2017, the prescriber and injured worker will be given 60 days to move to a covered form of fluoxetine tablets or another antidepressant.

c. Opana® ER; all doses of oxymorphone ER will continue to be covered.

1. In claims where Opana® ER was covered prior to October 1, 2017, the prescriber and injured worker will be given 60 days to move to a covered form of oxymorphone ER or another opioid analgesic.

d. Pexeva® (paroxetine mesylate); all doses of paroxetine HCl will continue to be covered.

1. In claims where Pexeva® (paroxetine mesylate) has not been previously covered,

reimbursement will be denied for all prescriptions for a Pexeva (paroxetine mesylate).

2. In claims where Pexeva® (paroxetine mesylate) was covered prior to October 1, 2017, the prescriber and injured worker will be given 60 days to move to a covered form of paroxetine or another antidepressant.

e. Menthol 5% pads and methyl salicylate liquid.

MEDICATIONS TO BE ADDED TO THE FORMULARY:

a. Onfi® (clobazam) - with the limitation that a seizue disorder must be an allowed condition in the claim and that the injured worker must have tried and failed (as defined in O.A.C. 4123-6-21 (J), two first line anticonvulsants before Onfi® will be covered.

b. All anti-diabetic medications - and will be covered in claims with diabetes as an allowed condition. (See the appendix to the rule for the complete list of products to be covered)

c. All oral inhalation respiratory medications and will be covered in claims with an allowed pulmonary condition. (See the appendix to the rule for the complete list of products to be covered)

d. Entresto®.

e. Xiidra®.

f. Coverage of several over the counter topical analgesics (e.g. BioFreeze, Aspercreme, IcyHot Lidocaine). (See the appendix to the rule for the complete list of products to be covered)

MEDICATIONS WITH REVISIONS TO COVERAGE

a. Coverage of Marinol® (dronabinol) for nausea and vomiting will require a Prior Authorization documenting a previous trial and therapeutic failure (as defined in O.A.C.4123.6.21 (J)) with either promethazine, ondansetron, or meclizine.

1. In claims where Marinol® (dronabinol) was covered prior to October, 2017, the medication will continue to be allowed at the current dose.

2. Marinol® (dronabinol) will be covered in injury claims with an allowed condition of chemotherapy induced nausea and vomiting.

b. Reimbursement for Lyrica® will be limited to a maximum of 3 capsules per day or 600 mg per day.

1. In claims where Lyrica® was covered for a quantity greater than 3 capsules per day or dose greater than 600 mg/day prior to October 1, 2017, the prescriber and

injured worker will be given 60 days to consolidate their dosing to a maximum of 3 capsules per day or 600 mg per day.

c. Reimbursement for erectile dysfunction medications (Viagra, Cialis) will be limited to one product per month.

1. In claims where concurrent use of erectile dysfunction medications were covered prior to October 1, 2017, the prescriber and injured worker will be given 60 days to move to a single product per month.

d. The Bureau will implement tiered coverage of medications used for the treatment of Opioid Induced Constipation (OIC).

1. Tier 1 will require documentation of a diagnoses of OIC due to opioids covered by BWC and the use of at least two courses of over counter laxatives covered by the Bureaubefore a Tier 2 prescription OIC drug is covered.

2. Tier 2 medications are Movantik®, and Amitiza® 24 mcg and will require Prior Authorization with documentation of therapeutic failure of the first tier medications (as defined in O.A.C. 4123-6-21 (J))

3. Tier 3 medications are the oral and injectable forms of Relistor®. Coverage of either dosage form will require a Prior Authorization and documentation of therapeutic failure (as defined in O.A.C. 4123-6-21(J)) of one of the second tier medications.

4. In claims where Movantik®, Relistor®, or Amitiza® was covered prior to October 1, 2017, the medication will continue to be allowed at the current dose.

e. The Bureau will implement tiered coverage of topical medications containing lidocaine.

1. Tier 1 will require documentation of a trial and therapeutic failure (as defined in O.A.C. 4123-6-21(J)) of an over the counter topical lidocaine product in the 4% or less concentration before a higher concentration product will be covered.

2. Tier 2 will contain topical lidocaine ointment, cream and transdermal (patch) products with a concentration of 5%. A Prior Authorization will be required and documentation of a trial and therapeutic failure (as defined in O.A.C. 4123-6-21 (J)) with a tier one lidocaine product will be required before a lidocaine 5% product will be covered.

3. Transdermal lidocaine 5% patches will still require that an allowance for Post Herpetic Neuralgia be in the claim for coverage of the product.

4. In claims where lidocaine 5% products were covered prior to October 1, 2017, the product will continue to be covered at the current dosage.

8. If the rule incorporates a text or other material by reference and the agency claims the incorporation by reference is exempt from compliance with sections 121.71 to 121.74 of the Revised Code because the text or other material is **generally available** to persons who reasonably can be expected to be affected by the rule, provide an explanation of how the text or other material is generally available to those persons:

This response left blank because filer specified online that the rule does not incorporate a text or other material by reference.

9. If the rule incorporates a text or other material by reference, and it was **infeasible** for the agency to file the text or other material electronically, provide an explanation of why filing the text or other material electronically was infeasible:

This response left blank because filer specified online that the rule does not incorporate a text or other material by reference.

10. If the rule is being **rescinded** and incorporates a text or other material by reference, and it was **infeasible** for the agency to file the text or other material, provide an explanation of why filing the text or other material was infeasible:

Not Applicable.

11. If **revising** or **refiling** this rule, identify changes made from the previously filed version of this rule; if none, please state so. If applicable, indicate each specific paragraph of the rule that has been modified:

Not Applicable.

12. Five Year Review (FYR) Date: **2/1/2020**

(If the rule is not exempt and you answered NO to question No. 1, provide the scheduled review date. If you answered YES to No. 1, the review date for this rule is the filing date.)

NOTE: If the rule is not exempt at the time of final filing, two dates are required: the current review date plus a date not to exceed 5 years from the effective date for Amended rules or a date not to exceed 5 years from the review date for No Change rules.

FISCAL ANALYSIS

13. Estimate the total amount by which *this proposed rule* would **increase / decrease** either **revenues / expenditures** for the agency during the current biennium (in dollars): Explain the net impact of the proposed changes to the budget of your agency/department.

This will have no impact on revenues or expenditures.

0.00

n/a

14. Identify the appropriation (by line item etc.) that authorizes each expenditure necessitated by the proposed rule:

n/a

15. Provide a summary of the estimated cost of compliance with the rule to all directly affected persons. When appropriate, please include the source for your information/estimated costs, e.g. industry, CFR, internal/agency:

The prescriber and pharmacy business communities are the only two business communities involved with medication prescribing and dispensing. The impacted segments of those communities are the Bureau providers who prescribe and those network pharmacies enrolled with the bureau that dispense the prescriptions.

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. And any prescriptions that result from the changes in the drug regimen would continue to be processed by a pharmacy.

16. Does this rule have a fiscal effect on school districts, counties, townships, or municipal corporations? **No**

17. Does this rule deal with environmental protection or contain a component dealing with environmental protection as defined in R. C. 121.39? **No**

S.B. 2 (129th General Assembly) Questions

18. Has this rule been filed with the Common Sense Initiative Office pursuant to R.C. 121.82? **Yes**

19. Specific to this rule, answer the following:

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 bureau 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 this rule.