Medicare Drug Price Negotiation Selection Process

In an effort to promote transparency, CMS is providing the following information to give additional insight into the drug selection process for qualifying single source drugs (QSSDs) for initial price applicability year (IPAY) 2027 using a hypothetical drug (Drug Hypothetical). Additional information on the drug selection process for IPAY 2027 can be found in the **Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027**. CMS will be releasing guidance for IPAY 2028 in the future and looks forward to stakeholders' feedback at that time.

Hypothetical Example

Drug Hypothetical is a biologic and has three Biologics License Applications (BLAs): BLA #1, BLA #2, and BLA #3. The BLAs share the same active ingredient (Molecule XYZ) and BLA holder (Manufacturer DEF) and are aggregated together as a potential qualifying single source drug.

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Selection Criteria

Covered Part D drugs/exclude drugs newer than 7 or 11 years: Drug Hypothetical is covered under the Medicare Part D Program. BLAs #1, #2, and #3 have approval dates of 1/1/2011, 1/1/2016, 1/1/2022, respectively. The earliest approval date is 1/1/2011, and the drug is not on FDA's list of "deemed biologics" originally approved under NDAs subsequently deemed to be BLAs effective March 23, 2020, so Drug Hypothetical meets the timing criterion of at least 11 years between the earliest approval date and the selected drug list publication date.

Low-spend Medicare drug: Drug Hypothetical's total Part D expenditures are $1,000,000,000 and therefore, it does not meet the low-spend Medicare exclusion.

Orphan drug: Drug Hypothetical has an orphan drug designation for only one rare disease/condition, but BLA #2 has a separate approved indication outside of that rare disease/condition. Drug Hypothetical is not eligible for the orphan drug exclusion since it has an approved indication outside of the rare disease/condition.

Plasma-derived drug: Drug Hypothetical is not plasma-derived and therefore, it does not qualify for the plasma-derived exclusion.

Bona fide marketing: Drug Hypothetical is a reference product for an approved biosimilar, but that biosimilar is not bona fide marketed because the biosimilar has not yet entered the market due to ongoing patent litigation.

Small Biotech Exception and selected drugs: Drug Hypothetical did not meet the criteria for the Small Biotech Exception and is not a selected drug for IPAY 2026. It is therefore eligible to be on the negotiation-eligible drug list.

Negotiation-eligible drugs: Drug Hypothetical is ranked in the top 50 QSSDs that have the highest total Part D expenditures. Therefore, it is a negotiation-eligible drug.

Biosimilar delay: No manufacturer of a biosimilar for which Drug Hypothetical is the reference product submitted a biosimilar delay request. Therefore, it cannot qualify for the Biosimilar Delay and remains on the list of negotiation-eligible drugs.

Covered Part D drugs at active moiety or active ingredient/NDA or BLA holder level

Exclude drugs newer than 7 (small molecule) or 11 (biologic) years

Exclude low-spend drugs, orphan drugs, plasma-derived, or when a generic/biosimilar is marketed

Exclude small biotech and "cycle 1" (IPAY 2026) selected drugs

Negotiation-eligible drugs

Exclude drugs with a high likelihood of biosimilar entry within 2 years

Selected Drug:

IPAY 2027 selected drugs (for negotiation in 2025): Drug Hypothetical is one the 15 highest ranked negotiation-eligible drugs remaining on the ranked list of the top 50 QSSDs. Therefore, it is selected.