Operational Policy		
SUBJECT: **Brand Drug Definition, Benefit Administration and Payment Policy**	DEPARTMENT: **Pharmacy**	
ORIGINAL EFFECTIVE DATE: **08/09**	DATE(S) REVIEWED/REVISED: **04/12, 04/13, 02/15, 03/16, 1/17, 01/18, 01/19, 05/19, 02/20, 03/21, 03/22, 03/23, 07/23 (AA)**	
EFFECTIVE DATE: **9/1/2023**		
APPROVED BY: **Oregon Region Pharmacy and Therapeutics Committee**	NUMBER: **ORPTCOPS079.0823**	PAGE: **1 of 10**

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

APPLIES TO:

Fully Insured						
Individual	Small Group	Large Group	Self-Insured	Medicare	Medicaid	Delegated Services to Ayin
☐ Oregon On Exchange ☐ Oregon Off Exchange ☐ Washington Off Exchange	☐ Oregon On Exchange (SHOP) ☐ Oregon Off Exchange (SHOP)	☐ Oregon ☐ Washington	☐ ASO ☐ PBM	☐ Medicare	☐ Medicaid	☐ YCCO ☐ WHA
☒ APPLIES TO ALL ABOVE LINES OF BUSINESS						

POLICY:
This policy provides the criteria for determining the copay, administration and payment of brand drugs that have a GPI of 2 and have a GI of 1 or 2 (pharmacy benefit) and for medications reimbursed through the medical benefit.

DEFINITIONS:
Brand Drug - A drug that is not classified as a Generic Drug. When a drug is classified as a Brand Drug, it shall be considered a Brand Drug for all purposes, including adjudication, therapeutic classification, pricing, and all guarantees related thereto. Brand Drugs include Biosimilar Drugs unless they are required to be classified as Generic Drugs under Food and Drug Administration (FDA) standards. Please refer to ORPTCOPS0163, Generic Drug Definition Benefit Administration and Payment Policy.

The Companies recognizes that a Brand Name Drug is protected by a patent issued to the original

innovator or marketer of such drug, which is manufactured and distributed by the innovator company or its licensee. The Companies determination of a Brand Name Drug is based on applying a rules-based algorithm using indicators from First Databank. As such, Brand Name Drugs shall be determined by the following First Databank information fields: GNI (Generic Name Indicator), INNOV (Innovator indicator that identifies the original patent holder of the drug or first-to-market), NDA (New Drug Application), and ANDA (Abbreviated New Drug Application).

Biosimilar Drug - A type of biological product that is licensed (i.e., approved) by the FDA because the product is highly similar to an already FDA-approved biological product, known as the reference product, and has been shown to have no clinically meaningful differences from the reference product. For purposes of this policy and this definition, a "Biosimilar Drug" also shall include an "interchangeable biological product" which, in addition to meeting the biosimilarity standard, is expected to produce the same clinical result as the reference product in any given patient.

Biosimilar Drugs are Brand Drugs unless they are required to be classified as Generic Drugs under FDA standards. Biosimilar Drugs which are determined by the FDA are published in FDA's Purple Book (presently found at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm).

Multi-source Brand - A drug product marketed or sold by two or more manufacturers or labelers. Multi-source drugs are those that are available both as the brand-name drug, and as generic equivalents or generic alternatives.

Single-source Brand - A drug that is marketed or sold by one manufacturer or labeler, is referred to by its trade name, and is protected under patent exclusivity.

Specialty Drug - Please refer to ORPTCOPS061, Specialty Drug Definition and Benefit Administration policy.

Pharmacy Drug – A medication that does not need to be administered by a healthcare professional, rather it can be self-administered. For Medicare members, these drugs are usually covered under their Part D benefit.

Medical Drugs - Medications that are administered in the outpatient/inpatient setting under healthcare professional supervision. These drugs are covered under the member's medical benefit

rather than their outpatient pharmacy benefit. For Medicare members, these drugs are covered under their Part B benefit.

Usual and Customary - Amount charged by the dispensing pharmacy at the time of dispensing of a drug product or service to a customer with no coverage by a third-party payor, exclusive of tax or discounts claimed. The amount charged (or Usual and Customary amount) means the lowest cash price which a cash paying customer of Pharmacy would pay for a Covered Service. This price includes all applicable discounts including, but not limited to, senior citizen discounts, frequent shopper and special customer discounts or other discounts.

Pharmacy Claim Processing Logic:
GI - Generic Indicator - The GI indicates whether a specified drug is a single or multiple source drug. If the GI field is populated with a "1" then the specified drug is a multiple source drug. If the GI field is populated with a "2" then the specified drug is a single source drug.

GPI - Generic Price Indicator - This field defines a product as either a generic or a branded product. If the GPI field is populated with a "0" then the specified drug is a non-drug item (medical supplies). If the GPI field is populated with a "1", then the specified product is a generic drug. If the GPI field indicator is populated with a "2", then the specified drug is a brand drug. If the field is populated with a "3", then the specified drug is a multiple source drug meaning the product is sold under more than one brand name but is NOT a generic drug**.**

Combinations of these two indicators form the general basis for how brand/generic status is currently determined:

GI	GPI	Definition
1	0	Undetermined;(supplies; non-drug products)
1	1	Multi-source Generic
1	2	Multi-source Brand
2	2	Single-source Brand

A brand drug has a Generic Price Indicator (GPI) of 2 and can have a Generic Indicator (GI) of 1 or 2.

A common data source for these fields is the First Databank Drug (FDB) File. On Oct. 1, 2007, FDB announced an editorial decision to discontinue publishing the Generic Price Indicator (FDB GPI). As a result of this decision a GPI methodology was required and developed by SS&C (the Company's pharmacy claims processor) to continue to provide a stable generic definition to preserve

consistency for member copays and pharmacy reimbursement. See appendix for the SS&C's GPI methodology.

National Drug Code (NDC) - Is a unique eleven-digit identifier assigned to a drug product by the labeler/manufacturer under Federal Drug Administration (FDA) regulations. It is comprised of three segments configured in a 5-4-2 format.

PROCEDURE:

Pharmacy Drug Reimbursement

For a drug to be classified brand by the Companies for the purpose of pharmacy benefit copay/coinsurance and pharmacy reimbursement the following criteria and methodology will be used:

All single-source brand drugs with a GI of 2 and a GPI of 2 will be designated a brand drug.

1. All multi-source brand drugs with a GI of 1 and a GPI of 2 will be designated a brand drug unless:
    a. At least one generic equivalent or generic alternative product is available in First DataBank and is not noted to be obsolete or a repackaged product, then a member may be required to pay member pay difference (MPD), their applicable copayment amount plus the difference in cost between the generic drug and the multi-source brand name drug. Please have member refer to their pharmacy benefit materials for further information. The pharmacy may be reimbursed their contracted Non-MAC Generic rate or MAC Generic drug rate, depending on classification of the generic available and/or appropriate Dispense as Written (DAW) codes submitted by the dispensing pharmacy.
    b. Or, in extenuating circumstances, the Companies may alter the status of a multi-source brand drug to that of a single-source brand drug to allow the member greater access to a multi-source brand at the lowest possible copayment amount, without the penalty of MPD. The pharmacy will be reimbursed their contracted brand drug rate.
    c. Or, the Companies may alter the status of a multi-source brand drug to that of a multi-source generic drug on the claim to allow the member greater access to a multi-source brand at their generic copayment/coinsurance amount, without the penalty of the difference in cost between the generic product and the multi-source brand drug. The pharmacy will be reimbursed their contracted brand drug rate.
2. Drugs with a GPI of 1 will be reviewed using the Companies' policy ORPTCOPS013, Generic Drug Definition Benefit Administration and Payment Policy, and if not found to meet the criteria for a generic drug, may be considered a brand drug and adjudicated as such.
3. Products with a GPI of 0 and are determined to be supplies and/or non-drug products will reimburse at the brand drug rate.

Once a drug has been determined to meet the definition of a brand, every effort will be made to preserve the pharmacy's brand drug reimbursement unless there are extraordinary reasons.

Payment and reimbursement for brand drugs are defined in the Participating Drug Services Agreement with the Companies and the participating pharmacy. Reimbursement rates for Brand name drugs vary by pharmacy, as reimbursement rates are defined in Attachment A of the Participating Drug Services Agreement with each Pharmacy.

Claims will pay the lesser rate of the dispensing pharmacy's usual & customary charge. Reimbursement will be reduced by the applicable Copayment, Coinsurance or Deductible fee received.

Medical Drug Reimbursement

The Companies require the use of National Drug Codes (NDCs) and related information such as Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT®) codes, when drugs are billed on professional/ancillary electronic (ANSI 837P) and paper (CMS-1500) claims.

This information may also be submitted on institutional/facility electronic (ANSI 837I) and paper (UB-04) claims. This includes drug-related revenue codes to report drug products used for services rendered at medical outpatient facilities as well as unlisted HCPCS/CPT codes that require additional NDC information.

Vaccines supplied by the Department of Health (DOH) do not require an NDC. To designate a DOH supplied vaccine, providers must add an SL modifier to the vaccine procedure code.

Medical Drug Billing Information for Providers:

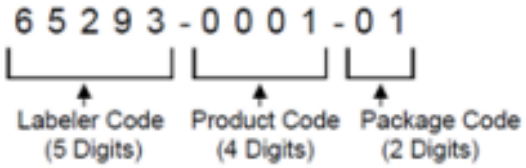
How to submit the NDC on a medical drug claim:

1. NDC must be the code of the actual administered drug for the date of service
   A drug may have multiple manufacturers, so it is vital to use the NDC of the administered drug and not another manufacturer's product, even if the chemical name is the same. It is not permissible to bill Providence Health Plan with any NDC other than the one administered. Invalid and discontinued drugs are not acceptable for payment.

2. Location of NDC
   The NDC is usually found on the drug label or medication's outer packaging. If the medication

comes in a box with multiple vials, using the NDC on the box (outer packaging) is recommended. The number on the packaging may be less than 11 digits. An asterisk may appear as a placeholder for any leading zeros.

The Labeler Code is the first five digits assigned by the Food and Drug Administration (FDA) to uniquely identify each firm that manufactures, repack, or distributes drug products. The Product Code is the next four digits that identify the specific drug, strength, and dosage form. The Package Code is the last two digits that identify the package size.



3. Data Elements Required to Report NDC
   (Examples provided below in 4. Submitting NDCs in Electronic or Paper claims)
   a. Service Procedure Information if it is required (HCPCS or CPT code)
   b. Drug Information (NDC)
      i. NDC must match HCPCS or CPT description
   c. Drug Quantity (Units Billed)
      i. Determined by HCPCS code for professional claims (HCFA 1500)
      ii. Determined by NDC for institutional claims (UB-04)
   d. Accepted units of measure
      i. F2 = International Unit
      ii. GR=Gram
      iii. ME=Milligram
      iv. ML=Milliliter
      v. UN=Unit

   Enter the N4 Qualifier code followed by the 11-character NDC, the unit of measure qualifier, and quantity, without hyphens or spaces.

   Example: N4xxxxxxxxxxML5

   Drug quantity is determined by the HCPCS for the professional (CMS 1500) and is determined by the NDC for the institutional (UB-04).

For example - If a patient is given 1000 mg Ceftriaxone Sodium:

- HCPCS: J0696 Injection, Ceftriaxone sodium 250 mg
- NDC: 00409-7338-01 Ceftriaxone sodium 500 mg / vial
    - HCPCS unit = 4 (CMS 1500)
    - NDC quantity = 2 (UB – 04)

    If milliliters are administered, then the total number administered is the quantity reported:

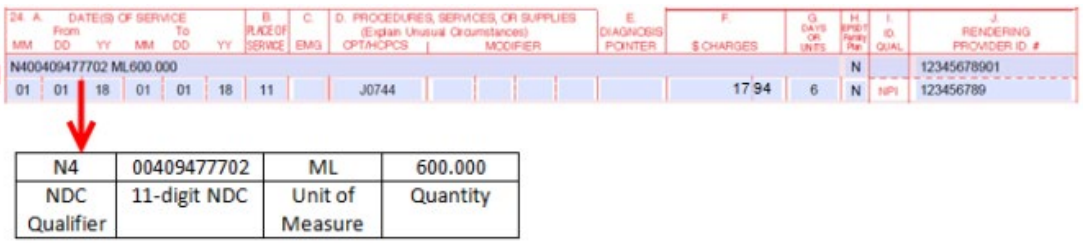
"Each" in the NDC description indicates a vial quantity reported is one each.

4. Submitting NDCs in electronic or paper claims
    a. Electronic Claims - Professional and institutional (ANSI 837P and ANSI 837I)

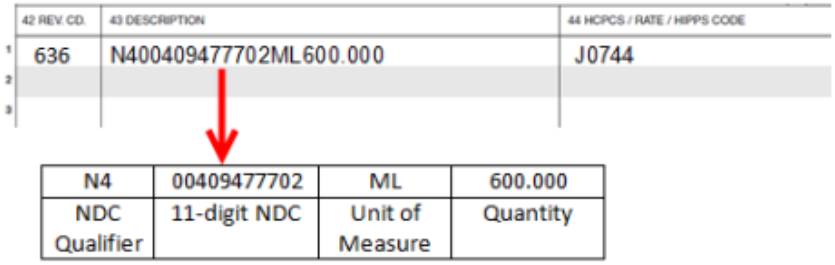
Field Name	Field Description	Loop ID	Segment
Product ID Qualifier	Enter N4 in this field	2410	LIN02
National Drug Code	Enter the 11-digit NDC billing format assigned to the drug administered	2410	LIN03
National Drug Unit Count	Enter the quantity (number of NDC units)	2410	CTP04
Unit or Basis for Measurement	Enter the NDC unit of measure for the prescription drug given (UN, ML, GR, or F2)	2410	CTP05

Note: The total charge amount for each line of service also must be included for the Monetary Amount SV102 Segment, 2400 loop.

b. Paper Claims
    i. Professional Paper Claims (CMS-1500)
    In the shaded portion of the line-item field 24A-24G on the CMS-1500, enter the qualifier N4 (left justified), immediately followed by the NDC. Next, enter one space for separation, then enter the appropriate qualifier for the correct dispensing unit of measure (UN, ML, GR, or F2), followed by the quantity (number of NDC units up to three decimal places), as indicated in the example below.



ii. Institutional Paper Claims (UB-04)
In the line-item field 42-46, enter the appropriate drug-related revenue code in field 42. In field 43, report the NDC qualifier N4 (left-justified), immediately followed by the 11-character NDC in the 5-4-2 format (no hyphens). Immediately after the last digit of the NDC, enter the appropriate qualifier for the correct package size, NDC unit of measure (UN, ML, GR, or F2), followed by the quantity (number of NDC units up to three decimal places), as indicated in the example below.



Note: Reimbursement for discarded drugs applies only to single-use vials. Multi-use vials are not subject to payment for discarded amounts of the drug

REFERENCES:

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3. Generic Drug Utilization in the Medicare Part D Program, Daniel R. Levinson, Inspector General, November 2007 OEI-05-07-00130 Available at: https://www.oig.hhs.gov/oei/reports/oei-05-07-00130.pdf (accessed March 6, 2023)
4. CMS Manual System, Department of Health and Human Services, PUB 100-04 Medicare Claims Processing, CMS; December 21, 2007, Available at: https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r1401cp.pdf
5. National Drug Code requirement for physician-administered drugs, Oregon Health Authority. Available at https://www.oregon.gov/oha/hsd/ohp/pages/ndc.aspx

Appendix – SS&C GPI Definition Methodology

SS&C will continue to populate the GPI based upon the new brand/generic rules. The GPI field will have the following values:

GPI	Definition
0	Undetermined (supplies; non-drug products)
1	Generic
2	Brand

The rules to define a drug as brand or generic will utilize four data elements from FDB, two of which are new:

1. Generic Name Indicator (GNI) – an existing indicator from FDB that specifies whether a product is a brand-named product or a generically named product using the product name as the criteria.
2. Innovator Indicator (INNOV) – an existing indicator from FDB that identifies the first-to-market product within a GCN. This will usually be the product with the New Drug Application (NDA) or Biologic License Application (BLA).
3. Abbreviated New Drug Application (ANDA) Indicator – The ANDA indicator identifies drug products that the FDA considers to have a generic status due to the manufacturer's acquisition of FDA approval under an ANDA application.
4. New Drug Application (NDA) Indicator – The NDA indicator identifies drug products that the FDA considers to have brand status due to the manufacturer's acquisition of FDA approval under a NDA application.
5. FDA Marketing Category Code – Product type or FDA approval type listed on the FDA Comprehensive NDC Structured Product Labeling (SPL) Data Elements File (NSDE). The label author chooses a category that most closely describes the FDA regulations for marketing the product.

Brand/Generic Rules:

Note: The following rules will be applied in sequential order. Once a NDC meets a rule, the GPI value is assigned and that NDC is excluded from subsequent rules. These rules may change based on future clarification from FDB. If the rules result in a brand/generic status that is clearly different from industry and marketplace expectations, an override process may be applied.

Rule #1: If GNI = 0 (non-drug item), then GPI = 0

Rule #2: If the FDA Marketing Category Code is BLA then GPI = 2

Rule #3: If GNI = 1 (generically-named) or Generic Name=Brand Name, then GPI = 1

Rule #4: If GNI = 2 (brand-named) AND INNOV =1 (innovator), then GPI = 2
Rule #5: If NDA = Y (yes), then GPI =2 (CMS regulations for Part D)
Rule #6: If ANDA = Y (yes), then GPI =1 (CMS regulations for Part D)
Rule #7: If INNOV = 0 (non-innovator) and re-packager indicator =0 (non-re-packager), then GPI = 1
Rule #8: If INNOV = 0 (non-innovator) and re-packager indicator =1 (re-packager), then GPI = 2