

January 31, 2024

CMS Price Offers Going Out As R&D Expensing Bipartisan Vote Takes Place Tonight

ALERT: Biopharma Friendly R&D Tax Deduction Could Clear House & Senate

Relevant Companies



»» Our Take & Next Up

CMS appears to be meeting the February 1 deadline for initial price offers to manufacturers while a surprise bipartisan tax provision helping Biopharma (R&D expensing) could pass the House as soon as tonight. We do not expect to see prices publicly (from CMS or pharma) as manufacturers have no real incentive to reveal prices, even if the initial offer is higher than expected. The spring-into-summer negotiation process will play out with twists and turns, so we do not envision companies leaking prices (and CMS likely won't). Following the end of the negotiation process and MFP release by September 1, 2024, companies may include pricing info in their ongoing litigation to show material harm. In the ongoing lawsuits, judges in the BMS & JNJ's combined case ([here](#)), as well as MRK's case ([here](#)), have completed their briefing schedule with a decision on summary judgments possible in the next few weeks.

»» Key Points

Separately, the R&D tax provision is a (surprise) win for biopharma – Bipartisan support exists, and the House will vote as soon as tonight. In tandem, we note that the House is set to vote (and will likely pass) a bill to restore immediate R&D expensing. The deal also temporarily restores several business tax benefits that recently ended or have begun to phase out. The benefits were originally part of the Republicans' 2017 *Tax Cuts and Jobs Act*.

- The agreement would once again allow businesses to immediately deduct the cost of their US-based research and experimentation investments instead of over five (5) years, as well as restore their ability to immediately deduct 100% of their investment in machinery and equipment.
- It would relax the tightened limits on the deductibility of interest expenses, which mainly affects companies that have significant debt.
- These three provisions would run through 2025.

On negotiation, CMS is legislatively required to send their initial offers to each manufacturer by February 1, 2024. Other key dates include:

- February 1, 2024 – Deadline for CMS to send initial offers with a justification
- August 1, 2024 – The negotiation period for 2026 ends (three meetings)
- September 1, 2024 – Maximum fair prices publication due date
- February 1, 2025 – CMS to announce the list of 15 drugs (Part D) subject to negotiations in 2027

- March 1, 2025 – Deadline for CMS to publish explanation of the maximum fair prices
- January 1, 2026 – Maximum fair prices are effective for selected drugs

Initial prices aren't likely to be disclosed by manufacturer; Pfizer was asked about Eliquis (BMY) government price offer on its earnings call yesterday. PFE noted that BMS is taking the lead and that they would not comment on price setting; it's an ongoing process. We expect the initial prices to differ as CMS will set each price taking into account factors including: clinical benefit, R&D costs, unit costs of production and distribution, evidence on alternative treatments, and the extent to which the drug and its alternatives address an unmet medical need.

- Manufacturers are expected to respond with a counteroffer within 30 days.
- It is likely that an agreement will not be met at that time, CMS will then invite each participating drug company for up to three (3) negotiation meetings before the negotiation period ends.
- The new Medicare drug prices for 2026 are expected by September 1.

As a reminder, CMS's offer will be the maximum fair price (MFP), which must fall below the legislatively restricted ceiling price. The IRA ceiling on the MFP is based on the lesser of:

- The weighted average net price under Part D, or
- A percentage of the nonfederal average manufacturer price (non-FAMP), a wholesaler price minus certain discounts, ranging from 75% of the non-FAMP for a drug approved for less than 16 years to 40% of the non-FAMP for a drug approved for 16 years or more.

Net price is likely to be ceiling price for heavily rebated drugs. Several of the selected drugs including Jardiance (Boehringer Ingelheim, LLY), Enbrel (AMGN), Symbicort (AZN), Januvia (MRK), Xarelto (Bayer, JNJ), and Breo Ellipta (GSK) are significantly rebated to ensure formulary coverage. For these drugs, the current net prices are the likely ceiling of what their negotiated prices will be. Unlike net prices, negotiated drugs may not have the benefit from a top tier formulary coverage and plans may seek to switch up their tiering to accommodate both Part D restructuring and cost for negotiated drugs.

INSURANCE CO'S NEED POLICING

Insurance tier placement of the negotiated drugs remains a concern for CMS, manufacturers, and patients. An MFP is calculated across all dosage forms and strengths of a drug and is in effect until the first year beginning at least nine months after a generic or biologic substitute for a drug is marketed. The negotiated drugs for 2026 will not be subject to rebates. By law, the negotiated price may not be higher than the net price Medicare plans currently pay after rebates or higher than a maximum percentage of the non-FAMP.

LEGAL UPDATE

Negotiation program lawsuit update: BMS/JNJ & MRK lawsuits have wrapped up their briefing schedule with a decision potentially coming in the next few weeks. As a reminder, BMS&JNJ combined case and MRK's case both argue a violation of the first amendment's compelled speech and fifth amendment's taking clause that the government is forcing manufacturers to sell their property without "just compensation". We are also waiting for a decision on the government motion to dismiss in the PhRMA's case in Western Texas. Other updates include:

- Oral arguments are scheduled for January 31 (today) for the AZN case in Delaware
 - In the Dayton Area Chamber case, the Government's deadline to reply in the motion to dismiss is now extended to February 14.
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