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

What's Changed?

 Added information on what modifiers different categories of 340B covered entities should use in CY 2024 and 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

Starting January 1, 2024, 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 report modifier "JG" or "TB" on claim lines for drugs acquired through the 340B Drug Pricing Program.¹

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

In CY 2024, 340B covered entities may do 1 of these:

- Continue to use the modifier you're currently using or have been instructed to use as per guidance
- Transition early to the "TB" modifier

The <u>Inflation Reduction Act of 2022</u> 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 allows 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.

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





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 these modifiers starting January 1, 2024. 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're issuing revised guidance now so that all provider types know of new 340B modifier requirements starting January 1, 2025.

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

All other 340B covered entities should either report the "JG" modifier for separately payable drugs acquired through the 340B Program² in CY 2024 or transition early to the "TB" modifier. All 340B covered entities must transition to the "TB" modifier by January 1, 2025. This includes 340B covered entities currently not reporting the "JG" or "TB" modifier, such as Ryan White clinics and hemophilia clinics, which should report the "JG" modifier on separately payable Part B claim lines for drugs acquired through the 340B Program in CY 2024. Providers and suppliers affiliated with 340B covered entities are also required to submit the appropriate modifier on separately payable claim lines for drugs.

Resources

- 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

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

