4123-6-21 **Payment for outpatient medication.**

(A) Except as otherwise provided in rule 4123-6-21.6 of the Administrative Code, medication must be for the treatment of 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. The bureau may deny a drug or therapeutic class of drugs as not being reasonably related to or medically necessary for treatment of the allowed conditions in a claim.

(B) Medication may be prescribed by any treating provider authorized by law to prescribe such medication; however, reimbursement for medication shall be denied under the following circumstances:

(1) Reimbursement for prescriptions written by providers who are not enrolled with the bureau and who refuse to become enrolled shall be denied.

(2) Reimbursement for prescriptions written by providers who are enrolled but non-certified shall be denied, except in the following situations:

(a) The prescription is written by a non-bureau certified provider during initial or emergency treatment of the injured worker if the injured worker's claim and treated conditions are subsequently allowed.

(b) The prescription is written by a non-bureau certified provider who is outside the state or within the state where no or an inadequate number of bureau certified providers exist and the MCO has determined that the treatment to be provided by the non-bureau certified provider is not reasonably available through a like bureau certified provider and has authorized the non-bureau certified provider to continue to provide the treatment.

(c) The prescription is written by a non-bureau certified provider for an injured worker with a date of injury prior to October 20, 1993, the provider was the injured worker's physician of record prior to October 20, 1993, and the injured worker has continued treatment with that non-bureau-certified provider.

(C) Drugs covered 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) The bureau may require prior authorization of certain drugs or therapeutic classes of drugs, drugs above a certain cost threshold, drugs submitted outside a certain time frame from the date of injury or the last prescription submitted. or drugs being prescribed for a condition or in a manner not approved by the FDA. The bureau will

publish a list of all such drugs or therapeutic classes of drugs, cost thresholds, or time frames for which prior authorization is required.

(E) Prescriptions for compounded drug products:

(1) Prior authorization may be required for compounded sterile drug products.

(2) Compounded non-sterile prescriptions.

(a) Reimbursement for non-sterile compounded prescriptions will be denied, except when a commercially available formulary product becomes unavailable (listed on the "Food & Drug Administration Drug Shortages List," or "American Society of Health-System Pharmacists Drug Shortages List").

(b) Reimbursement for non-sterile compounded prescriptions shall only be considered upon the submission of both:

(i) A prior authorization request, and

(ii) A copy of the signed prescription that lists all active pharmaceutical ingredients. The prescription must comply with the Ohio state board of pharmacy requirements for a valid prescription set forth in rules ~~4729-5-13~~ 4729:5-5-05 and ~~4729-5-30~~4729:5-5-15 of the Administrative Code.

(c) Approval for reimbursement of non-sterile compounded prescriptions will be for an initial period of thirty days with subsequent approvals contingent upon commercial product availability. Not more than one prescription for a non-sterile compounded prescription will be approved for reimbursement in any thirty day period.

(F) Drugs which fall into one of the following categories may be approved and reimbursed by an MCO as part of a comprehensive treatment plan submitted by the physician of record or treating physician:

(1) Drugs for the treatment of obesity;

(2) Drugs for the treatment of infertility;

(3) Non-compounded parenteral drugs not intended for self-administration;

(4) Drugs used to aid in smoking cessation;

(5) Drugs dispensed to a injured worker while the injured worker is admitted to a hospital during an approved inpatient admission or during the course of an outpatient visit in a hospital.

(G) 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, the product cost component shall be the lesser of the following: maximum allowable cost, if applicable, or the average wholesale price (AWP) of the commonly stocked package size minus ~~fifteen per cent~~a percentge determined by the bureau, subject to annual review.

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

(b) For compounded prescriptions, the product cost component shall be limited to the lesser of the maximum allowable cost, if applicable, for each ingredient, or the AWP of the commonly stocked package size minus ~~fifteen per cent~~the percentage determined by the bureau for each ingredient pursuant to paragraph (G)(1) of this rule.

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

(2) The dispensing fee ~~component~~components for non-compounded prescriptions, non-sterile compounded prescriptions, and sterile compounded prescriptions shall be ~~three dollars and fifty cents~~flat rate fees determined by the bureau, subject to annual review. 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.~~

(H) 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 by the bureau under paragraph (G) of this rule. The bureau shall not 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 bureau for payment. Pharmacy providers are required to submit for billing the 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 the bureau's pharmacy benefit manager's payment system must be used for billing purposes. The pharmacy provider shall:

(1) Include prescriber information within bills submitted electronically to the bureau or the bureau's pharmacy benefits manager for payment. The prescriber information must include the national provider identifier (NPI) or the drug enforcement administration (DEA) number;

(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, or 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 bureau, the bureau's pharmacy benefits manager, or MCO under Chapter 4121., 4123., 4127., or 4131. of the Revised Code;

(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.

(I) The bureau may establish a maximum allowable cost for single source or 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. The methodology used to determine a maximum allowable cost for a qualified drug product shall be determined by the bureau. The bureau may ~~choose to~~ utilize the maximum allowable cost list of a vendor or develop its own maximum allowable cost list.

(J) 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 pharmaceutically and therapeutically equivalent medication exist, as defined in paragraph (I) of this rule, shall be liable for the product cost difference between the AWP of the dispensed brand name drug minus ~~fifteen percent~~the percentage determined by the bureau pursuant to paragraph (G)(1) of this rule and the established maximum allowable cost price of the drug product. However, the bureau may approve reimbursement of the dispensed brand name drug at the AWP of the drug minus ~~fifteen per cent~~the percentage determined by the bureau pursuant to paragraph (G)(1) of this rule 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; or

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

(K) The following dispensing limitations may be adopted by the bureau:

(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.

(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.

(3) Requests submitted that exceed any published days supply limit or maximum quantity limit shall be denied. Denials may be overridden by the bureau 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.

(6) Denials may be overridden by the bureau for the following reasons with supporting documentation:

(a) 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) The injured worker is traveling out of the country and will be unable to refill medications during that time;

(c) 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.

(L) Except as otherwise provided in paragraph (F) of this rule, outpatient medications shall be billed to and reimbursed through the bureau's pharmacy benefits manager. Pharmacy providers must submit bills for medication by an on-line point-of-service authorization terminal or a host-to-host link with the bureau's pharmacy benefits manager's established bill processing system as a condition of provider enrollment or reimbursement. Submission by paper or by tape-to-tape will not be accepted by the bureau or the bureau's pharmacy benefits manager.

(M) A claimant may request outpatient medication reimbursement in accordance with rule 4123-6-26 of the Administrative Code using form C-17 or equivalent. Claimant reimbursement may be limited to the following situations:

(1) Claimants whose medication is not payable under division (I) of section 4123.511 of the Revised Code on the date of service, but later becomes payable;

(2) Emergency situations where an enrolled pharmacy provider is not available;

(3) Claimants who reside out of the country.

(N) A "pharmacy provider" designation and provider number can be obtained by a provider who meets all the following criteria:

(1) Has a valid "terminal distributor of dangerous drugs" as defined in section 4729.01 of the Revised Code if located within Ohio; or an equivalent state license if located outside of Ohio; and,

(2) Has a valid DEA number; and,

(3) Has a licensed registered pharmacist in full and actual charge of a pharmacy; and,

(4) Has the ability and agrees to submit bills at the point of service.

All state and federal laws and regulations relating to the practice of pharmacy and the dispensing of medication by a duly licensed pharmacist must be observed.

(O) The bureau may contract with a pharmacy benefit manager to perform drug utilization review and on-line bill processing, maintain a pharmacy provider network and prior authorization program for medications, and provide management reports. The bureau or its vendor may also contract rebate agreements with drug manufacturers. The bureau may utilize other services or established procedures of the pharmacy benefits manager which may enable the bureau to control costs and utilization and detect fraud.

(P) The bureau may identify circumstances under which it may consider reimbursement for pharmacist professional services (also known as cognitive services) when payment for such services results in a measurable, positive outcome. The bureau shall be responsible for developing the criteria which will be used to assess the compensability of billed pharmacist professional services. The bureau shall be responsible for developing the structure of the reporting of the measurable outcomes used to justify the payment of pharmacist professional services, which may include reimbursement for the dispensing fee component. The amount that could be reimbursed for pharmacist professional services shall be determined by the bureau.

(Q) The bureau shall retain a registered pharmacist licensed in the state of Ohio to act as the full-time pharmacy program director to assist the bureau in the review of drug bills. The pharmacy program director may assist the bureau in determining the appropriateness, eligibility, and reasonableness of compensation payments for drug services. The bureau may adopt a drug formulary with the recommendation of the bureau's pharmacy and therapeutics committee established by rule 4123-6-21.2 of the Administrative Code, and may consult with the committee on the development and ongoing annual review of the drug formulary and other issues regarding medications.

Effective:

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Certification

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