4123-6-21.1 **Payment for outpatient medication by self-insuring employer.**

(A) Medication must be for treatment of ~~an occupational~~ a work related injury or occupational disease in a claim either allowed by an order of the bureau or the industrial commission, or recognized by a self-insuring employer.

(B) Medication may be prescribed by any treating provider authorized by law to prescribe such medication.

(C) Drugs covered in self-insuring employer claims are limited to those that are approved for human use in the United States by the food and drug administration (FDA) and that are dispensed by a registered pharmacist ~~from an enrolled pharmacy provider~~.

(D) A self-insuring employer may approve and reimburse for various drugs as a part of a comprehensive treatment plan submitted by the physician of record or a treating physician when reasonably related to and medically necessary for treatment of the allowed conditions in the claim, provided that such approval and reimbursement shall not constitute the recognition of any additional conditions in the claim even if such drugs are used to treat conditions that have not been allowed in the claim.

(E) Payment for medications to pharmacy providers shall include both a product cost component and a dispensing fee component.

(1) Except as provided in this paragraph, product cost component shall be the lesser of the following: maximum allowable cost established under paragraph ~~(O)~~(N) of this rule, if applicable, or the average wholesale price (AWP) of the commonly stocked package size minus fifteen per cent.

(a) For repackaged brand name medications, the product cost component shall be calculated using the AWP of the original labeler.

(b) For ~~non-sterile~~ compounded prescriptions, the product cost component shall be limited to the lesser of the ~~usual and customary price~~ the maximum allowable cost, if applicable, for each ingredient or the AWP of the commonly stocked package size minus fifteen per cent for each ingredient.

(c) The maximum product cost component reimbursement for any one non-sterile compounded prescription will be four hundred dollars.

(2) The dispensing fee component for non-compounded prescriptions shall be three dollars and fifty cents, unless the self-insuring employer has negotiated a payment rate with the pharmacy provider pursuant to rule 4123-6-46 of

the Administrative Code. Only pharmacy providers are eligible to receive a dispensing fee.

(3) The dispensing fee component for non-sterile compounded prescriptions shall be eighteen dollars and seventy-five cents.

(4) The dispensing fee component for sterile compounded prescriptions shall be thirty-seven dollars and fifty cents.

(F) The pharmacy provider is required to bill medication at their usual and customary charge. The amount paid to the provider will be the lesser of the provider's usual and customary charge or the reimbursement allowed as determined in paragraph (E) of this rule, unless the self-insuring employer has negotiated a payment rate with the provider pursuant to rule 4123-6-46 of the Administrative Code. Pharmacy providers are required to submit for billing the national drug code (NDC) number of the stock bottle from which the dispensed medication is obtained. Drugs may be dispensed in unit dose packaging, but the NDC number of the closest comparable bulk package listed in the bureau or vendor payment system must be used for billing purposes.

(G) The pharmacy provider shall:

~~(1) Maintain a signature log verifying receipt of applicable covered medications;~~

~~(2)~~(1) Include prescriber information within bills submitted electronically to the self-insuring employer or its vendor for payment. The prescriber information must include the national provider identifier (NPI) or the drug enforcement administration (DEA) number;

~~(3)~~(2) Not pay, allow, or give, or offer to pay, allow, or give, any consideration, money, or other thing of value to an injured worker, of to any other person, firm, or corporation (including but not limited to free or discounted medications or other goods or services) as an inducement to or in return for the injured worker ordering or receiving from the provider any medications or other goods or services for which payment may be made by the self-insuring employer or its vendor or QHP under Chapter 4121., 4123., 4127., or 4131. of the Revised Code;

~~(4)~~(3) Comply with all applicable billing instructions contained in the bureau's provider billing and reimbursement manual in effect on the billed date(s) of service.

(H) Claimant reimbursement for medications shall be in accordance with rule 4123-6-26 of the Administrative Code and shall at least be equal to the bureau's established rate for the medication, unless the self-insuring employer has negotiated a payment

rate with the pharmacy provider utilized by the claimant pursuant to rule 4123-6-46 of the Administrative Code, in which case the claimant reimbursement shall be at least the rate negotiated with the provider. ~~Claimant requests for reimbursement shall comply with all applicable billing instructions contained in the bureau's provider billing and reimbursement manual in effect on the billed date(s) of service.~~ Requests for reimbursement must be paid within thirty days of receipt of the request.

(I) Self-insuring employers must obtain a drug utilization review from a physician before terminating payment for current medications, as follows:

(1) ~~Before~~ Except as otherwise provided in paragraph (I)(7) of this rule, before terminating payment for current medications, the self-insuring employer shall notify all parties to the claim (including authorized representatives) and the prescribing physician, in writing, that a physician drug review is being performed, or has been performed, regarding the necessity and appropriateness of the continued use of current medications (by therapeutic drug class).

(2) The written notice shall inform all parties to the claim (including authorized representatives) and the prescribing physician that they have twenty-one days from receipt of the notice to provide additional information and/or medical documentation to justify the need for continued use of the medications (by therapeutic drug class).

(3) The self-insuring employer shall provide all medically related information regarding the medications to an independent physician reviewer for review and opinion as to the necessity or appropriateness of the medications. If the self-insuring employer has obtained an independent physician reviewer's report prior to sending the notice required by paragraph (I)(1) of this rule and subsequently receives additional information and/or medical documentation pursuant to paragraph (I)(2) of this rule, the self-insuring employer shall provide the additional information and/or medical documentation to the independent physician reviewer and obtain an addendum. The independent physician reviewer's report (and addendum, if applicable) shall address the medical rationale, necessity and appropriateness of the drug treatment in the control of symptoms associated with the allowed conditions in the claim.

(4) When the independent physician reviewer's report (and addendum, if applicable) indicates the drug treatment is not medically necessary or appropriate for treatment or in the control of symptoms associated with the allowed conditions in the claim, the self-insuring employer may terminate reimbursement for the medications (by therapeutic drug class) effective as of the date of receipt of the independent physician reviewer's report, or addendum if one is obtained, or in the case that a drug is in a therapeutic class that requires a "weaning-off"

period, in accordance with the tapering schedules set forth in the appendix to rule 4123-6-21.5 of the Administrative Code or such other date as agreed to by the prescribing physician and self-insuring employer.

(5) In the event the self-insuring employer terminates reimbursement for the medications as set forth in paragraph (I)(4) of this rule, the self-insuring employer or its authorized representative shall provide all parties to the claim (including authorized representatives) and the prescribing physician with a copy of the independent physician reviewer's report (and addendum, if applicable) and the self-insuring employer shall notify the ~~employee~~ injured worker and the ~~employee's~~ injured worker's representative in writing of its decision to terminate. The employer's notification to the ~~employee~~ injured worker and ~~employee's~~ injured worker's representative shall indicate that the ~~employee~~ injured worker has the right to request a hearing before the industrial commission.

(6) In the event there is a dispute as to whether the drug treatment is medically necessary or appropriate for treatment of the symptoms associated with the allowed conditions in the claim, the disputed matter shall be adjudicated in accordance with paragraph (K)(5) of rule 4123-19-03 of the Administrative Code.

(7) The self-insuring employer may terminate current medications that have been removed from the bureau's outpatient medication formulary set forth in the appendix to rule 4123-6-21.3 of the Administrative Code without obtaining a physician drug review. However, the tapering schedules set forth in the appendix to rule 4123-6-21.5 of the Administrative Code would apply.

(J) Self-insuring employers may deny initial requests for a drug or therapeutic class of drugs as not being reasonably related to or medically necessary for the treatment of the allowed conditions in a claim.

~~(K) Self-insuring employers may utilize medication utilization protocols formulated by the bureau for select conditions or diseases consistent with current medical texts and peer reviewed medical literature.~~

~~Refusal to comply with the established protocols shall result in refusal of reimbursement for the medications which are not within the established protocols. This rule does not require the discontinuation of treatment with medications that are not within the established protocols, but simply states the bureau's or self-insured employer's refusal to reimburse for such medications.~~

~~(L)~~(K) ~~Through internal development or through vendor contracts, self-insuring~~ Self-insuring employers may ~~implement a point-of-service adjudication system~~ contract with a pharmacy benefits manager. ~~Upon implementation, a~~ A self-insuring employer utilizing a pharmacy benefits manager may require pharmacy providers to submit bills for medication by an on-line point-of-service authorization terminal or a host-to-host link with the pharmacy benefits manager's established bill processing system as a condition of reimbursement, and may refuse submission by paper or by tape-to-tape. Self-insuring employers utilizing a ~~point-of-service adjudication system~~ pharmacy benefits manager may refuse to reimburse any third-party pharmacy biller that submits pharmacy bills on behalf of a pharmacy provider or that has purchased pharmacy bills from a pharmacy provider for subsequent submission to the self-insuring employer for payment.

~~(M)~~(L) Self-insuring employers utilizing a ~~point-of-service adjudication system~~ pharmacy benefits manager may require prior authorization of drugs or therapeutic classes of drugs which appear on the bureau's published list of drugs or therapeutic classes of drugs for which prior authorization is required. Notwithstanding rule 4123-19-03 of the Administrative Code, the self-insuring employer shall approve or deny a prior authorization request within three business days of the request.

~~(N)~~(M) Self-insuring employers utilizing a ~~point-of-service adjudication system~~ pharmacy benefits manager may apply the following dispensing limitations, adopted by the bureau, to medications approved and reimbursed by the self-insuring employer:

(1) The bureau may publish supply limitations for drugs which represent the maximum number of days supply that may be dispensed at any one time for a single prescription.

~~(1)~~(2) The bureau may publish maximum prescription quantities which represent the largest number of units per drug that may be dispensed at any one time for a single prescription.

~~(2)~~(3) Requests submitted that exceed either the days supply limit or maximum quantity limit shall be denied; provided, however, that the pharmacy provider may still fill the prescription up to the days supply limit or maximum quantity limit, as applicable. Denials may be overridden by the self-insured employer in cases where medical necessity and appropriateness have been determined.

(4) Refills of drugs not scheduled by the DEA requested before eighty per cent of any published days supply limit has been utilized will be denied.

(5) Refills of drugs scheduled by the DEA requested before ninety per cent of any published days supply limit has been utilized will be denied.

~~(3)~~(6) ~~Refills requested before seventy-five per cent of the days supply has been utilized will be denied, except in cases where the dosage of a drug has been changed and has a new prescription number.~~ Denials may be overridden by the self-insured employer for the following ~~documented~~ reasons with supporting documentation:

(a) ~~Pharmacist entered previous wrong day supply~~The injured worker's pharmacy is submitting an early refill for a shortened days supply to support synchronizing the filling or refilling of the prescription in a manner that allows the dispensed drug to be obtained on the same date each month;

(b) ~~Out of country vacation or travel~~The injured worker is traveling out of the country and will be unable to refill medications during that time;

(c) ~~Pharmacy~~ The injured worker's pharmacy will be closed for more than two days.

(d) An emergency or disaster, as defined in division (O) of section 4123.511 of the Revised Code, is declared by the governor of Ohio or the president of the United States.

~~(O)~~(N) Self-insuring employers utilizing a ~~point-of-service adjudication system~~ pharmacy benefits manager may apply the maximum allowable cost list of the ~~point-of-service adjudication system vendor for multi-source medications which are pharmaceutically and therapeutically equivalent, that is, contain identical doses of the active ingredient and have the same biological effects as determined by the FDA and designated by an "A" code value in the FDA publication, "Approved Drug Products With Therapeutic Equivalence Evaluations" in effect on the billed date(s) of service. For single source drugs, self-insuring employers utilizing a point-of-service adjudication system may utilize as a maximum allowable cost the drug's AWP minus fifteen per cent~~ pharmacy benefits manager.

~~(P)~~(O) ~~Claimants~~ Injured workers who request a brand name drug or whose physician specifies a brand name drug designated by "dispense as written" on the prescription for a medication for which ~~single source or multi-source medications exist that are~~ pharmaceutically and therapeutically equivalent medications exist, as defined in paragraph ~~(O)~~ (I) of ~~this~~ rule 4123-6-21 of the Administrative Code, shall be liable for the product cost difference between ~~the established maximum allowable cost price of the drug product and~~ the AWP of the dispensed brand name drug minus fifteen per cent and the established maximum allowable cost price of the drug product. However, the self-insuring employer or its vendor may approve reimbursement of the dispensed

brand name drug at the AWP of the drug minus fifteen per cent if the following circumstances are met:

(1) The injured worker has a documented, systemic allergic reaction as a result of taking the generic equivalent which is consistent with known symptoms or clinical findings of a medication allergy; ~~and~~or

(2) The injured worker has been prescribed, and has tried, ~~other A code drugs in the therapeutic class~~ another generic equivalent and the intended therapeutic benefit has not been achieved or an unacceptable adverse event has occurred.

~~(Q)~~(P) A self-insuring employer has sufficient grounds to refuse to pay for the dispensing of drugs and other medications when a pharmacy provider fails to observe any state or federal law relating to his or her professional licensure or to the dispensing of drugs and other medication.

Effective:

Five Year Review (FYR) Dates: 1/5/2021

Certification

Date

Promulgated Under:	119.03
Statutory Authority:	4121.12, 4121.121, 4121.30, 4121.31, 4121.44, 4121.441, 4123.05, 4123.35, 4123.66
Rule Amplifies:	4121.12, 4121.121, 4121.44, 4121.441, 4123.66
Prior Effective Dates:	02/01/2010, 09/01/2011, 01/01/2012, 12/01/2013, 04/10/2014, 11/13/2015, 01/01/2017, 06/02/2017