Payment Policy: 340B Drug Payment Reduction

Reference Number: CC.PP.070
Last Review Date: 01-18-2021

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Policy Overview
In 1992, Congress enacted Section 340B of the Public Health Service Act requiring pharmaceutical manufacturers to enter into a pharmaceutical pricing agreement (PPA) with the Health and Human Services (HHS) secretary in exchange for having their drugs covered by Medicaid and Medicare Part B. As part of this agreement, pharmaceutical companies provide up front discounts directly to outpatient eligible providers that deliver health care services to a large number of underserved, underinsured, and vulnerable populations (safety-net providers). The program is administered by the Office of Pharmacy Affairs (OPA), a division within the Health Resources and Services Administration (HRSA).

Qualifying covered entities (see below) purchase drugs at discounted prices and either dispense or administer them to patients. These providers receive reimbursement for the drugs from the insurance companies at standard or higher than standard rates. The discounts allow hospitals to expand or improve care for vulnerable populations. Monies saved from the discounts is intended for expand health care services for these populations.

The purpose of this policy is to ensure that providers participating in the 340B Drug Pricing Program are correctly reporting 340B acquired drugs according to guidelines established by the Centers for Medicare and Medicaid Services (CMS).

Effective January 1, 2018, CMS reduced payment to participating providers paid under an Outpatient Prospective Payment System (OPPS) for specific drugs acquired through the 340B program. Providers are required to report either modifier "JG" or "TB" on these claims. Modifier "TB' is reported for informational purposes. Modifier "JG" indicates the 340B drug is payable at a reduced rate of Average Sales Price (ASP) minus 22.5 percent.

Eligible patients are those that are patients of the covered entity. The entity must maintain records of healthcare services furnished to the patient and the health care

Application
- Medicare
- Outpatient Prospective Payment System claims (bill type 13X)
- Disproportionate Share Hospitals
- Medicare Dependent Hospital
- Rural Referral Center
- Non-Rural Sole Community Hospital

Exclusions
The following entities are not subject to the ASP minus 22.5 percent reimbursement reduction

- Rural Sole Community Hospitals (SCH)
- Children's Hospitals
- PPS exempt cancer hospitals

Reimbursement Guidelines

- Each separately payable, non-pass through, drug must be billed on a separate claim line with the appropriate 340B modifier.
- **Modifier "JG"** applies drug payment rate of ASP minus 22.5 percent.
- **Modifier "TB"** is informational and does not affect payment. The modifier is used by entities that are paid under the OPPS, have acquired 340B drugs, but have been excluded from the 340B Payment adjustment.

Pre-Payment Reimbursement Edit Review of Required Modifier

1. The Health Plan's pre-payment review process will evaluate outpatient claims for the appropriate use of modifier **"JG"** or **"TB."**
2. The review will validate on the HRSA website that the entity is participating in the 340B Drug Pricing Program.
3. The review validates that each code billed is a covered drug under the 340B Drug Pricing Program.
4. This applies to Healthcare Common Procedure Coding System (HCPCS) separately payable OPPS drugs assigned a **status indicator of "K"** by CMS (and meet the definition of "covered outpatient drug.'
5. This edit does not apply to vaccines or pass-through drugs assigned a status indicator of "F", "G", "L" or "M".
6. Validate on the Health Resources Services Administration (HRSA)website that the facility is participating in the 340B drug discount program and the drug is a 340B covered drug:
    a. **If yes** and the modifier is missing:
        i. The code editing software will deny the original service line(s) billed without modifier **"JG"** and replace with a new service line(s) with the modifier **"JG"** appended.
        ii. Service line(s) is priced at ASP minus 22.5 percent.
    b. **If no** (provider is not a participant in the 340B Drug Pricing Program, the drug is not covered under the program, or the entity is excluded from the 340B Drug Pricing Program):
        i. The payment reduction will not apply.
        ii. The claim will adjudicate per the provider fee schedule.
        iii. Modifier **'TB"** is an informational modifier and not subject to payment reduction.
        iv. Modifier **"TB"** is billed by entities paid under the OPPS, have acquired 340B drugs, but are excluded from the CMS rate reduction policy.
7. Drugs billed appropriately with modifier **"JG"** are auto-adjudicated and reimbursement is applied in the claims payment system.

Documentation Requirements
CMS established two HCPCS Level II modifiers to identify 340B-acquired drugs:

- Modifier "**JG**" *Drug or biological acquired with 340B drug pricing program discount*.
- Modifier "**TB**" *Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes*
- Applicable providers report either modifier **"JG"** or **"TB"** on OPPS claims (bill type 13X)
- Claims billed without the required modifiers **"JG" and "TB"** and the drug is assigned a status indicator of **"K"** will have the **"JG"** and/or "**TB"** modifier added to the claim to ensure appropriate claims payment.

Coding and Modifier Information
This payment policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT® codes and descriptions are copyrighted 2020, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this payment policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

Modifier	Descriptor
JG	Drug or biological acquired with 340B drug pricing program discount
TB	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes.

Definitions:

Hospital Outpatient Prospective Payment System (OPPS)
System established by the Centers for Medicare and Medicaid Services that determines the rate of reimbursement that a hospital or community mental health center will receive for outpatient care to patients with Medicare.

Health Resources Services Administration (HRSA)
Federal agency for improving access to health care services for people who are uninsured, isolated or medically vulnerable

Healthcare Common Procedure Coding System (HCPCS)
A standardized code system used by medical providers to submit healthcare claims to Medicare and other health insurances in a consistent an orderly manager. HCPCS contains two medical code sets, HCPCS Level I and HCPCS Level II.

Average Sales Price (ASP)
Refers to the average sales price of goods or services.

Non-Pass Through Drugs
Drugs and biologicals, is the amount by which 95 percent of the average wholesale price exceeds the applicable fee schedule amount associated with the drug or biological. A non-pass through drug does not meet this definition.

Additional Information
NA

Related Documents or Resources
NA

References
1. **https://www.hrsa.gov/opa/eligibility-and-registration/hospitals/childrens-hospitals/index.html**
2. **https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/billing-340b-modifiers-under-hospital-opps.pdf**
3. *Current Procedural Terminology (CPT®)*, 2019
4. *Centers for Medicare and Medicaid Services,* CMS Manual System and other CMS publications and services.

Revision History	
01/18/2021	Initial Policy Draft

Important Reminder
For the purposes of this payment policy, "Health Plan" means a health plan that has adopted this payment policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any other of such health plan's affiliates, as applicable.

The purpose of this payment policy is to provide a guide to payment, which is a component of the guidelines used to assist in making coverage and payment determinations and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage and payment determinations and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable plan-level administrative policies and procedures.

This payment policy is effective as of the date determined by Health Plan. The date of posting may not be the effective date of this payment policy. This payment policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this payment policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. Health Plan retains the right to change, amend or withdraw this payment policy, and additional payment policies may be developed and adopted as needed, at any time.

This payment policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This payment policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this policy are independent contractors who exercise independent judgment and over whom Health Plan has no control or right of control. Providers are not agents or employees of Health Plan.

This payment policy is the property of Centene Corporation. Unauthorized copying, use, and distribution of this payment policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this payment policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this payment policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs and LCDs should be reviewed prior to applying the criteria set forth in this payment policy. Refer to the CMS website at http://www.cms.gov for additional information.