# Medicare Price Negotiation of Part B Drugs: Implications for Provider Reimbursement and Commercial Spillover

THE CHOICE INSTITUTE

School of Pharmacy

# Moderator and Speakers

- Introduction and Background
  - **Sean D. Sullivan, PhD**, Professor University of Washington; Visiting Professor, London School of Economics and Political Science
- Perspectives on the Inclusion and Negotiation of Part B Drugs
  - **Kristi Martin, MA, MPH**, Former Chief of Staff, Center for Medicare, CMS, Washington DC and Camber Collective
- Impact of Part B Negotiation and MFP Determination on Clinics and Provider Groups
  - **Ramesh Srinivasan, PhD**; Senior Vice President, Strategic Pricing and Manufacturer Relations, McKesson Corporation
- Moderated Discussion

# Selection of Negotiation-Eligible Drugs

**How Many Drugs?**

- 10 Part D drugs published August 29, 2023 (MFP Implemented in 2026)
- Up to 15 Part D drugs selected - February 1, 2025 (MFP Implemented in 2027)
- Up to 15 **Part B** and D drugs selected in 2026 (MFP Implemented in 2028 – **IPAY 2028**)
- Up to 20 Part B and D drugs selected in 2027 and beyond (MFP Implemented in 2029)

# Medicare Price Determination Prior to the IRA

## Part B Payment:

**Prices are determined by statutory formula**

**In most cases, Medicare pays providers a drug's average sales price (ASP) plus 6% (4.3%). IRA provision increases to ASP+8% for biosimilars**

**Fundamentally a different payment mechanism compared to Part D (outpatient drugs).**

# Average Sales Price (ASP)

$$ASP_{Q+2} = \frac{\text{Manufacturer's sales (sum of prices) of drug to all purchasers in US in calendar quarter (Q)}}{\text{Total number of units of drug sold by manufacturer in same quarter (Q)}}$$

- **Manufacturers' price reporting must account for concessions including any discounts, chargebacks, and rebates (some exclusions)**
- **Q+2 indicates the two-quarter lag in implementation of ASP**

# 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.

## 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.**

# Selection of Negotiation-Eligible Drugs

**Time on Market**

> Small Molecule Drugs - 7 (9) years from FDA approval

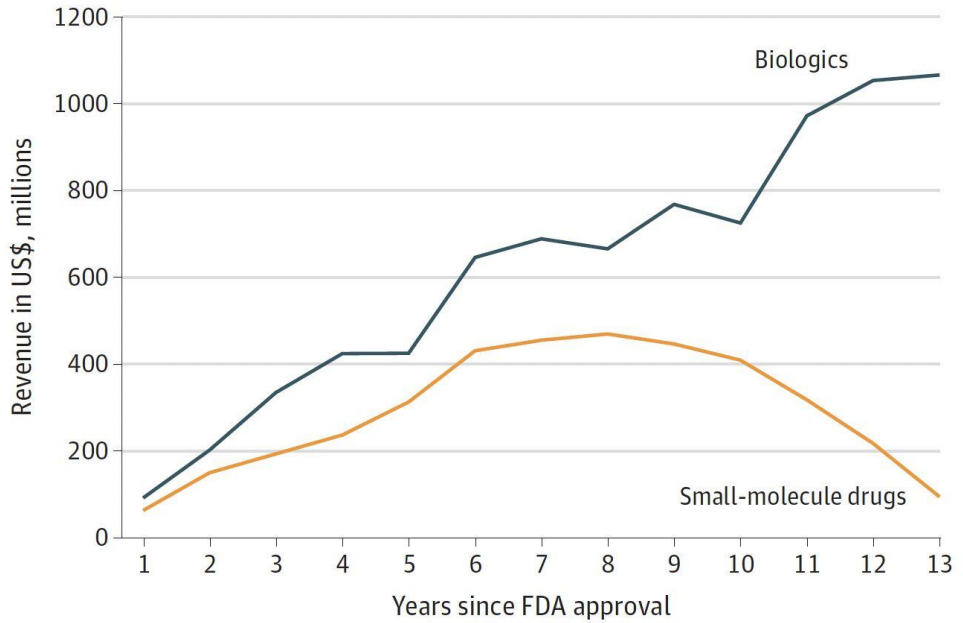
> Biologics - 11 (13) years from FDA approval

# Pill Penalty or Biologic Bonus?

- **Length of time on market**
  - **Proposed legislation to change the 'pill penalty' for small molecule products from 7 years to 11 years for selection. Medicare-negotiated prices remain in effect until generic competition begins.**

Wouters, et al. 2024.
https://jamanetwork.com/journals/jama/article-abstract/2827104

Figure 4. Median Annual Revenues Following US Food and Drug Administration (FDA) Approval for Biologics vs Small-Molecule Drugs



# CMS Selected Therapeutic Alternatives – IPAY 2026

| Selected Drug | Therapeutic Alternatives |
|---|---|
| **Farxiga** | empagliflozin, canagliflozin, dulaglutide, liraglutide, semaglutide, glimepiride, glipizide, metformin, pioglitazone, sitagliptin |
| **Jardiance** | dapagliflozin, canagliflozin, dulaglutide, liraglutide, semaglutide, glimepiride, glipizide, metformin, pioglitazone, sitagliptin |
| **Januvia** | dapagliflozin, dulaglutide, empagliflozin, glimepiride, glipizide, linagliptin, metformin, pioglitazone, semaglutide |
| **Novolog/Fiasp** | Insulin lispro |
| **Entresto** | enalapril, lisinopril, losartan, spironolactone, valsartan |

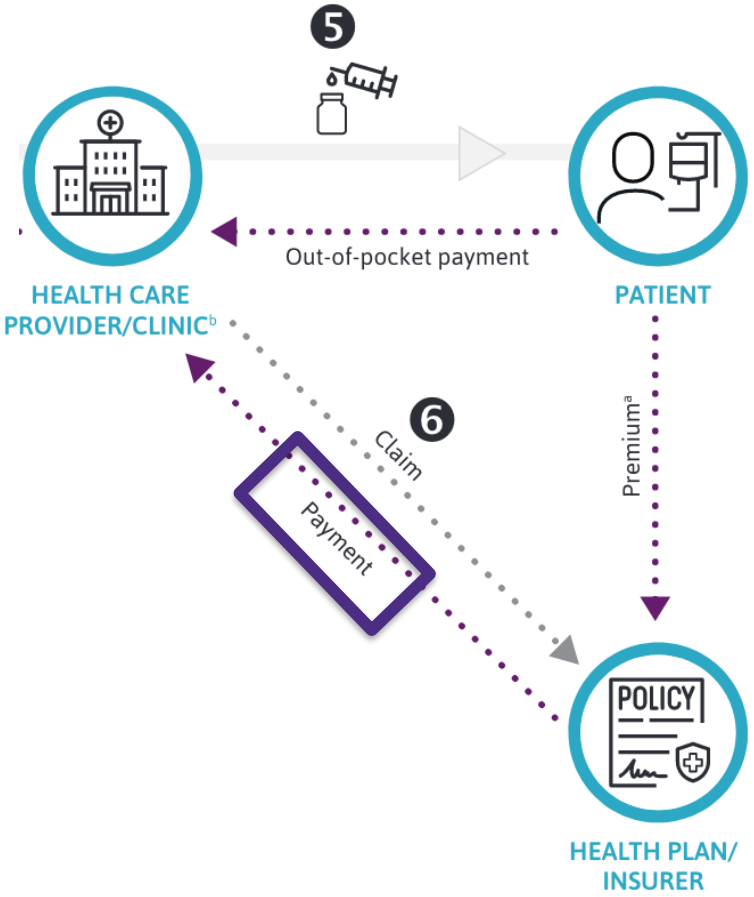
| Selected Drug | Therapeutic Alternatives |
|---|---|
| **Eliquis** | dabigatran, rivaroxaban |
| **Xarelto** | apixaban, dabigatran, ticagrelor, clopidogrel, enoxaparin, warfarin |
| **Stelara** | adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, vedolizumab |
| **Enbrel** | adalimumab, infliximab, risankizumab, secukinumab, ustekinumab |
| **Imbruvica** | acalabrutinib, zanubrutinib, venetoclax + obintuzumab, venetoclax + rituximab, bendamustine + rituximab, dexamethasone + rituximab + cyclophosphamide, belumosudil, ruxolitinib |

# Net Prices, MFPs and International Prices (at list price)

| Brand Name | Active Ingredient | Primary Indication | United States | | Australia | Canada | France | Germany | Switzerland | United Kingdom |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | Net Price (est.) | Maximum Fair Price | | | | | | |
| Stelara | Ustekinumab | Crohn's disease, psoriasis, psoriatic arthritis, and ulcerative colitis | 7,859.9 | 4,695.0 | 1341.6 | 1813.1 | 1219.9 | 2504.0 | 1730.0 | 1291.7 |
| Enbrel | Etanercept | Rheumatoid arthritis | 3,571.6 | 2,355.0 | 754.4 | 1135.4 | 646.5 | 974.3 | 1176.5 | 851.9 |
| Imbruvica * | Ibrutinib | Chronic lymphocytic leukemia | 462.5 | 306.7 | 213.7 | 232.0 | 197.6 | 197.0 | 210.0 | 184.6 |
| Entresto | Sacubitril / valsartan | Heart failure | 458.4 | 295.0 | 138.9 | 181.9 | 156.6 | 150.4 | 145.1 | 117.9 |
| Eliquis | Apixaban | Non-valvular atrial fibrillation | 309.0 | 231.0 | 57.1 | 80.4 | 63.8 | 68.7 | 82.2 | 68.6 |
| Xarelto | Rivaroxaban | Non-valvular atrial fibrillation | 261.3 | 197.0 | 51.2 | 70.7 | 58.7 | 86.4 | 86.4 | 65.0 |
| Jardiance | Empagliflozin | Type 2 diabetes | 251.7 | 197.0 | 33.5 | 67.1 | 38.3 | 50.6 | 50.9 | 47.2 |
| Januvia | Sitagliptin | Type 2 diabetes | 195.6 | 113.0 | 30.5 | 75.8 | 26.4 | 35.9 | 43.6 | 42.9 |
| Farxiga | Dapagliflozin | Type 2 diabetes | 193.8 | 178.5 | 33.5 | 64.9 | 38.6 | 41.9 | 48.9 | 47.1 |
| Novolog / Fiasp * | Insulin aspart | Type 2 diabetes | 13.0 | 9.0 | 5.4 | 9.9 | 6.9 | 11.1 | 9.6 | 7.4 |

# Biologics & Biosimilars Reimbursement

- **Payment amounts differ based on plan**
  - Providers buy at +/- Wholesale Acquisition Cost (WAC)
  - They will get reimbursed at MFP for negotiated drugs
  - Manufacturers may need to provide back-end rebates to providers to keep providers whole (NCR)
  - These rebates go into the ASP calculation, leading to spiraling down of the ASP.




Hernandez I, Hung A. A primer on brand-name prescription drug reimbursement in the United States. *J Manag Care Spec Pharm.* 2024;30(1):99-106. doi:10.18553/jmcp.2024.30.1.99

# Medicare Price Negotiation of Part B Drugs: Implications for Provider Reimbursement and Commercial Spillover

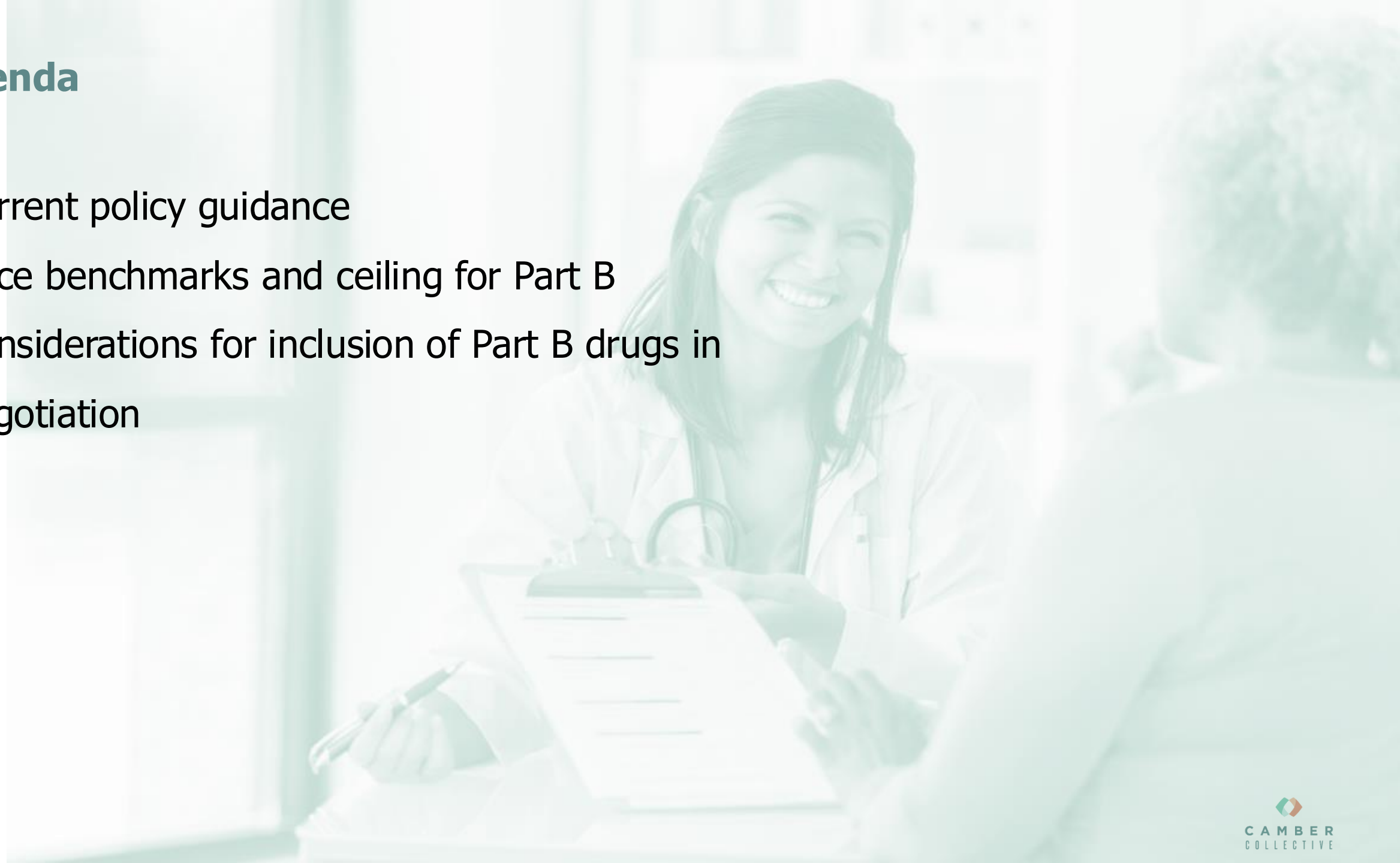
May 14, 2025

Kristi Martin, Director, Camber Collective

CAMBER COLLECTIVE

# Agenda

- Current policy guidance
- Price benchmarks and ceiling for Part B
- Considerations for inclusion of Part B drugs in negotiation



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# CMS Policy Guidance for Medicare Drug Price Negotiation Program

- Draft guidance published May 12, 2025 for IPAY 2028
- Comment period is 45 days; comments due June 26, 2025
  - First guidance was 30-day comment period
  - Second guidance was 60-day comment period
- New policy areas of interest:
  - Inclusion of Part B drugs
  - Renegotiation

| Selection Year | Negotiated Prices Application Year | Number of Drugs | Scope of Qualifying Single Source Drugs |
|---|---|---|---|
| **2023** | 2026 | 10 | Part D |
| **2025** | 2027 | 15 | Part D |
| **2026** | 2028 | 15 | Part B and Part D |
| **2027+** | 2029+ | 20 | Part B and Part D |

# Changes in Guidance

*This is the third, and final year, of program guidance. CMS will move into formal rulemaking for the next cycle of negotiation policy and operations.*

| IPAY | Framework for Evaluating Evidence | Opportunities for Meetings between CMS & Drug Companies | Public Input Opportunities |
|---|---|---|---|
| **2026** | CMS uses a qualitative approach to review information submitted by drug companies and the public and will consider the evidence, including real-world evidence, clinical input, and patient and caregiver input, in totality. | • 1 optional meeting offered immediately after data submission.<br>• Up to 3 meetings between drug company response to initial offer and deadline for CMS to send final offer, if applicable | • Submission of data on therapeutic alternatives to the selected drug<br>• 10 CMS hosted patient-focused listening events |
| **2027** | CMS uses a qualitative approach to review information submitted by drug companies and the public and will consider the evidence, including real-world evidence, clinical input, and patient and caregiver input, in totality. | • 1 optional negotiation meeting between CMS and drug company after the initial offer is issued and before the deadline drug companies respond to initial offer from CMS.<br>• Up to 2 optional negotiation meetings during the negotiation period as well as additional written price exchanges. | • Submission of data on therapeutic alternatives to the selected drug<br>• 15 CMS hosted patient-focused roundtable events<br>• CMS town hall meeting to receive patient-focused and clinically oriented information |
| **2028 (proposed)** | CMS uses a qualitative approach to review information submitted by drug companies and the public and will consider the evidence, including real-world evidence, clinical input, and patient and caregiver input, in totality. | • 1 optional negotiation meeting between CMS and drug company after the initial offer is issued and before the deadline drug companies respond to initial offer from CMS.<br>• Up to 2 optional negotiation meetings during the negotiation period as well as additional written price exchanges. | • Submission of data on therapeutic alternatives to the selected drug<br>• Up to 15 CMS hosted patient-focused roundtable events<br>• CMS town hall meeting to receive patient-focused and clinically oriented information |

# Price Benchmarks and Ceiling

## Part D

- Initial offer based on:

1. Identification of therapeutic alternative(s) (TAs), if any, for the selected drug;
2. Use the lower of Part D net price for TAs, or the MFPs of prior years selected drugs that are TAs
3. Evaluate the selected drug (including compared to its TAs) for the purposes of adjusting the starting point using the negotiation factors outlined in section 1194(e)(2)
4. Further adjust the preliminary price by the negotiation factors outlined in section 1194(e)(1) of the Act

## Part B

- Initial offer based on:

1. Identification of therapeutic alternative(s) (TAs), if any, for the selected drug;
2. Use the lesser of ASP or WAC
3. Evaluate the selected drug (including compared to its TAs) for the purposes of adjusting the starting point using the negotiation factors outlined in section 1194(e)(2)
4. Further adjust the preliminary price by the negotiation factors outlined in section 1194(e)(1) of the Act

# Price Benchmarks and Ceiling

## Part D

- Ceiling calculated as:

1. Based on 30-day equivalent supply
2. The lower of…
    - Average Part D net price based on plan-specific enrollment weighted amounts
    - 25% to 60% discount of average non-FAMP

## Part B

- Ceiling calculated as:

1. Based on 30-day equivalent supply
2. The lower of…
    - Part B payment (ASP or WAC) for prior year
    - 25% to 60% discount of average non-FAMP

# Considerations – Both Policy and Operations

- Different payment and reimbursement system by statute
- Coding differences (e.g., HCPCS)
- Implications for Medicare Administrative Contractors (MACs), Medicare Transaction Facilitator (MTF), hospitals and outpatient clinics, and Medicare Advantage (MA)

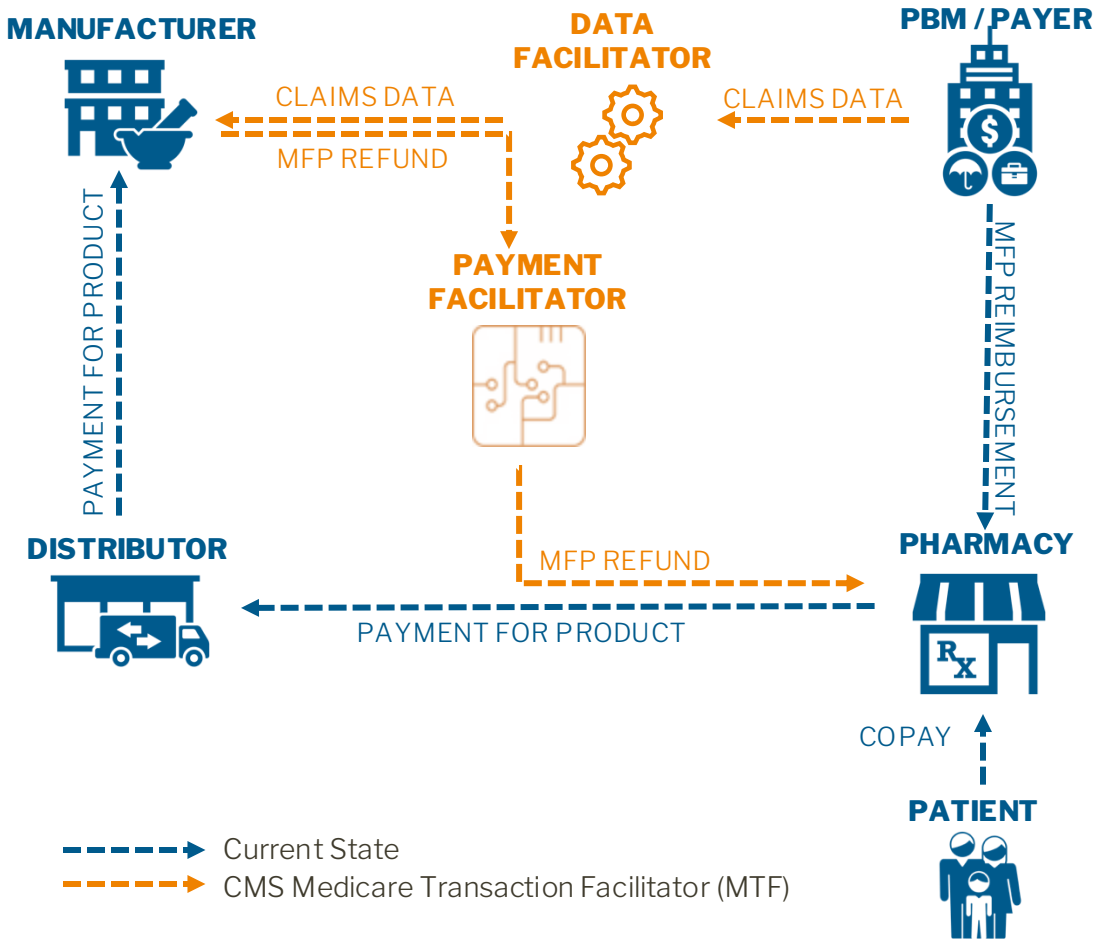
# Part B negotiated prices will introduce new complexity across the U.S. pharmaceutical value chain

**High-Level Implications**

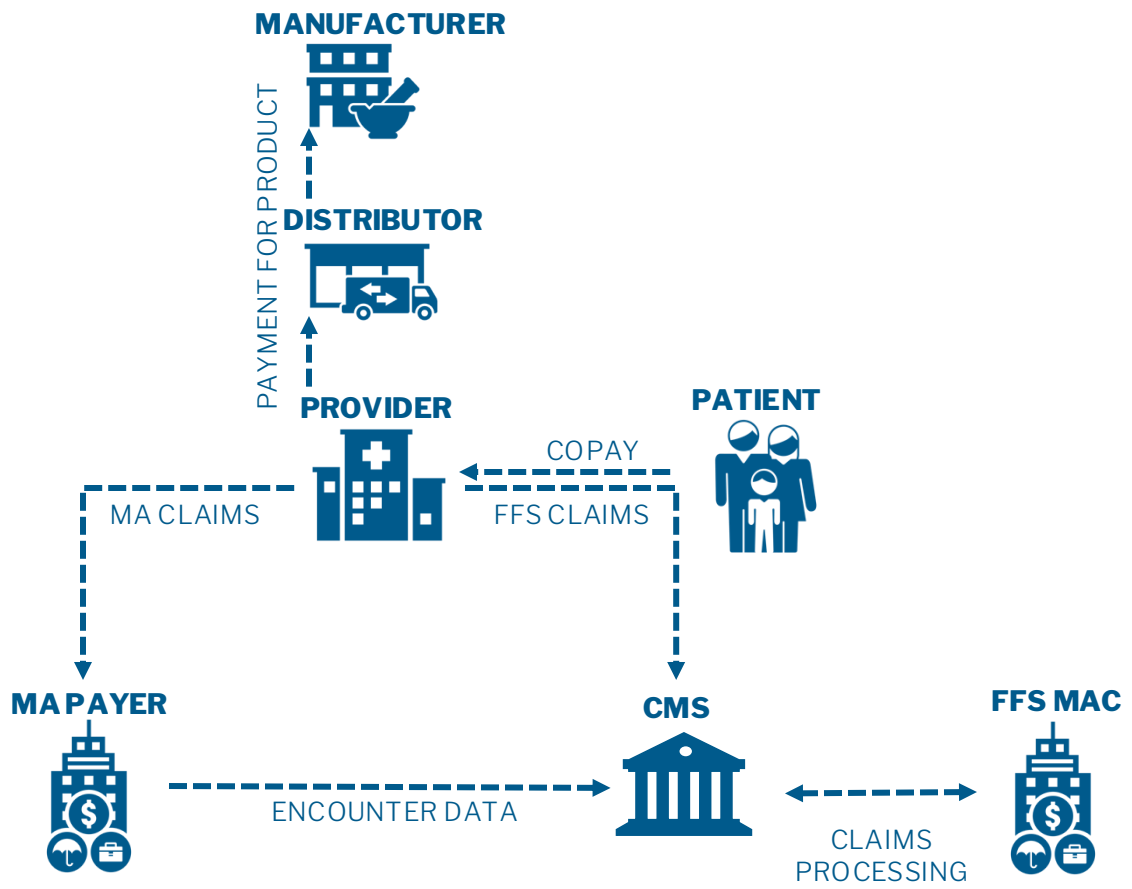
1. Effectuation Differences
2. Pressure on Manufacturer Margins
3. Pressure on Provider Margins
4. Commercial Spillover: Payer & Provider
5. Payer Cross-Benefit Mitigation

# Part B effectuation will need to consider Fee-For-Service (FFS) and Medicare Advantage (MA) data and financial flows

## Part D Effectuation




## Part B Current State



# Manufacturer Implications

| Stakeholder | Segment |
| --- | --- |
| **Manufacturers**  | ⊖ **Negotiated Brand**<br>⊕⊖ **Branded Alternative**<br>⊖ **Biosimilars** |
| Providers  | • Clinics<br>• Covered Entities<br>• Specialty Pharmacies |
| Payers  | • Medicare FFS<br>• Medicare Advantage<br>• Commercial |





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# Provider Implications

| Stakeholder | Segment |
| --- | --- |
| Manufacturers  | • Negotiated Brand<br>• Branded Alternative<br>• Biosimilars |
| **Providers**  | ⊖ **Clinics**<br>⊖ **Covered Entities**<br>⊕ **Specialty Pharmacies** |
| Payers  | • Medicare FFS<br>• Medicare Advantage<br>• Commercial |

# Payer Implications

| Stakeholder | Segment |
| --- | --- |
| Manufacturers  | • Negotiated Brand<br>• Branded Alternative<br>• Biosimilars |
| Providers  | • Clinics<br>• Covered Entities<br>• Specialty Pharmacies |
| **Payers**  | ± **Medicare FFS**<br>⊕ **Medicare Advantage**<br>⊕ **Commercial** |

# Questions and Moderated Discussion

**IPAY 2028 Draft Guidance?**

**International Price Referencing?**

**Other Changes to the Negotiation Program?**