Reimbursement Policy

High Dollar Drug Review

REIMBURSEMENT POLICY NUMBER: 10

Effective Date: 8/1/2024

Last Review Date: 7/2024

Next Annual Review: 7/2025

INSTRUCTIONS FOR USE: Company reimbursement policies serve as guidance for the administration of plan benefits. Reimbursement policies do not constitute medical advice nor a guarantee of coverage. Company reimbursement policies are reviewed annually. The Companies reserve the right to determine the application of reimbursement policies and make revisions to reimbursement policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Reimbursement Policy will be resolved in favor of the coverage agreement.

SCOPE AND APPLICATION

Provider Type:

☐ Professional Claims

☒ Facilities

Plan Product:

☒ Commercial

☒ Medicare

☐ Medicaid/Oregon Health Plan (OHP)

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as "Company" and collectively as "Companies").

POLICY STATEMENT

Note: Provider contract language may apply and will supersede this policy, including but not limited to, negotiated fee schedule amounts. This policy does not apply to the following:

- Compounded (compound) drugs (separate Pharmacy policy exists for *Compound Prescription Drug Pricing*, ORPTCOPS084).
- Generic drug pricing for medications dispensed at a Pharmacy (separate Pharmacy policy exists for *Maximum Allowable Cost (MAC) Pricing*, ORPTCOS080).
- Behavioral health facilities, skilled nursing facilities, and inpatient rehabilitation facilities

General

I. Claims may be selected for high dollar drug cost reviews when **all** of the following (A.-C.) criteria are met:

   A. Revenue code 636; **and**
   B. The billed charges for the drug(s) meets or exceeds $10,000; **and**
   C. Drug charges are reported with active HCPCS codes in the "C," "J," and "Q" sections. (NOTE: The Company does not accept codes in the "S" section; see Coding Policy 22.0 for *HCPCS S-Codes and H-Codes* [See Cross References]. Reimbursement for S-codes is on a limited contract exception basis. Otherwise, providers should use unlisted codes in lieu of an S-code.)

II. If the billed charges for the drug(s) selected for review based on criterion I. is marked up by 150% or more of the average sales price (ASP) or 100% of the average wholesale price (AWP), the drug will be **denied as not reimbursable**.

   A. *In order to be considered for reimbursement, a corrected claim or additional facility documentation to support the reasonableness of the charges submitted will be required.*

III. In addition to criterion I. and II. above, review of high dollar drug claims may also include, but is not limited to, the following elements (A.-C.):

   A. Medical necessity the drug/medication and the indication(s) it is being used for (including off-label drug use).
   B. Discarded drugs/waste. (See Policy Guidelines below.)
   C. Maximum daily units (aka, medically unlikely edits, or MUEs).
      i. The Company will use the following to determine daily unit allowances:
         1. U.S. Food and Drug Administration (FDA) guidelines limiting the allowed units for drugs, **or**
         2. Centers for Medicare & Medicaid Services (CMS) Facility Outpatient Services MUE Table. In the absence of *inpatient* guidelines, *outpatient* MUEs are followed.
      ii. Charges for undocumented drug/medication use. (See Policy Guidelines below.)

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

In order to provide an effective and accurate review, the following documentation **must** be provided. If any of these items are not submitted, the review may be delayed and any decision outcome could be affected:

- National Drug Code (NDC) (if applicable); **and**
- Total quantity of the drug that was administered (in units of measure applicable to the drug/biological substance); **and**
- The date(s) the product (e.g., drug, biologic, etc.), was provided or administered to the patient; **and**
- Indication for which the drug/product was being provided; **and**
- When applicable, any discarded or wasted drug must be clearly documented as discarded or wasted in the medical records.
    - JZ or JW modifiers to be used with HCPCS to document any wastage

DEFINITIONS

Average Wholesale Price: AWP

Average Sale Price: ASP

Egregious: "In general, the term egregious is used to describe a conduct by a person intentionally committing an act or omission that involves knowing the violation of law. In a legal context, egregious conduct refers to an action that is obviously wrong, beyond a reasonable degree." *(Cornell Law School, https://www.law.cornell.edu/wex/egregious)*

Medically Unlikely Edit: MUE

National Drug Code: NDC

Not Otherwise Classified: NOC

BACKGROUND

According to the Centers for Medicare and Medicaid Services (CMS) Provider Reimbursement Manual – Part 1, Chapter 21- Costs Related to Patient Care, §2102.1 Reasonable Costs *(changing font to **bold, italics, and underline** has been added by the Company for emphasis)*:

*"Implicit in the intention that **actual costs be paid to the extent they are reasonable is the expectation that the provider seeks to minimize its costs and that its actual costs do not exceed what a prudent and cost-conscious buyer pays for a given item or service.** (See §2103.) If costs are determined to exceed the level that such buyers incur, in the absence of clear evidence that the higher costs were unavoidable, the excess costs are not reimbursable under the program."*[1]

CMS Provider Reimbursement Manual – Part 1, Chapter 21- Costs Related to Patient Care, §2119 Cost of Drugs and Related Medical Supplies:

"A. Reasonable Cost and Maximum Allowable Cost Limitation (MAC).--The cost of drugs and related medical supplies furnished by providers to Medicare beneficiaries are reimbursed by the program on a reasonable cost basis. To meet the test of reasonableness, the cost of the drug or related medical supply may not exceed the amount a prudent and cost-conscious buyer would pay for the same item.

"A reasonable cost limitation will be set on certain multiple-source drugs that involve the expenditures of significant amounts of Federal funds and are purchased at significantly different prices. This maximum allowable cost limitation, called the "MAC" for a particular drug, will be based on the lowest unit price at which the drug is widely and consistently available to pharmacists from any formulator or labeler, and the most frequently purchased package size. Final MAC determinations will be published in the Federal Register. These MAC determinations are also published as an appendix to this chapter. This appendix includes the MAC limitation and its effective date, the generic name of the drug, and a listing of the most frequently purchased brand names of the drug.

"For purchases made on or after the effective date of the final MAC determinations, the allowable cost for any multiple-source drug for which a MAC has been established may not exceed the lowest of:

(1) the actual cost,

(2) the amount which would be paid by a prudent and cost-conscious buyer for the drug if obtained from the lowest-priced"[2]

Drug Wastage

Every attempt should be made to utilize the drug or biological in a responsible manner to avoid wastage. During the review of the submitted charges, the plan will only consider what was used or provided to the patient to arrive at the nearest whole vial using the smallest commercially available vial size and dose that results in the least amount of wastage. If the drug is being supplied from a "single-use" vial or "single-use" package, then the "wastage" or unused portion may be considered in the review, provided the smallest commercially available vial size and dose was used.

The physician's orders for the drug must be clearly and completely documented in the medical record, taking into account patient specific factors (e.g., age, weight, body surface area, etc.) and the amount of drug administered must be clearly and completely documented in the medical record. The discarded or wasted drug must be clearly documented as discarded or wasted in the medical records provided. When

the claim is submitted, the amount of drug that is **administered to the patient** should be billed on one line on the claim. The amount of drug that was **wasted or discarded** is billed as a separate or second line item, with modifier JW attached.

Undocumented Drug Charges

During the review of the submitted charges, the plan will only consider what was provided to the patient. If the medical record or clinical documentation does not substantiate the submitted charges for the drug/medication/substance, or when the number of units reported on the claim are not supported in the clinical documentation, any charges determined to be associated with an **undocumented medication or undocumented units** will be disallowed from the final calculation. In the event payment is made inadvertently for undocumented medication or undocumented units of product, recovery efforts may be made to recoup the erroneous payment.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

As of 5/6/2024, the following Centers for Medicare & Medicaid (CMS) references were identified, which address the use of average sales price (ASP) for facility claims:

- Medicare Claims Processing Manual, Chapter 17 - Drugs and Biologicals
  - §10 - Payment Rules for Drugs and Biologicals
  - §20.1 - MMA Drug Pricing - Average Sales Price
  - §20.1.2 - Average Sales Price (ASP) Payment Methodology
  - §20.1.3 - Exceptions to Average Sales Price (ASP) Payment Methodology
  - §20.4 - Calculation of the AWP
  - §90.3 - Hospital Outpatient Payment Under OPPS for New, Unclassified Drugs and Biologicals After FDA Approval But Before Assignment of a Product-Specific Drug or Biological HCPCS Code
- Centers for Medicare and Medicaid Services (CMS) Provider Reimbursement Manual – Part 1, Chapter 21- Costs Related to Patient Care, §2102.1 Reasonable Costs
- Quarterly CMS ASP Drug Pricing Files
- CMS web page for MS-DRG Classifications and Software
- Noridian web page for Drugs, Biologicals and Injections
- Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §50.4.2 - Unlabeled Use of Drug

BILLING AND CODING GUIDELINES

HOSPITAL OUTPATIENT BILLING OF DRUGS AND BIOLOGICALS

From the Medicare Claims Processing Manual, Chapter 17 - Drugs and Biologicals, §90.2[6]:

- "Hospitals should report charges for all drugs, biologicals, and radiopharmaceuticals, regardless of whether the items are paid separately or packaged, using the correct HCPCS codes for the items used."

- "It is also of great importance that hospitals billing for these products make certain that the reported units of service of the reported HCPCS code are consistent with the quantity of a drug, biological, or radiopharmaceutical that was used in the care of the patient."
- "HCPCS code C9399, Unclassified drug or biological, is for new drugs and biologicals that are approved by FDA on or after January 1, 2004, for which a specific HCPCS code has not been assigned."
- "Payment for drugs, biologicals and radiopharmaceuticals under the OPPS is inclusive of both the acquisition cost and the associated pharmacy overhead or nuclear medicine handling cost. Hospitals should include these costs in their line-item charges for drugs, biologicals, and radiopharmaceuticals."

The latest payment rates associated with each APC and HCPCS code may be found in the most current Addendum A and Addendum B, respectively that can be found under the CMS quarterly provider updates on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/HospitalOutpatientPPS/index.html

- Addendum B includes OPPS Payment by HCPCS Code for CY 2024
- Addendum A includes OPPS APCs for CY 2024

The following apply to drug claims, as stated in the *Medicare Claims Processing Manual, Chapter 17 - Drugs and Biologicals, §70 - Claims Processing Requirements – General*[7]*:*

• On ***inpatient*** hospital claims, the drug is identified by the appropriate HCPCS code for the drug administered **and** billed under revenue code 0636 unless specific instruction states otherwise;
• On ***outpatient*** hospital claims, the drug is identified by the applicable HCPCS code;
• Where HCPCS is required, units are entered in multiples of the units shown in the HCPCS narrative description. Facilities use the units field as a multiplier to arrive at the total dosage amount. For example, if the description for the code is 50 mg, and 200 mg are provided, units are shown as 4.
• Where the NDC is required, units are entered in multiples of the units shown in the NDC label description. For example, if the description for the code is 50 mg., and 200 mg are provided, units are shown as 4;
• If the units provided exceed the size of the units field, or require more characters to report than spaces available in the format, repeat the HCPCS or NDC code on multiple lines until all units can be reported;
• Covered administration codes for injections may be billed in addition to billing for the drug. The drug maximum payment allowance is for the drug alone. However, if payment is under a PPS, such as OPPS, the injection would be included in the APC rate.

CROSS REFERENCES

Pharmacy Policies

- Compound Prescription Drug Pricing, ORPTCOPS084
- Compounded Drugs Policy, ORPTCOTH015
- Maximum Allowable Cost (MAC) Pricing, ORPTCOPS080

- Specialty Drugs Shipped from Pharmacies to Providers and Facilities, ORPTCOPS145

Coding Policies

- HCPCS S-Codes and H-Codes, CP22.0

The full Company portfolio of current Reimbursement Policies is available online and can be accessed here.

REFERENCES

1. Centers for Medicare and Medicaid Services (CMS). Provider Reimbursement Manual – Part 1, Chapter 21- Costs Related to Patient Care, §2102.1 Reasonable Costs
2. CMS. Provider Reimbursement Manual – Part 1, Chapter 21- Costs Related to Patient Care, §2119 Cost of Drugs and Related Medical Supplies
3. CMS. Medicare Claims Processing Manual, Chapter 17 - Drugs and Biologicals, §10 - Payment Rules for Drugs and Biologicals. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf. Accessed 6/24/2024.
4. CMS. Medicare Claims Processing Manual, Chapter 17 - Drugs and Biologicals, §20.1.2 - Average Sales Price (ASP) Payment Methodology. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf. Accessed 6/24/2024.
5. CMS. Medicare Claims Processing Manual, Chapter 17 - Drugs and Biologicals, §20.1.3 - Exceptions to Average Sales Price (ASP) Payment Methodology. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf. Accessed 6/24/2024.
6. CMS. Medicare Claims Processing Manual, Chapter 17 - Drugs and Biologicals, §90.2 - Drugs, Biologicals, and Radiopharmaceuticals. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf. Accessed 6/24/2024.
7. CMS. Medicare Claims Processing Manual, Chapter 17 - Drugs and Biologicals, §70 - Claims Processing Requirements – General. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf. Accessed 6/24/2024.
8. CMS. Quarterly CMS ASP Drug Pricing Files: https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files. Accessed 6/24/2024.
9. CMS. Medicare Claims Processing Manual, Chapter 17 - Drugs and Biologicals, §20.1 - MMA Drug Pricing - Average Sales Price; https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf. Accessed 6/24/2024.
10. CMS. Medicare Claims Processing Manual, Chapter 17 - Drugs and Biologicals, §§20.4 - Calculation of the AWP; https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf. Accessed 6/24/2024.
11. Noridian web page for Drugs, Biologicals and Injections; https://med.noridianmedicare.com/web/jfa/topics/drugs-biologicals-injections. Accessed 6/24/2024.
12. CMS. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §50.4.2 - Unlabeled Use of Drug; https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf. Accessed 6/24/2024.
13. CMS. Medicare Claims Processing Manual, Chapter 17 - Drugs and Biologicals, §90.3 - Hospital Outpatient Payment Under OPPS for New, Unclassified Drugs and Biologicals After FDA Approval But Before Assignment of a Product-Specific Drug or Biological HCPCS Code; https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf. Accessed 6/24/2024.

POLICY REVISION HISTORY

Date	Revision Summary
8/2024	New reimbursement policy