Applicable To:
☑ Medicare – excluding KY

Claims and Payment Policy: 340B Drug Payment Reduction

Policy Number: CPP-133

Original Effective Date: 12/18/2019
Revised Date(s): N/A

BACKGROUND

The 340B Drug Discount Program is a US federal government program that requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices. The intent of the program is to allow covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.

Generally, the 340B Program includes FDA-approved prescription drugs, over-the-counter (OTC) drugs written on a prescription, biological products that can be dispensed only by a prescription (other than vaccines), or FDA-approved insulin.

POSITION STATEMENT

Effective 1/1/2018, the Centers for Medicaid and Medicare (CMS) reduced the payment to participating providers paid under an Outpatient Prospective Payment System (OPPS) for certain drugs acquired through the 340B program. CMS established two Healthcare Common Procedure Coding System (HCPCs) Level II modifiers to identify 340B-acquired drugs. Providers are required to report either modifier "JG" or "TB" on OPPS claims. Modifier "JG" indicates the 340B as payable and modifier "TB" as informational.

Pre Pay Review

Verified 340B providers who submit claims with 340B covered codes without required modifiers "JG" and "TB" in POS 22 (outpatient hospital) or 23 (emergency room) and the drug has an assigned status indicator of "K", will have the "JG" and/or "TB" modifier added to the claim. This will ensure the claim is reimbursed at the appropriate rate.

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Post Pay Review

Verified 340B providers who submit claims with 340B covered codes without required modifiers "JG" and "TB" in POS 22 (outpatient hospital) or 23 (emergency room) and the drug has an assigned status indicator of "K", may be eligible for recovery of overpayments.

The 340B payment adjustment applies to separately payable OPPS drugs with an assigned status indicator of "K", the payment adjustment doesn't apply to vaccines (status indicator="F","F","M") or drugs on pass-through payment status (status indicator ="G"). Rural Sole Community Hospitals, Children's Hospitals and PPS-exempt cancer Hospitals are excepted from the 340B adjustment.

If a participating 340B provider purchases a 340B drug outside of the 340B program, providers will have the opportunity to submit a dispute to WellCare. The Health Resources and Services Administration (HRSA) requires that providers submit an invoice that indicates the 340B drug was purchased outside of the 340B program. According to HRSA, if the drug was purchased as part of the 340B program, the invoice will have "PHS" in the contract section. If "PHS" is not present, the drug was purchased outside of the 340B program.

CODING & BILLING

If the provider is a 340B participant billing in POS 22 (outpatient hospital) or 23 (emergency room) and the drug has an assigned status indicator of "K", then the provider is required to bill with either "JG" modifier or a "TB" modifier.

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

MODIFIERS

Modifier	Modifier Description
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 only

REFERENCES

1. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Billing-340B-Modifiers-under-Hospital-OPPS.pdf
2. https://www.340bhealth.org/members/340b-program/overview/
3. https://www.hrsa.gov/opa/eligibility-and-registration/index.html

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IMPORTANT INFORMATION ABOUT THIS DOCUMENT

Claims and Payment Policies (CPPs) are policies regarding claims or claim line processing and/or reimbursement related to the administration of health plan benefits. They are not recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for diagnosing, treating, and making clinical recommendations to the member. CPPs are subject to, but not limited to, the following:

- State and federal laws and regulations;
- Policies and procedures promulgated by the Centers for Medicare and Medicaid Services, including National Coverage Determinations and Local Coverage Determinations;
- The health plan's contract with Medicare and/or a state's Medicaid agency, as applicable;
- Other CPPs and clinical policies as applicable including, but not limited to, *Pre-Payment and Post-Payment Review*.
- The provisions of the contract between the provider and the health plan; and
- The terms of a member's particular benefit plan, including those terms outlined in the member's Evidence of Coverage, Certificate of Coverage, and other policy documents.

In the event of a conflict between a CPP and a member's policy documents, the terms of a member's benefit plan will always supersede the CPP.
The use of this policy is neither a guarantee of payment, nor a prediction of how a specific claim will be adjudicated. Any coding information is for informational purposes only. No inference should be made regarding coverage or provider reimbursement as a result of the inclusion, or omission, in a CPP of a CPT, HCPCS, or ICD-10 code. Always consult the member's benefits that are in place at time of service to determine coverage or non-coverage. Claims processing is subject to a number of factors, including the member's eligibility and benefit coverage on the date of service, coordination of benefits, referral/authorization requirements, utilization management protocols, and the health plan's policies. Services must be medically necessary in order to be covered.
References to other sources and links provided are for general informational purposes only, and were accurate at the time of publication. CPPs are reviewed annually but may change at any time and without notice, including the lines of business for which they apply. CPPs are available at www.wellcare.com. Select the "Provider" tab, then "Tools" and then "Payment Guidelines".

'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona
WellCare Prescription Insurance
WellCare (Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)

RULES, PRICING & PAYMENT COMMITTEE HISTORY AND REVISIONS

Date	Action
12/18/2019 01/27/2020	• Approved by Recovery RGC • Approved by RGC

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