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US Price Negotiation Pioneers: The Unique Position Of Imbruvica

by Michael McCaughan

The first 10 drugs picked for price negotiation in the US Medicare program will all be unwilling trailblazers. But the position of Abbvie's Imbruvica stands out as unique in several important ways.

[Abbvie Inc.](#)'s Imbruvica (ibrutinib) stands out as a unique test case among the first 10 drugs picked for negotiation in the US Medicare program.

While each of the sponsors of the 10 drugs selected for the first price negotiation class will be unwilling pioneers in shaping the new process, Imbruvica stands out as a unique member of an already unique group. (Also see "[Patent Cliff Likely Accelerated By Two Years For Most Drugs On Medicare Price Negotiation List](#)" - Pink Sheet, 29 Aug, 2023.)

1. *It is the only anti-cancer drug on the list*

The US has a long history of treating cancer as a special case when it comes to public policy around health care. The Biden Administration's "Moonshot" program is only the latest iteration in a long cycle of initiatives dating back to the Nixon White House's "War on Cancer."

It is no coincidence that cancer drugs have special status already when it comes to coverage in Medicare Part B – the only class where reimbursement is mandatory for FDA-approved indications and for "off-label" uses recommended by key compendia. There has never been and (barring new legislation) will never be a cancer drug facing the types of restrictions that novel Alzheimer's agents now face in Medicare. (Also see "[Medicare's 'Aduhelm' Policy A Precedent For Accelerated Approvals But Not Cancer Drugs – Gottlieb](#)" - Pink Sheet, 1 Aug, 2023.)

And it is also no coincidence that anti-cancer drugs are one of the six "protected classes" in the Part D program, ensuring that the private plan sponsors cannot exclude any FDA approved

therapy from formularies. Which leads to the second reason Imbruvica is unique:

2. It is the only ‘protected class’ drug on the list.

For now, at least, none of the antipsychotics, antidepressants, antipsychotics, HIV medicines or immunosuppressants sold in the US meets the negotiation criteria. That means Imbruvica is the only drug selected for negotiation that isn’t subject to the full range of formulary management tools – a setting where historically rebates have been minimal or non-existent in the program. That stands in contrast to most of the pioneer negotiation class, where the gap between gross spending in Part D and net costs to the program is vast. (Also see "[Big Rebates Already A Big Factor For Drugs On Medicare Negotiation List](#)" - Pink Sheet, 29 Aug, 2023.)

So, unlike for most of the products facing price cuts in the first negotiation cycle, even a “minimum” cut for Imbruvica would make a significant difference on net program costs. By law, the negotiated price must be reduced by at least 25% – and in this case that is likely to translate almost directly into a reduction in actual spending in the program.

That reality also plays into the third reason Imbruvica is a unique case:

3. It has by far the highest out of pocket costs of any of the first 10 drugs picked.

As has been the case with most of the Inflation Reduction Act drug pricing reforms, the Biden Administration is attempting to emphasize the impact on beneficiary out-of-pocket spending, and so the announcement of the list was accompanied by a [report](#) from the Assistant Secretary for Planning & Evaluation drilling down into the cost-sharing associated with each brand.

ASPR’s report highlights Imbruvica as the product with by far the highest average out-of-pocket spending on the list, over \$6,000 per beneficiary (not counting those with low-income subsidies). However, the IRA has separately established a \$2,000 per year out-of-pocket cap in Part D, meaning that any price cut negotiated for the brand likely will not reduce OOP spending in 2026.

Only two other drugs had average annual OOP costs over the \$2,000 limit. [Johnson & Johnson’s](#) Stelara (at \$4,205) also may not end up falling below the new cap. Amgen’s Enbrel (at \$2,005) will likely see significantly lower OOP costs, however, since the brand is subject to a price reduction of at least 60% as one of the oldest members of the first negotiation class.

There will be plenty of interested spectators watching to see how Abbvie’s negotiation plays out – and not just its marketing partner [Janssen Pharmaceuticals Inc.](#)

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The second negotiation class is very likely to include more anti-cancer drugs. Indeed, [*Astellas Pharma US Inc.*](#) was so certain that Xtandi would qualify for the first negotiation class that it pre-emptively sued CMS. (The firm subsequently withdrew its suit after the anti-androgen did not make the list.) But many predictions included [*Pfizer Inc.*](#)'s Ibrance as a potential negotiation target, and [*AstraZeneca PLC*](#) has cited a potential that Kysqali could soon make the list as well. (Also see "[*Medicare Negotiation List Surprises Highlight The Importance Of Current Spending Data*](#)" - Pink Sheet, 30 Aug, 2023.)

And in the third negotiation cycle, the candidate list will expand to include the top drugs in Part B, which all but ensures that [*Merck & Co., Inc.*](#)'s Keytruda and [*Bristol Myers Squibb Company*](#)'s Opdivo will be up for negotiation then.