

J&J Maximum Fair Price (“MFP”) Implementation Plan for IPAY 2026

Contents

I. Implementation Plan Overview..... 2

II. Operations Overview 2

III. Good Faith Inquiry (GFI) / Dispute Process Overview 5

IV. Access Information..... 6

V. Attachments 7

VI. Transition Instructions 8

VII. Frequently Asked Questions 9

I. Implementation Plan Overview

The “Maximum Fair Price” (“MFP”) is a government-mandated price established under the Inflation Reduction Act (IRA) that drug manufacturers must offer to eligible individuals under Medicare Part D on selected medicines beginning January 1, 2026. Johnson & Johnson (J&J) is aligning its strategies, systems and workflows to incorporate these new mandated prices, ensure compliance with federal law, and provide Medicare beneficiaries access to the “MFP.” STELARA, USTEKINUMAB (unbranded STELARA), and XARELTO are the J&J Part D drugs for “MFP” effectuation in 2026.

Centers for Medicare and Medicaid Services (CMS) requires that dispensing entities (DEs) register with the Medicare Transaction Facilitator (MTF) Data Module (DM) to receive “MFP” refund payments from J&J beginning in January 2026. DEs can register at <https://mtf.cms.gov/mtfdm/login>.

For additional information about the “Medicare Drug Price Negotiation Program,” please see the following resources from the Centers for Medicare & Medicaid Services (CMS):

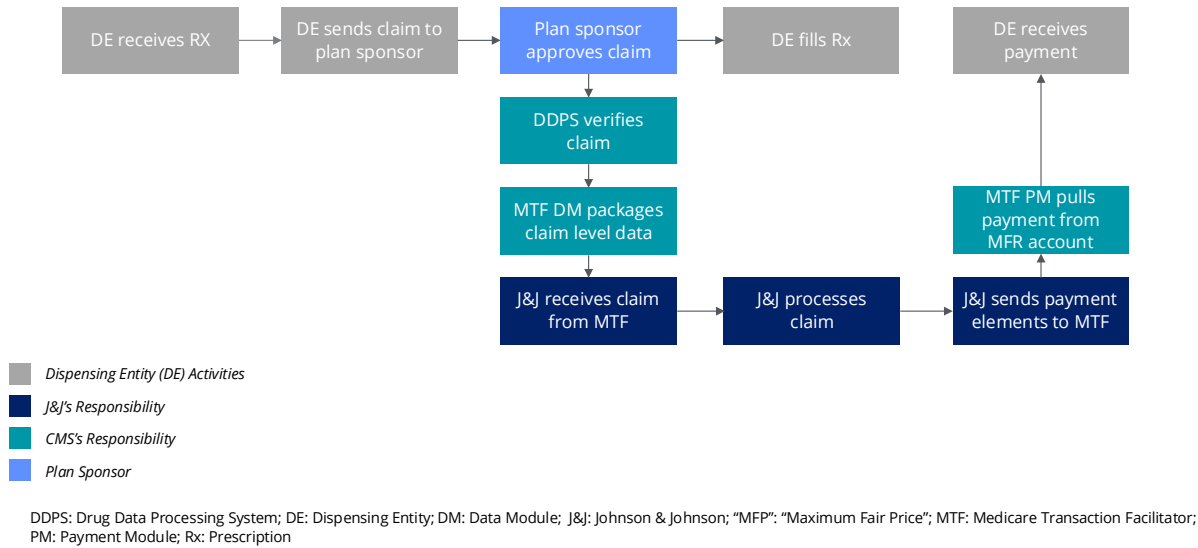
- [Medicare Drug Price Negotiation Program Overview](#)
- [Medicare Drug Price Negotiation Program](#): Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027
- [Medicare Drug Price Negotiation Program](#): Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028

II. Operations Overview

A. Process for Effectuation of “MFP,” in accordance with CMS guidance

J&J will use the CMS-provided Medicare Transaction Facilitator (MTF) Data Module (DM) and Payment Module (PM) to effectuate “MFP” for STELARA, USTEKINUMAB (unbranded STELARA), and XARELTO. The process flow below provides an overview of how J&J will effectuate “MFP” based on CMS final guidance.

Attachment A: High-Level “MFP” Effectuation Process Flow



B. Key Components of Effectuation Process, in accordance with CMS guidance

J&J plans to transmit claim level payment elements to the MTF DM as required by CMS guidance in order to meet the “MFP” payment cycle time (14 days after J&J receives complete claim level detail for eligible claims from the MTF DM). Refer to the timeline below for details on “MFP” claim and refund processing timing.

Attachment B: High-Level Timeline: “MFP” Claim & Refund Processing



CMS: Centers for Medicare & Medicaid Services; DE: Dispensing Entity; DM: Data Module; J&J: Johnson & Johnson; “MFP”: “Maximum Fair Price”; MTF: Medicare Transaction Facilitator; PDE: Prescription Drug Event; PM: Payment Module

J&J will use the MTF, as described in CMS guidance, to dispute or offset claims deemed to be ineligible for “MFP.” For example, J&J is not required to pay “MFP” refunds to dispensing entities (DEs) on 340B claims when the 340B price is lower than MFP. In addition, J&J is not required to pay “MFP” refunds in instances where a claim is deemed ineligible for other reasons (duplication, unit of measure error, etc.). J&J will work with DEs on refunds and offsets through the MTF and its provided ledger capabilities.

C. “MFP” Refund Calculation

J&J plans to primarily use the Standard Default Refund Amount (SDRA) set forth in the final guidance to calculate and make the retrospective “MFP” refund payments to a DE.

$$\text{“MFP” refund} = \text{Wholesaler Acquisition Cost (WAC)} - \text{“MFP”}$$

Where contracted otherwise, the “MFP” refund will be calculated using contract price(s) as follows:

$$\text{“MFP” refund} = \text{contract price} - \text{“MFP”}$$

For claims that are also 340B-eligible, if the “MFP” is lower than 340B price, the “MFP” refund will be calculated using the 340B price as follows:

$$\text{“MFP” refund} = \text{340B price} - \text{“MFP”}$$

For claims where the “MFP” refunds are calculated using contract price(s), J&J will retain all claim history including the claim basis price used to calculate the refund and contract(s) which includes the agreed upon contract price(s). For 340B-eligible claims where the “MFP” is less than the 340B price, all claim history will be maintained, including the determination that the claim basis price was used to calculate the refund. The DE will have visibility to the basis of price in a third-party vendor portal called Beacon Channel Management, or “Beacon.”

D. IRA “MFP” 340B Deduplication Policy

Per HRSA’s 340B Rebate Model Pilot Program guidance, J&J has submitted a plan to participate in the program. If J&J is able to move forward based on HRSA’s approval and any subsequently issued guidance, J&J will provide a 60-day notice period to covered entities (CEs) and stakeholders prior to go-live, ensuring time for CEs to prepare, register on IT platforms, and work in good faith with CEs to address operational issues with the IT platform ahead of implementation of HRSA’s 340B Rebate Model Pilot Program.

If J&J’s plan to participate is approved, J&J will deduplicate 340B & “MFP” discounts for Part D claims for STELARA, USTEKINUMAB (unbranded STELARA), and XARELTO using HRSA’s 340B Rebate Model Pilot Program, as specified in J&J policy and J&J’s rebate model plan submitted to HRSA. J&J’s “MFP”/340B deduplication process will be effectuated by a third-party Second Sight Solutions and its Beacon platform. Additional details will be provided upon approval of J&J’s plan to participate in the 340B Rebate Model Pilot Program.

III. Good Faith Inquiry (GFI) / Dispute Process Overview

A. Approach to Supporting Good Faith Inquiries (GFIs) and Disputes

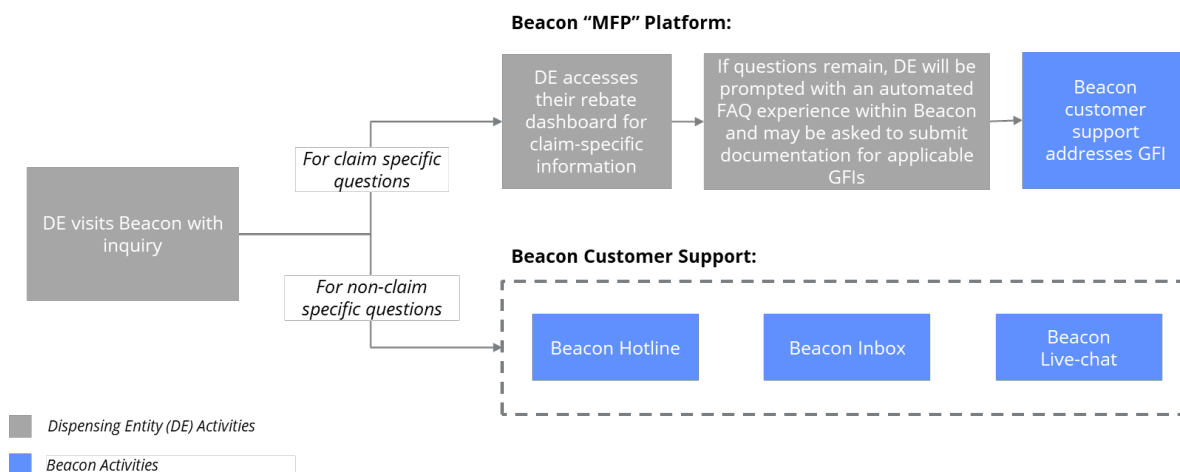
CMS encourages DEs and Primary Manufacturers to work together in good faith to resolve any issues regarding “MFP” access. DEs can initiate Good Faith Inquiries (GFIs) related to “MFP” Effectuation with J&J through Beacon.

The Beacon support team is available M-F 9 AM-9 PM ET via chat and phone and DEs can review online support materials or submit inquiries via email at any time. DEs should use the platform to proactively understand the status of claims related to “MFP” effectuation for STELARA, USTEKINUMAB (unbranded STELARA), and XARELTO. If a DE has further questions, they should refer to the Good Faith Inquiry (GFI) Process or customer support. Note, for “Technical Disputes,” as defined by CMS, the DE should contact CMS directly. The Beacon platform will have “MFP” information available to the DEs, including claim status, submission status, basis of pricing type, and key dates and payment amounts. J&J recommends DEs reference their respective Beacon dashboard prior to submitting an inquiry or dispute.

B. Good Faith Inquiry (GFI) Process

If open questions related to “MFP” effectuation claims for STELARA, USTEKINUMAB (unbranded STELARA), or XARELTO still remain, a DE can begin the Good Faith Inquiry (GFI) process. A GFI should be submitted via Beacon’s Resolution Center, referencing the ICN (Invoice Control Number). To support the GFI process, DEs may be required to submit documentation to support their inquiry. Following submission of a GFI and supporting documentation, the customer support team will assess the submitted documentation and share a response via Beacon. Reference Attachment C for more details on the GFI process, including for claim-specific and non-claim-specific questions.

Attachment C: Good Faith Inquiry Process Flow



DE: Dispensing Entity; GFI: Good Faith Inquiry

C. Dispute Process

According to [CMS Medicare Drug Price Negotiation Program Guidance](#) (section 90.2.2) published in May 2025, under the “Medicare Drug Price Negotiation Program,” a dispute is “a specific, identifiable challenge to a technical aspect of the MTF system and process (e.g., claims included as potentially requiring an “MFP” refund).”

DEs should submit disputes directly to CMS through the MTF DM using the following CMS final guidance published in May 2025: “The first track is a dispute functionality within the MTF for qualifying disputes from Primary Manufacturers or DEs, and, beginning in 2028, Part B providers regarding a technical aspect of the MTF process...CMS will evaluate disputes and issue findings as appropriate based on available relevant factual information.”

IV. Access Information

Beacon Information

- [Link](#) to Beacon’s “MFP” Platform (**available beginning October 1, 2025**)

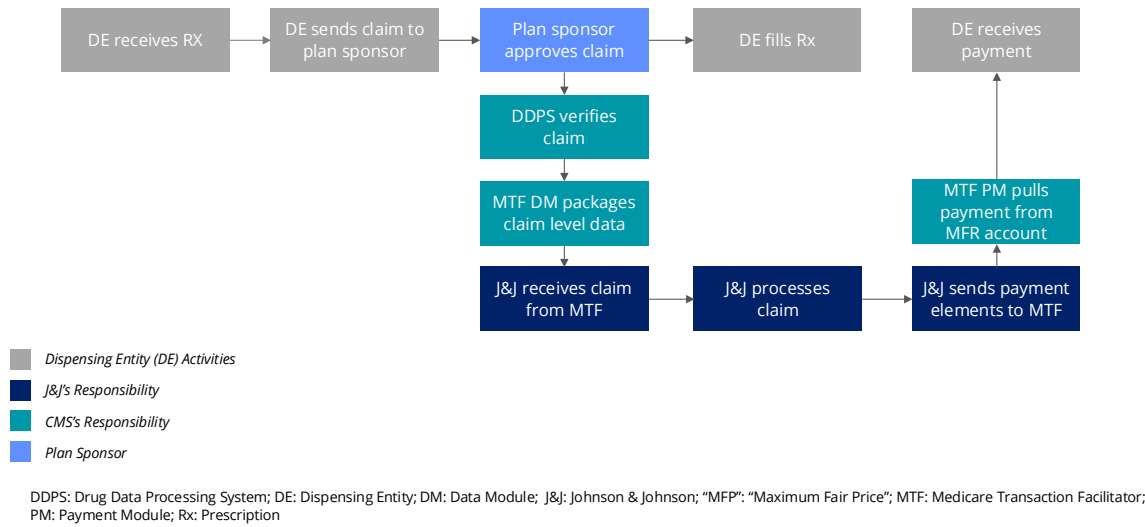
CMS Website Information

- For questions related to payment logistics or timing, please visit the CMS website at the following [link](#)

V. Attachments

Attachment A

High-Level "MFP" Effectuation Process Flow



Attachment B

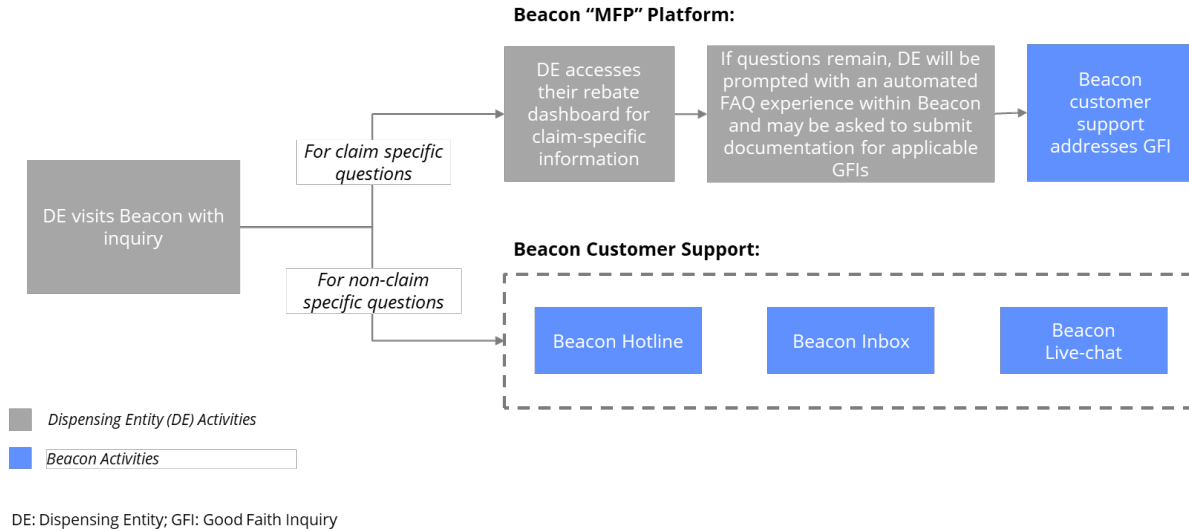
High-Level Timeline: "MFP" Claim & Refund Processing



CMS: Centers for Medicare & Medicaid Services; DE: Dispensing Entity; DM: Data Module; J&J: Johnson & Johnson; "MFP": "Maximum Fair Price"; MTF: Medicare Transaction Facilitator; PDE: Prescription Drug Event; PM: Payment Module

Attachment C

Good Faith Inquiry Process Flow



Attachment D

Additional Available Resources / Webpages

1.	J&J “MFP” Effectuation FAQs (<i>see FAQ section below</i>)
2.	Beacon’s “MFP” platform (available beginning October 1, 2025)
3.	CMS Medicare Drug Price Negotiation Program Information

VI. Transition Instructions

For more information about enrollment, please see the CMS provided [Pharmacy and Dispensing Entity Resources](#)

DEs can take the following actions to facilitate “MFP” refunds as quickly as possible:

- Participate in the MTF DM and MTF PM processes as outlined by CMS guidance
- Completely identify all data fields in claim level data
- Ensure only “MFP”-eligible claims are submitted for the “MFP” effectuation process
- Set up the CMS prescribed financial/banking procedure to ensure an automated flow of “MFP” payments from the MTF PM

VII. Frequently Asked Questions

1. When will the “Maximum Fair Price” (“MFP”) take effect and how is Johnson & Johnson preparing to comply with the Inflation Reduction Act (IRA)?

Under the IRA, the “Maximum Fair Price” (“MFP”) is the price ceiling for certain Medicare drugs, as determined by CMS. The first round of selected Part D drugs will have the “MFP” take effect on **January 1, 2026**.

Johnson & Johnson is aligning its systems and workflows to incorporate these new prices, ensure compliance with federal law and provide pharmacies access to the “MFP.”

2. Which Johnson & Johnson Drugs are Affected by “MFP” Effectuation?

XARELTO®, STELARA®, and USTEKINUMAB (unbranded STELARA) are the J&J medicines selected for “MFP” effectuation in 2026.

3. How does the “MFP” program overlap with the 340B program?

If the “Maximum Fair Price” (“MFP”) is lower than the 340B ceiling price, manufacturers must provide access to the “MFP” in a nonduplicated amount to the 340B ceiling price. If the 340B ceiling price is lower than the “MFP,” manufacturers are not required to provide access to the “MFP.” CMS has stated to date that it will not determine 340B eligibility of “MFP” claims, therefore manufacturers must implement processes for identifying 340B-eligible “MFP” claims and deduplicating discounts between “MFP” and 340B.

4. How will Johnson & Johnson handle 340B deduplication for “MFP” claims?

If the “Maximum Fair Price” (“MFP”) is lower than the 340B ceiling price, manufacturers must provide access to the “MFP” in a nonduplicated amount. If the 340B ceiling price is lower than the “MFP,” manufacturers are not required to provide access to the “MFP.” While CMS does not determine 340B eligibility, manufacturers are responsible for identifying and preventing duplicate discounts between “MFP” and 340B.

To meet this requirement, Johnson & Johnson has applied to participate in the Health Resources & Services Administration (HRSA) 340B Rebate Model Pilot Program, with approval decisions expected by October 15, 2025. If participation in the HRSA program is not viable, Johnson & Johnson will implement alternative processes to ensure proper deduplication of “MFP” and 340B discounts. Johnson & Johnson will provide additional guidance in October, if necessary.

5. Can you please clarify the role of Beacon?

Johnson & Johnson will use [Beacon’s “MFP” platform](#) (available starting October 1st, 2025), a secure, third-party platform to support DEs in managing “MFP” claims. Through Beacon, users can:

- View real-time updates on submitted claims or issues.
- Access claim details (status, ICN number, invoice date, validated price, basis of price type, applicable WAC/ “MFP”/SDRA pricing).

- Upload supporting documentation for open good faith inquiry cases if applicable.

6. How does Beacon facilitate the effectuation of the “MFP?”

Beacon facilitates the effectuation of the “MFP” by:

- Ingesting and validating refund data received from the MTF DM.
- Management of a system displaying the status of all “MFP” refund requests and payments.
- Communication of “MFP” refund request status back to J&J for submission to the MTF DM.

7. How do I submit a Good Faith Inquiry?

Johnson & Johnson will leverage Beacon’s “MFP” platform to centralize and manage all inquiry submissions, and track and support the Good Faith Inquiry (GFI) process outlined in CMS guidance. Users can initiate a Good Faith Inquiry through the Beacon Resolution Center. All GFI communications are recorded and tracked to ensure transparency and timely resolution.

8. How long does it take to receive an “MFP” refund?

CMS Guidance requires that the Primary Manufacturer must transmit claim-level payment elements to the MTF DM within 14 days after the MTF DM sends claims-level data to the Primary manufacturer. MTF PM will be responsible for issuing payments directly to DEs. J&J will make funds available to the MTF PM within the 14-day timeline, and the MTF PM is then responsible for issuing payments to DEs. We are not aware of how long their payment process may take.

9. What should I do if I believe the “Maximum Fair Price” (“MFP”) refund from Johnson & Johnson is incorrect?

If your entity has concerns about a “Maximum Fair Price” (“MFP”) refund received from Johnson & Johnson, you should submit an inquiry via the Beacon Resolution Center. Beacon’s “MFP” platform offers a centralized, transparent, and efficient process for resolving disputes, addressing refund discrepancies, and managing other issues related to the “MFP” program.

10. What should I do if I have a cash flow concern related to “MFP” implementation?

If you anticipate a significant cash flow concern, follow CMS guidance by reporting it at the start of the initial price applicability year. For questions related to payment logistics or timing, please visit the CMS website at the following [link](#).