



## Ohio Administrative Code

### Rule 5160-9-03 Pharmacy services: covered drugs and associated limitations.

Effective: February 16, 2024

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#### (A) Covered prescribed drugs

Drugs covered by the Ohio department of medicaid (ODM) pharmacy program, or a managed care entity as defined in rule 5160-26-01 of the Administrative Code, are prescribed drugs as defined in rule 5160-9-05 of the Administrative Code that are dispensed to an eligible recipient for use in the recipient's residence, including a nursing facility (NF), as defined in section 5165.01 of the Revised Code, or intermediate care facility for individuals with intellectual disabilities (ICF/IID), as defined in section 5124.01 of the Revised Code, and fall into one of the following categories:

(1) "Dangerous drugs" as defined in section 4729.01 of the Revised Code that meet the definition of a "covered outpatient drug (COD)" as defined in 42 C.F.R. 447.502 (November 19, 2021) that are not non-covered drugs as described in paragraph (B) of this rule.

(2) Over-the-counter (OTC) drugs listed on the "OH PBM OTC List" located on the ODM pharmacy website at <https://pharmacy.medicaid.ohio.gov>. The list is updated regularly and is recorded with the effective date included in each new version.

(3) Compounded prescriptions in accordance with paragraph (E) of this rule, when compounded with ingredients described in paragraphs (A)(1) to (A)(2) of this rule or with active pharmaceutical ingredients (API) and excipients listed on the ODM pharmacy program website at <https://pharmacy.medicaid.ohio.gov>.

(4) Vaccines, inoculations, and immunizations, other than influenza and coronavirus vaccines, are covered under fee-for-service by the ODM pharmacy program only for residents of a NF or ICF/IID; otherwise these services should be billed as physician services in accordance with Chapter 5160-4 of the Administrative Code. Influenza and coronavirus vaccines may be billed by the pharmacy for a recipient who is not a resident of a NF or ICF/IID if the vaccine will be administered at the pharmacy, or for a recipient who is a resident of a NF or ICF/IID to be administered by facility staff.



(B) Non-covered drugs

Drugs that fall into one of the following categories are non-covered by the Ohio medicaid pharmacy program:

- (1) Drugs for the treatment of obesity.
- (2) Drugs for the treatment of infertility.
- (3) Drugs for the treatment of erectile dysfunction.
- (4) Drug efficacy study implementation (DESI) drugs or drugs that are determined to be identical, similar, or related.
- (5) Drugs that are covered or are eligible to be covered by medicare part D, when prescribed for a recipient who is eligible for medicare.
- (6) Over-the-counter drugs that are not listed on the "OH PBM OTC List" located on the ODM pharmacy program website.
- (7) Drugs being used for indications not approved by the food and drug administration unless there is compelling clinical evidence to support the experimental use.

(C) The prescribed drugs covered under the ODM pharmacy program without prior authorization are specified on the ODM website at <https://pharmacy.medicaid.ohio.gov>. This list indicates the drugs for which co-payments are necessary in accordance with rule 5160-9-09 of the Administrative Code, and specifies whether the drug is covered for a dual eligible as described in rule 5160-1-05 of the Administrative Code. Drugs not listed that meet the requirements of paragraph (A)(1) of this rule and are antidepressants or antipsychotics are exempted from prior authorization if the pharmacy claim indicates that the prescription meets the criteria listed in section 5167.12 of the Revised Code.

(D) Prior authorization



Dangerous drugs not listed in accordance with paragraph (C) of this rule that are medically necessary for treatment require prior authorization; however, noncovered drugs listed in paragraphs (B)(1) to (B)(5) of this rule and APIs and excipients not on the list described in paragraph (A)(3) of this rule are not eligible for prior authorization.

(1) Prior authorization of pharmacy services is administered in compliance with section 1927 of the Social Security Act (January 1, 2020), including a response by telephone or other telecommunication device within twenty-four hours of receipt of a request for prior authorization, and provisions for the dispensing of a seventy-two-hour supply of a COD in an emergency situation.

(2) Drugs not listed in accordance with paragraph (C) of this rule may be covered with prior authorization if medical necessity is documented, the drug is not excluded per paragraphs (B)(1) to (B)(5) of this rule, and a drug that does not require prior authorization cannot be used.

(3) Prior authorization must be obtained from ODM or its designee before the drug claim may be paid. All requests must be submitted in accordance with instructions issued by ODM or its designee.

(a) Only the prescribing provider or a member of the prescribing provider's staff may request prior authorization except as described in paragraph (D)(3)(b) of this rule.

(b) A pharmacist may request prior authorization for an alternative dosage form of a drug to be administered through a tube for recipients who are tube fed, if no comparable drugs that do not require prior authorization can be administered through a tube. A pharmacist may also request prior authorization of a seventy-two-hour supply of a dangerous drug that is a COD in an emergency situation if the prescribing provider or prescribing provider's staff is not available to request prior authorization. A pharmacist may also request prior authorization for a recipient resident in long term care.

(4) Drugs in therapeutic classes that are covered or are eligible to be covered under medicare part D are not available for prior authorization for a recipient who is eligible for medicare. Prior authorization may be requested for drugs in drug classes that may be covered by medicaid for a dual eligible as indicated in the list described in paragraph (C) of this rule and are subject to any stated



limits.

(5) When a request for prior authorization is denied, the recipient is informed in writing of the denial and the right to a state hearing.

(E) Compounded drugs

(1) Compounded drugs are covered if the recipient's medical need cannot be met by a covered product that is a COD and at least one ingredient meets the requirements of paragraph (A) of this rule.

(2) Compounded drug claims must be submitted to ODM or its designee using the national drug code (NDC) for each ingredient that is a part of the compound.

(3) An ingredient in a compounded drug that is both a COD and a dangerous drug, not listed in accordance with paragraph (C) of this rule, will require prior authorization. If a prior authorization is not approved or if an ingredient is not eligible for authorization (i.e., not covered as described in paragraph (A) of this rule, excluded from coverage as described in paragraph (B) of this rule, or excluded from separate payment as described in paragraph (I) of this rule), the pharmacy provider may elect to receive payment only for those ingredients in the compound that are directly payable by ODM, in accordance with billing instructions issued by ODM or its designee.

(F) Dispensing limitations

(1) Days' supply limits

(a) Acute medications are limited to a thirty-four-day supply.

(b) Select chronic maintenance medications and select durable medical equipment (DME) products covered under the pharmacy benefit are limited to a one-hundred-two-day supply.

(2) Maximum quantity limits



Maximum prescription quantities are listed on the ODM pharmacy program website and represent the largest number of units per drug that may be dispensed at any one time for a single prescription or the largest number of units per drug per day (or other time period) of therapy.

(3) Maximum equivalent daily dose limits

Maximum equivalent daily doses are listed on the ODM pharmacy program website and establish the highest equivalent dose of certain therapeutic classes that may be dispensed when equivalent doses of all drugs in the therapeutic class are summed.

(4) Maximum prescription claim limits

Maximum prescription claim limits are listed on the ODM pharmacy program website and establish the maximum number of claims for drugs that are therapeutic duplicates that are paid within specified time limits .

(5) Claims submitted that exceed the limits described in paragraphs (F)(1) to (F)(4) of this rule are denied. Denials may be overridden by ODM or its designee in cases where medical necessity was determined through the prior authorization process.

(G) Refill prescriptions

(1) Unless the pharmacy is submitting an early refill for a shortened days' supply to support medication synchronization described in section 5164.7511 of the Revised Code and the claim is submitted pursuant to billing instructions for medication synchronization issued by ODM or its designee, the following limitations apply:

(a) Refills of drugs not scheduled by the federal drug enforcement administration (DEA) requested before eighty per cent of the days' supply was utilized will be denied.

(b) Refills of drugs scheduled by the DEA requested before ninety per cent of the days supply was utilized will be denied.



(2) If a new prescription was issued by the prescriber that requires increased dosing frequency, the existing prescription must be utilized until the days supply per cent threshold was met, calculated using the increased dosing frequency.

(3) Denials may be overridden by ODM or its designee for the following documented reasons:

(a) Previous supply was lost, stolen, or destroyed. ODM or its designee may limit the number of instances denials may be overridden in cases of suspected fraud, waste, or abuse, and may request additional documentation before an override is authorized.

(b) Previous claim was submitted with wrong days' supply.

(c) Vacation or travel, for not more than three total months during a twelve month period.

(d) Multiple supplies of the same medication are needed, for example in a school or workshop setting. Multiple supplies are limited to products that cannot be broken into multiple containers, such as inhalers or other unit-of-use containers.

(e) Hospital or police kept the medication.

(f) Brand or generic was ineffective and the recipient was switched to generic or brand.

(g) The recipient is in the custody of the public children's services agency (PCSA) or other Title IV-E agency.

(H) Selected pharmaceuticals, including injectable drugs, are not covered under the pharmacy program if they are administered by a healthcare provider as defined in rule 4123-6-01 of the Administrative Code other than in a NF, ICF/IID, or pharmacy.

(1) Long-acting injectable pharmaceuticals used for substance use disorder or mental health conditions may be billed by the pharmacy for administration in a provider setting under the following circumstances:



- (a) The pharmaceutical is dispensed pursuant to a valid prescription; and
  - (b) The pharmaceutical is labeled with the recipient name; and
  - (c) The pharmaceutical will be administered by a qualified healthcare professional in a provider setting; and
  - (d) The pharmacy and administering provider follow any special handling requirements in the package labeling; and
  - (e) The pharmacy releases the pharmaceutical only to the administering provider or member of the provider's staff, and followed all regulations for a prescription pick-up station required by the Ohio state board of pharmacy. The pharmacy cannot dispense the pharmaceutical directly to the recipient, caregiver, or recipient's representative.
- (2) Pharmaceuticals not described in paragraph (H)(1) of this rule administered in the physician's office must be purchased by the physician's office and billed as a professional service claim.
- (I) Selected over-the-counter drugs are not separately payable when prescribed for a recipient residing in a NF. Such drugs are the responsibility of the NF and are included in the facility per diem payment. The over-the-counter drugs not separately payable are those that are classified into the following drug classes:
- (1) Analgesics, including urinary analgesics;
  - (2) APIs and excipients used in compounded prescriptions;
  - (3) Cough and cold preparations and antihistamines;
  - (4) Ear preparations;
  - (5) Gastrointestinal agents, except histamine-2 receptor antagonists, proton pump inhibitors, and loperamide;



- (6) Hemorrhoidal preparations;
- (7) Nasal preparations, except nasal corticosteroids;
- (8) Ophthalmic agents, except antihistamines;
- (9) Saliva substitutes;
- (10) Sedatives;
- (11) Topical agents, except antifungal and acne preparations; or
- (12) Vitamins and minerals, except prenatal vitamins and fluoride.