Ohio Administrative Code

Rule 5160-9-05 Pharmacy services: payment for prescribed drugs.

Effective: April 24, 2021

(A) Definitions.

(1) "340B ceiling price" means the highest price allowed to be charged by a manufacturer to a 340B covered entity as described in section 340B(a)(4) of the "Public Health Service Act," 42 U.S.C. 256b(a)(4) (in effect as of January 7, 2011).

(2) "Actual acquisition cost (AAC)" means the best determination by the Ohio department of medicaid (ODM) of the actual amount the provider paid to purchase the prescribed drug. ODM acquires AAC data through one or more of the following: national survey of retail pharmacy providers, e.g., national average drug acquisition cost (NADAC) rate process, states' surveys of retail pharmacy providers, and published compendia prices, e.g., wholesale acquisition cost (WAC).

(3) "Administration fee" means the maximum amount payable to a provider to administer a vaccine or injectable drug that is payable under this chapter and authorized to be administered by a pharmacist or pharmacy intern in accordance with section 4729.45 of the Revised Code and the rules promulgated thereunder.

(4) "Calculated allowable" means the sum of the ingredient cost plus any applicable administration fee or professional dispensing fee.

(5) "Equivalent drug product" means drug products with the same active ingredient, strength, and dosage form.

(6) "Equivalent generic drug products" means equivalent drug products that are identified by the medicaid drug rebate program (MDRP) drug product data files as non-innovator products. MDRP files are available on the federal centers for medicare and medicaid services (CMS) web site at https://www.medicaid.gov.

(7) "Ingredient cost" means the portion of the total medicaid payment amount attributable to the cost of the drug product, or in the case of a compound drug, the sum of the cost of the ingredients that are covered in accordance with rule 5160-9-03 of the Administrative Code.

(8) "Long-term care facility (LTCF)" means a nursing facility as defined in section 5165.01 of the Revised Code or intermediate care facility for individuals with intellectual disabilities as defined in section 5124.01 of the Revised Code.

(9) "NADAC" means the rate determined by the CMS to be the average AAC for retail community pharmacies. NADAC rates are on the CMS website at https://www.medicaid.gov.

(10) "Prescribed drug" has the same meaning as in section 5164.01 of the Revised Code.

(11) "Professional dispensing fee (PDF)" means the fee or fees determined pursuant to section 5164.753 of the Revised Code and set forth in this rule.

(12) "State maximum allowable cost (SMAC)" means the maximum amount determined by ODM, based upon an estimate of the statewide AAC for a particular equivalent generic drug group, to be paid to Ohio medicaid providers for an equivalent generic drug group.

(13) "WAC" means the amount reported by a pharmaceutical manufacturer to pharmacy pricing compendia as the list price for a drug and may not represent the actual price of a particular transaction.

(B) Payment for prescribed drugs is the lesser of the provider's billed charges or the calculated allowable, after any coordination of benefits is applied as described in paragraph (F) of this rule. For prescribed drugs that are subject to a co-payment, the amount paid by ODM will be decreased by the amount equal to the co-payment that is to be billed to the individual in accordance with rules 5160-1-09 and 5160-9-09 of the Administrative Code.

(C) The ingredient cost portion of the calculated allowable shall be determined in accordance with the following criteria:

(1) No ingredient cost shall be allowed for a pandemic vaccine that is provided by the Ohio department of health or other government entity at no cost to the provider.

(2) For dates of service on or after April 1, 2017, for any drug purchased under the 340B program, the ingredient cost is the 340B ceiling price. If the 340B ceiling price is not available, the ingredient cost shall be fifty per cent of WAC.

(3) For dates of service on or after April 1, 2017, for a clotting factor, the ingredient cost shall be the payment limit shown in the current medicare part B drug pricing file, minus the furnishing fee assigned by medicare part B. The medicare part B pricing file is available at https://www.cms.gov.

(4) For all other ingredients not captured in paragraphs (C)(1) to (C)(3) of this rule:

(a) For dates of service prior to April 1, 2017, including drugs purchased under the 340B program and clotting factors:

(i) Maximum allowable cost (MAC) pharmaceuticals.

(a) Maximum allowable costs have been determined by the federal department of health and human services for selected drugs. ODM shall not make payment for these products, in the aggregate, at a rate higher than the federal upper limit prices.

(b) ODM established a SMAC for additional selected drugs where either bio-equivalency of the drugs has been established or bio-inequivalency of the drugs has not been established. Payment for SMAC drugs shall be based on the sixty-fifth percentile of the estimated acquisition cost of all readily available equivalent generic drug products.

(ii) Estimated acquisition cost (EAC) pharmaceuticals. All products, other than those designated as MAC drugs, will be considered EAC drugs. Reimbursement will be based on the estimate of WAC determined by periodic review of pricing information from Ohio drug wholesalers, pharmaceutical manufacturers and a pharmacy pricing update service. Maximum reimbursement for these drugs will be WAC plus seven per cent.

(b) For dates of service on or after April 1, 2017, the ingredient cost shall be the NADAC. If CMS has not published a NADAC for the ingredient for the date of service, the ingredient cost shall be the lesser of WAC or SMAC.

(D) For dates of service on or after April 1, 2017, the administration fee portion of the calculated allowable for a vaccine, except for a vaccine for COVID-19, or other injectable drug administered at the pharmacy shall be nineteen dollars thirty-five cents. The administration fee for a vaccine for COVID-19 equals the medicare rate. For dates of service prior to April 1, 2017, the administration fee shall be ten dollars. A vaccine, except for a vaccine for COVID-19, or other drug that is dispensed by a pharmacy to be administered outside the pharmacy, for example at a LTCF, is not eligible for a pharmacy administration fee but may be eligible for a professional dispensing fee.

(E) The PDF portion of the calculated allowable shall be determined in accordance with the following criteria:

(1) Non-compounded drugs.

(a) For dates of service prior to April 1, 2017, only pharmacy and hospital providers as defined in rule 5160-9-01 of the Administrative Code are eligible to receive a dispensing or administration fee. The dispensing fee shall be one dollar eighty cents.

(b) For dates of service on or after April 1, 2017, the PDF paid to a provider for dispensing a non-compounded drug shall be assigned based on the total number of prescriptions filled by the provider during the provider's last completed fiscal year prior to completing the survey required by rule 5160-9-01 of the Administrative Code and reported on the survey. The PDF shall be assigned in accordance with the following criteria:

(i) For providers reporting fewer than fifty thousand prescriptions, thirteen dollars and sixty-four cents.

(ii) For providers reporting between fifty thousand and seventy-four thousand nine hundred ninety-nine prescriptions, ten dollars and eighty cents.

(iii) For providers reporting between seventy-five thousand and ninety-nine thousand nine hundred ninety-nine prescriptions, nine dollars and fifty-one cents.

(iv) For providers reporting one hundred thousand or more prescriptions, eight dollars and thirty cents.

(v) For a provider that failed to submit a complete response to the cost of dispensing survey required by rule 5160-9-01 of the Administrative Code for the previous reporting period, eight dollars and thirty cents.

(vi) For providers newly enrolled as medicaid providers as described in rule 5160-9-01 of the Administrative Code, the PDF shall be as follows:

(a) For a new provider located in Ohio, the provider shall be assigned a PDF of thirteen dollars and sixty-four cents.

(b) For a new provider located outside of Ohio, the provider shall be assigned a PDF of eight dollars and thirty cents.

(2) Compounded drugs. The PDF paid to a provider for dispensing compounded drugs shall be paid in accordance with the following criteria:

(a) The PDF for claims for dispensing total parenteral nutrition (TPN) shall be fifteen dollars per one-day supply on the claim, with a maximum total PDF of one hundred fifty dollars for the claim. To qualify for the TPN PDF, the TPN compound must be mixed by the pharmacy to the final form under sterile conditions. If the products are mixed or activated at the point of administration by connecting components or breaking seals without the need for sterile conditions, the dispensing does not qualify for payment of the compounded PDF.

(b) For dates of service prior to April 1, 2017, claims submitted for infusion compounds will receive a dispensing fee of ten dollars per day, with a maximum dispensing fee of seventy dollars. Infusion compounds include intravenous (IV) therapy for chemotherapy, pain management and antibiotics.

(c) For dates of service on or after April 1, 2017, the PDF for dispensing sterile compounds, other than TPN, that are required to be sterile for a route of administration including inhaled, infused, instilled, implanted or injected, shall be ten dollars per days supply, with a minimum PDF of twenty dollars and a maximum of seventy dollars for the claim. To qualify for payment of the sterile compound PDF, the sterile compound must be mixed by the pharmacy to the final form under sterile conditions. Products that are mixed or activated at the point of administration by connecting components or breaking seals without the need for sterile conditions are not eligible for a sterile compound PDF.

(d) Compounded drugs other than TPN or sterile compounds.

(i) For dates of service prior to April 1, 2017, compounded drugs that are not infusion compounds or TPN claims will receive a single six dollar dispensing fee per prescription.

(ii) For dates of service on or after April 1, 2017, compounded drugs that are not eligible for the TPN or sterile compound PDF will receive the PDF determined under paragraph (E)(1)(b) of this rule.

(3) Vaccine or injectable drug dispensing that qualifies for payment of an administration fee shall not qualify for medicaid payment of a PDF.

(4) Notwithstanding paragraph (E)(1) of this rule, prescribed drugs, other than compounded drugs, dispensed to patients residing in LTCFs shall be limited to one PDF per patient, per equivalent product, per rolling twenty-five days. In the event that multiple supplies of an equivalent product are dispensed within twenty-five days, only the ingredient cost shall be paid. Exceptions to the one PDF per patient, per product rule are:

(a) Situations where the prescriber has ordered a second round of medication for an acute condition within the twenty-five day period.

(b) Situations where the prescriber has changed the dosage.

(c) Situations where the drug has been compromised by accident, for example contaminated or

destroyed.

(d) Dispensing of controlled substances, which is limited to two PDFs per twenty-five days.

(F) Coordination of benefits.

(1) Claims for medicare part B cost sharing as described in rule 5160-1-05 of the Administrative Code shall be submitted using the medical claim format and shall not be payable under this chapter.

(2) No payment shall be made under this chapter for any drug that may be covered by medicare part D for an individual who is eligible for coverage by medicare part D, regardless of whether the individual is actually enrolled in a part D plan or the particular drug is covered by the individual's part D plan.

(3) Cost-sharing for claims involving neither medicare part B nor medicare part D is determined in accordance with rule 5160-1-08 of the Administrative Code.