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Medicare Part B Inflation Rebate Guidance: Use of the 340B Modifier

What's Changed?

- Added information on which modifier 340B covered entities should discontinue or use starting January 1, 2025 (pages 1-2)

You'll find substantive content updates in dark red.

Who's Affected

Medicare providers and suppliers who bill for separately payable Part B drugs and biologicals and participate in the 340B Drug Pricing Program.

Summary of Change

CMS is requiring all 340B covered entities, including hospital-based and non-hospital-based entities, that submit claims for separately payable Part B drugs and biologicals to discontinue the use of modifier "JG" on claim lines for drugs acquired through the 340B Drug Pricing Program[1] after December 31, 2024.

Starting January 1, 2025, if you're a 340B covered entity, you must report the "TB" modifier on claims.

The Inflation Reduction Act of 2022 establishes a Part B inflation rebate by manufacturers for certain single source drugs and biologicals with prices increasing faster than the rate of inflation. The "JG" or "TB" modifiers allow us to identify units of drugs acquired through the 340B Program to effectively implement the Part B inflation rebate program because units of 340B drugs are excluded from the Part B inflation rebates.

Time to Prepare for the Change

While these modifiers are already required for a variety of hospitals paid under the Outpatient Prospective Payment System (OPPS), all 340B covered entities must use the "TB" modifier starting January 1, 2025. We issued guidance on December 20, 2022, so that provider types newly having to report these modifiers would have time to make changes to their billing systems. We also issued revised guidance on December 14, 2023, so that all provider types know of new 340B modifier requirements starting January 1, 2025.

[1] These modifiers, as established under regulation, have been in use by many 340B covered entities since 2018. https://www.govinfo.gov/content/pkg/FR-2017-12-14/pdf/R1-2017-23932.pdf

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Report the Correct Modifier

For claims with dates of service starting January 1, 2024, the following provider types should continue to report the "TB" modifier on separately payable claim lines for drugs acquired through the 340B Program:

- Critical Access Hospitals
- Maryland All-Payer or Total Cost of Care Model hospitals
- Non-excepted off-campus provider-based departments
- Rural sole community hospitals
- Children's hospitals
- PPS-exempt cancer hospitals

During CY 2024, all other 340B covered entities, including Ryan White clinics and hemophilia clinics, should have either reported the "JG" modifier on claim lines for separately payable drugs acquired through the 340B Program[2] or transitioned early to the "TB" modifier. **All 340B covered entities must transition to the "TB" modifier by January 1, 2025.** All 340B covered entities that previously reported the "JG" modifier on claim lines for separately payable Part B drugs acquired through the 340B program in CY 2024 should switch to reporting the "TB" on those same claim lines. Providers and suppliers affiliated with 340B covered entities (for example, contract pharmacies) are also required to submit the modifier on separately payable claim lines for separately payable Part B drugs acquired through the 340B program. All 340B covered entities must discontinue the use of "JG" modifier after December 31, 2024.

Resources

- CY 2025 Physician Fee Schedule final rule for information on the Part B inflation rebates
- Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Revised Guidance, Implementation of Section 1847A(i) of the Social Security Act
- Revised Part B inflation Rebate Guidance: Use of the 340B Modifiers

[2] 340B covered entities paid under the OPPS should continue to report the "TB" modifier for pass-through drugs acquired