

	Reimbursement Policy Manual		Policy #:	RPM063
Policy Title:	340B Drug Discount Program-Acquired Drugs and Biologicals (Modifiers JG & TB)			
Section:	Modifiers	Subsection:	Drugs & Biologicals	
Scope:	This policy applies to the following Medical (including Pharmacy/Vision) plans:			
Companies:	<input type="checkbox"/> All Companies: Moda Partners, Inc. and its subsidiaries & affiliates <input checked="" type="checkbox"/> Moda Health Plan <input checked="" type="checkbox"/> Moda Assurance Company <input checked="" type="checkbox"/> Summit Health Plan <input type="checkbox"/> Eastern Oregon Coordinated Care Organization (EOCCO) <input type="checkbox"/> OHSU Health IDS			
Types of Business:	<input type="checkbox"/> All Types <input checked="" type="checkbox"/> Commercial Group <input checked="" type="checkbox"/> Commercial Individual <input checked="" type="checkbox"/> Commercial Marketplace/Exchange <input checked="" type="checkbox"/> Commercial Self-funded <input type="checkbox"/> Medicaid <input checked="" type="checkbox"/> Medicare Advantage <input checked="" type="checkbox"/> Short Term <input type="checkbox"/> Other: _____			
States:	<input checked="" type="checkbox"/> All States <input type="checkbox"/> Alaska <input type="checkbox"/> Idaho <input type="checkbox"/> Oregon <input type="checkbox"/> Texas <input type="checkbox"/> Washington			
Claim forms:	<input checked="" type="checkbox"/> CMS1500 <input checked="" type="checkbox"/> CMS1450/UB (or the electronic equivalent or successor forms)			
Date:	<input checked="" type="checkbox"/> All dates <input type="checkbox"/> Specific date(s): _____ <input type="checkbox"/> Date of Service; For Facilities: <input type="checkbox"/> n/a <input type="checkbox"/> Facility admission <input type="checkbox"/> Facility discharge <input type="checkbox"/> Date of processing			
Provider Contract Status:	<input checked="" type="checkbox"/> Contracted directly, any/all networks <input checked="" type="checkbox"/> Contracted with a secondary network <input checked="" type="checkbox"/> Out of Network			
Originally Effective:	1/22/2019	Initially Published:	2/6/2019	
Last Updated:	11/3/2022	Last Reviewed:	11/9/2022	
Last update includes payment policy changes, subject to 28 TAC §3.3703(a)(20)(D)? No				
Last Update Effective Date for Texas:		11/9/2022		

Reimbursement Guidelines

A. Billing Requirements

1. Effective for dates of service April 15, 2019 and following, all Commercial and Medicare claims for drugs and biologicals purchased through the 340B Drug Pricing Program must be billed using the appropriate modifier, JG or TB.
 - a. These requirements apply to all providers, whether or not they participate in our network.
 - b. We expect your claims to comply with CMS requirements by including the necessary modifiers to issue proper reimbursement.
 - c. For claims processed on or after September 28, 2022 modifier JG or TB continue to be required for data collection and reporting purposes.
2. For a claim with multiple drug lines, the appropriate 340B modifier is required on each line of a 340B-acquired drug.
3. A 340B modifier is not required on claim lines of a non-340B-acquired drug, a vaccine, or a packaged drug.

4. We will follow CMS reporting requirements for which modifier, JG or TB, should be reported depending upon the provider/facility type and the pertinent drug or biological status indicator (SI).
5. Effective for claims processed on or after July 1, 2021, in compliance with Oregon SB 1067, ORS 243.256, and ORS 243.879:
 - a. Line items meeting all the following requirements will be denied if not submitted with modifier JG:
 - i. Claims for OEBC and PEBC plans.
 - ii. Submitted by a hospital that is eligible for the 340B program.
 - iii. Line item for a drug that is eligible for the 340B program (procedure code has status indicator K on the OPPS fee schedule for the date of service).
 - b. A corrected claim with the required modifier will be needed to resolve the denial.

B. Reimbursement Adjustments

1. For claims processed on or after September 28, 2022 the CMS 340B pricing adjustment will not be applied. (CMS³)
2. For claims processed January 22, 2019 – September 27, 2022:
 - a. Separately payable drugs and biological agents purchased through the 340B program are reimbursed at an adjusted amount equal to the current CMS 340B reimbursement.
 - i. **Note:** For facility claims priced based upon a percent of Medicare OPPS, beginning January 1, 2018 when the CMS pricing rule became effective this pricing adjustment has automatically been applied when calculating the Medicare rate for line items with modifier JG appended.
 - ii. Beginning January 1, 2019, CMS extended the pricing reduction for line items with modifier JG appended to non-excepted off-campus provider based department claims priced based upon a percent of Medicare PFS.
 - b. For contracted facilities not reimbursed using OPPS methodology, modifiers JG and TB will be informational only.
 - c. This pricing adjustment applies to all out-of-network (OON) providers.
 - i. CMS has advised that Medicare Advantage plans are required to pay non-contracted providers the rate for 340B drugs that the care provider would receive under Original Medicare. Thus, we've updated our pricing methodology to align with CMS' updated rates.
 - ii. For Commercial plans, Moda Health applies the 340B rates to OON providers.

C. Additional Information

For more information regarding the CMS reporting requirements, you can access answers to frequently asked questions at [cms.gov](https://www.cms.gov) > Medicare > Medicare Fee-for-Service Payment > Hospital Outpatient PPS > Downloads > [Billing 340B Modifiers under the Hospital Outpatient Prospective Payment System \(OPPS\)](#).

D. Monitoring

1. Not all covered outpatient drugs acquired by a 340B hospital are purchased through the 340B program (see # A.3 above). However, hospitals that participate in the 340B program must maintain documentation regarding whether a drug was purchased through the discount program (CMS¹), comply with the applicable reporting requirements, and append the appropriate modifier when required.
2. The Pharmacy team will monitor claims submitted to ensure we are receiving the needed modifiers on all eligible 340B claims and line items.

E. Alignment with CMS

This policy aligns with Centers for Medicare & Medicaid Services (CMS) payment policy.

Codes, Terms, and Definitions

Acronyms & Abbreviations Defined

Acronym or Abbreviation		Definition
AMA	=	American Medical Association
ASP	=	Average Sales Price
CCI	=	Correct Coding Initiative (see "NCCI")
CMS	=	Centers for Medicare and Medicaid Services
CPT	=	Current Procedural Terminology
DRG	=	Diagnosis Related Group (also known as/see also MS DRG)
HCPCS	=	Healthcare Common Procedure Coding System (acronym often pronounced as "hick picks")
HIPAA	=	Health Insurance Portability and Accountability Act
MS DRG	=	Medicare Severity Diagnosis Related Group (also known as/see also DRG)
NCCI	=	National Correct Coding Initiative (aka "CCI")
OHP	=	Oregon Health Plan (Oregon Medicaid Program)
PVP	=	Prime Vendor Program
RPM	=	Reimbursement Policy Manual (e.g., in context of "RPM052" policy number, etc.)
SI	=	Status Indicator
UB	=	Uniform Bill

Definition of Terms

Term	Definition
340B-Acquired Drug	The drug was purchased at or below the 340B ceiling price from the manufacturer and includes 340B drugs purchased through the Prime Vendor Program (PVP).

Modifier Definitions:

Modifier	Modifier Description & Definition
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.

Coding Guidelines & Sources - (Key quotes, not all-inclusive)

“Each separately payable, non-pass through 340B-acquired drug should be billed on a separate claim line with the appropriate 340B modifier....

For a claim with multiple drug lines, the appropriate 340B modifier is required on each line of a 340B-acquired drug. A 340B modifier is not required on claim lines of a non 340B-acquired drug (regardless of status indicator), a vaccine (assigned status indicator “F”, “L” or “M”), or a packaged drug (assigned status indicator “N”), but could be appended if a hospital chooses.” (CMS¹)

“The discarded drug amount should be billed on a separate claim line with the JW modifier and the appropriate 340B modifier. Modifier “PO” or “PN” is also required if the 340B-acquired drug is furnished in an off-campus outpatient provider-based department of a hospital, in which case three modifiers will be reported on the drug HCPCS line.” (CMS¹)

“As a reminder, when multiple modifiers are reported, providers should report pricing modifiers first followed by descriptive modifiers.” (CMS¹)

Cross References

[“Drugs and Biologicals, Wastage and/or Discarded Amounts \(Modifier JW\).”](#) Moda Health Reimbursement Policy Manual, RPM015.

References & Resources

1. CMS. “Billing 340B Modifiers under the Hospital Outpatient Prospective Payment System (OPPS).” April 2, 2018: last accessed January 24, 2019. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Billing-340B-Modifiers-under-Hospital-OPPS.pdf> .
2. Ellison, Ayla. “CMS' Final Outpatient Payment Rule For 2019: 7 Things To Know.” Becker’s Hospital CFO Report. November 2, 2018: last accessed January 24, 2019.

<https://www.beckershospitalreview.com/finance/cms-final-outpatient-payment-rule-for-2019-7-things-to-know.html> .

3. CMS. "Vacating Differential Payment Rate for 340B-Acquired Drugs in 2022 Outpatient Prospective Payment System Final Rule with Comment Period." Medicare Learning Network. 2022-10-13-MLNC. MLN Connects Weekly Edition. October 13, 2022. Last accessed October 21, 2022. https://www.cms.gov/outreach-and-education/outreach/ffsprovpartpro/provider-partnership-email-archive/2022-10-13-mlnc#_Toc116466499 .

Background Information

340B Drug Pricing Program

Effective January 1, 2018 the Centers for Medicare and Medicaid (CMS) established two Healthcare Common Procedure Coding System (HCPCS) Level II modifiers to identify 340B-acquired drugs and biologicals, modifier JG and modifier TB.

On Jan. 1, 2018, CMS began paying hospitals 22.5 percent less than the average sales price for drugs purchased through the 340B program. That's compared to the previous payment rate of average sales price plus 6 percent. Under the final OPPS rule for 2019, CMS is extending the average sales price minus 22.5 percent payment rate to 340B drugs provided at nonexcepted off-campus provider-based departments. (Ellison²)

Modifiers

Modifiers are two-character suffixes (alpha and/or numeric) that are attached to a procedure code. CPT modifiers are defined by the American Medical Association (AMA). HCPCS Level II modifiers are defined by the Centers for Medicare and Medicaid Services (CMS). Like CPT codes, the use of modifiers requires explicit understanding of the purpose of each modifier.

Modifiers provide a way to indicate that the service or procedure has been altered by some specific circumstance but has not been changed in definition or code. Modifiers are intended to communicate specific information about a certain service or procedure that is not already contained in the code definition itself. Some examples are:

- To differentiate between the surgeon, assistant surgeon, and facility fee claims for the same surgery.
- To indicate that a procedure was performed bilaterally.
- To report multiple procedures performed at the same session by the same provider.
- To report only the professional component or only the technical component of a procedure or service.
- To designate the specific part of the body that the procedure is performed on (e.g. T3 = Left foot, fourth digit).
- To indicate special ambulance circumstances.

More than one modifier can be attached to a procedure code when applicable. Not all modifiers can be used with all procedure codes.

Modifiers do not ensure reimbursement. Some modifiers increase or decrease reimbursement; others are only informational.

Modifiers are not intended to be used to report services that are "similar" or "closely related" to a procedure code. If there is no code or combination of codes or modifier(s) to accurately report the service that was performed, provide written documentation and use the unlisted code closest to the section which resembles the type of service provided to report the service.

IMPORTANT STATEMENT

The purpose of this Reimbursement Policy is to document our payment guidelines for those services covered by a member's medical benefit plan. Healthcare providers (facilities, physicians, and other professionals) are expected to exercise independent medical judgment in providing care to members. Our Reimbursement Policy is not intended to impact care decisions or medical practice.

Providers are responsible for submission of accurate claims using valid codes from HIPAA-approved code sets and for accurately, completely, and legibly documenting the services performed. Billed codes shall be fully supported in the medical record and/or office notes. Claims are to be coded appropriately according to industry standard coding guidelines (including but not limited to UB Editor, AMA, CPT, CPT Assistant, HCPCS, DRG guidelines, CMS' National Correct Coding Initiative [CCI] Policy Manual, CCI table edits and other CMS guidelines).

Benefit determinations will be based on the member's medical benefit plan. Should there be any conflicts between our Reimbursement Policy and the member's medical benefit plan, the member's medical benefit plan will prevail. Fee determinations will be based on the applicable provider fee schedule, whether out of network or participating provider's agreement, and our Reimbursement Policy.

Policies may not be implemented identically on every claim due to variations in routing requirements, dates of processing, or other constraints; we strive to minimize these variations.

***** The most current version of our reimbursement policies can be found on our provider website. If you are using a printed or saved electronic version of this policy, please verify the information by going to https://www.modahealth.com/medical/policies_reimburse.shtml *****

Policy History

Date	Summary of Update
11/9/2022	Content/Update: Sections A.1.c & B.1: New information per 2022-10-13-MLNC; not subject to 28 TAC. Cross References: Hyperlink added. References & Resources: 1 entry added (2022-10-13-MLNC).
10/12/2022	Content/Update: Change to new header; includes Idaho. Section A.1.c added & section B updated for changes in 2022-10-13-MLNC. (CMS ³) Changes initiated at CMS, not subject to 28 TAC. References & Resources: 1 entry added. Policy History section: Added. Entries prior to 2022 omitted (in archive storage).
2/6/2019	Policy initially approved by the Reimbursement Administrative Policy Review Committee & initial publication.
1/22/2019	Original Effective Date (with or without formal documentation). Policy based on CMS 340B policy.