

# International Availability and Price of Ultra-Expensive Drugs in Medicare Part D

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# Background

- The **growing use of high-cost drugs** has raised financial concerns for policymakers, patients, and payers.
- Furthermore, spending is increasingly concentrated among a small number of high-cost drugs.
- These trends have generated policy **interest in cost-containment strategies**, especially as recent caps on patient cost-sharing in Medicare Part D have shifted more financial liability onto payers.
- One strategy is **external reference pricing (ERP)**: comparing a drug's price across multiple countries to derive a benchmark price.

# Background

- Renewed U.S. interest in **external reference pricing (ERP)** has emerged through current **most favored nation (MFN) policies** from the Trump administration.
- Yet because past ERP proposals were blocked before implementation, feasibility questions remain unaddressed for current policies.
- One widely cited concern is that drugs may not be available across all reference countries, creating gaps in reference price data → **but little is known about the scope** of this issue in a U.S. context.



# Research Questions

To inform the feasibility of MFN pricing for high-cost drugs, we examined the following questions:

- 1) **To what extent** are these drugs available across industrialized reference countries?
- 2) **How** do U.S. prices for these drugs compare with prices in those countries?

# Data & Sample

- **Data:** Centers for Medicaid and Medicare Services (CMS) “Medicare Part D Spending by Drug” dataset (2019–2023); Eversana NAVLIN Price & Access database
  - NAVLIN database cited in CMS Innovation Center MFN models
- **Sample:** 161 ultra-expensive drugs in 2023
  - Ultra-expensive: Gross average annual per-beneficiary spending > U.S. GDP per capita (2023: \$81,000)
  - Spending category established in previously published peer-reviewed research

# Analysis

- Outcomes:
  - 1) **International availability**, defined as being commercially marketed with a publicly available list price, across 36 OECD member nations
  - 2) **U.S.-to-reference country list price ratio**, across 15 OECD countries with GDP per capita  $\geq 60\%$  of U.S.
- Analysis: Drug and drug-country level descriptive analysis

# Summary of ultra-expensive drugs in Medicare Part D 2019–2023.

Gross average annual per-beneficiary spending categories > U.S. GDP per capita

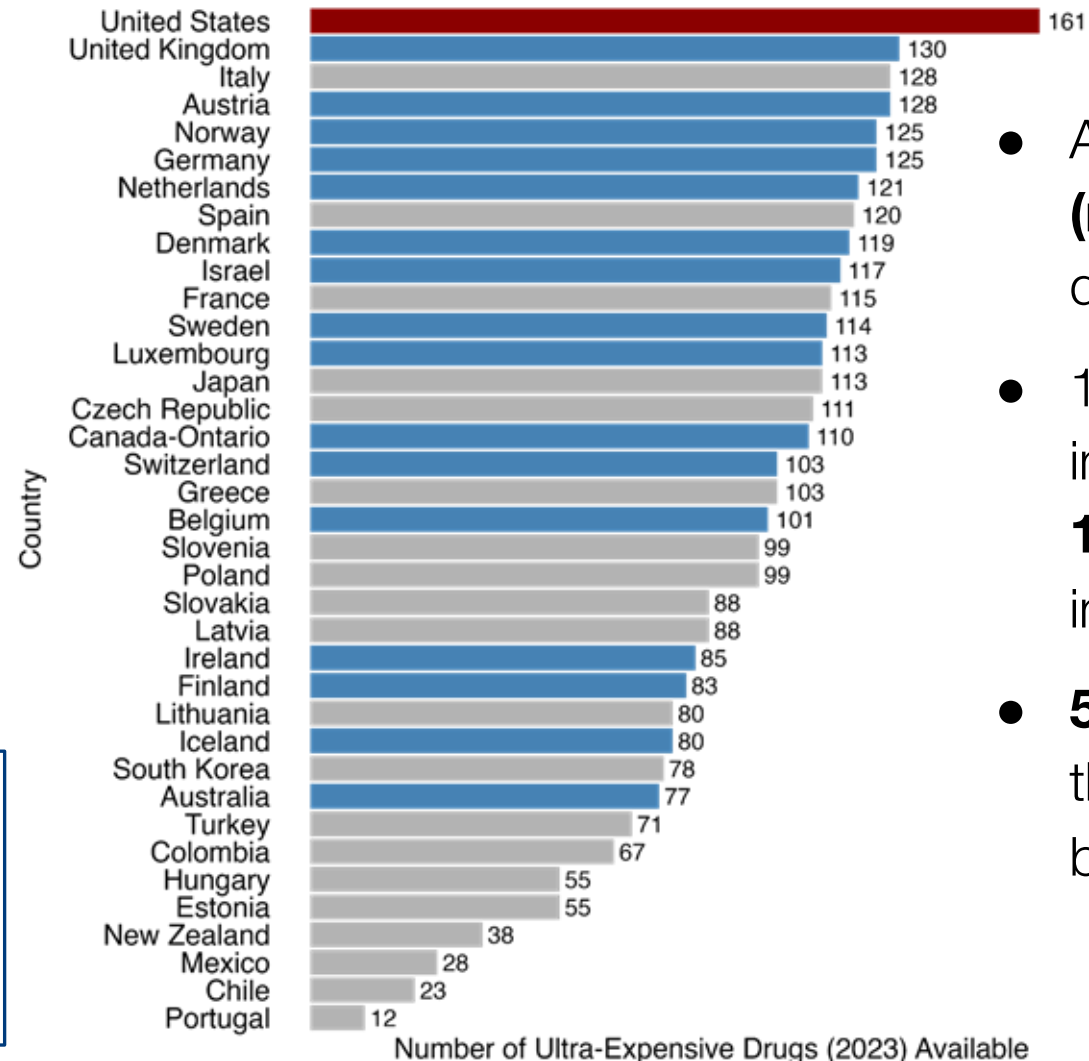


<b>Ultra-Expensive Drug Characteristics</b>	<b>2019</b>	<b>2020</b>	<b>2021</b>	<b>2022</b>	<b>2023</b>
Total no. of drugs	102	139	139	156	161
Total spending (\$ millions)	28,954	36,950	39,736	41,851	44,764
Median beneficiaries per drug	404.5	336	277	215	321
Median drug-level per-beneficiary spending (\$)	106,939	99,625	114,373	124,897	133,291

## Characteristics (2023):

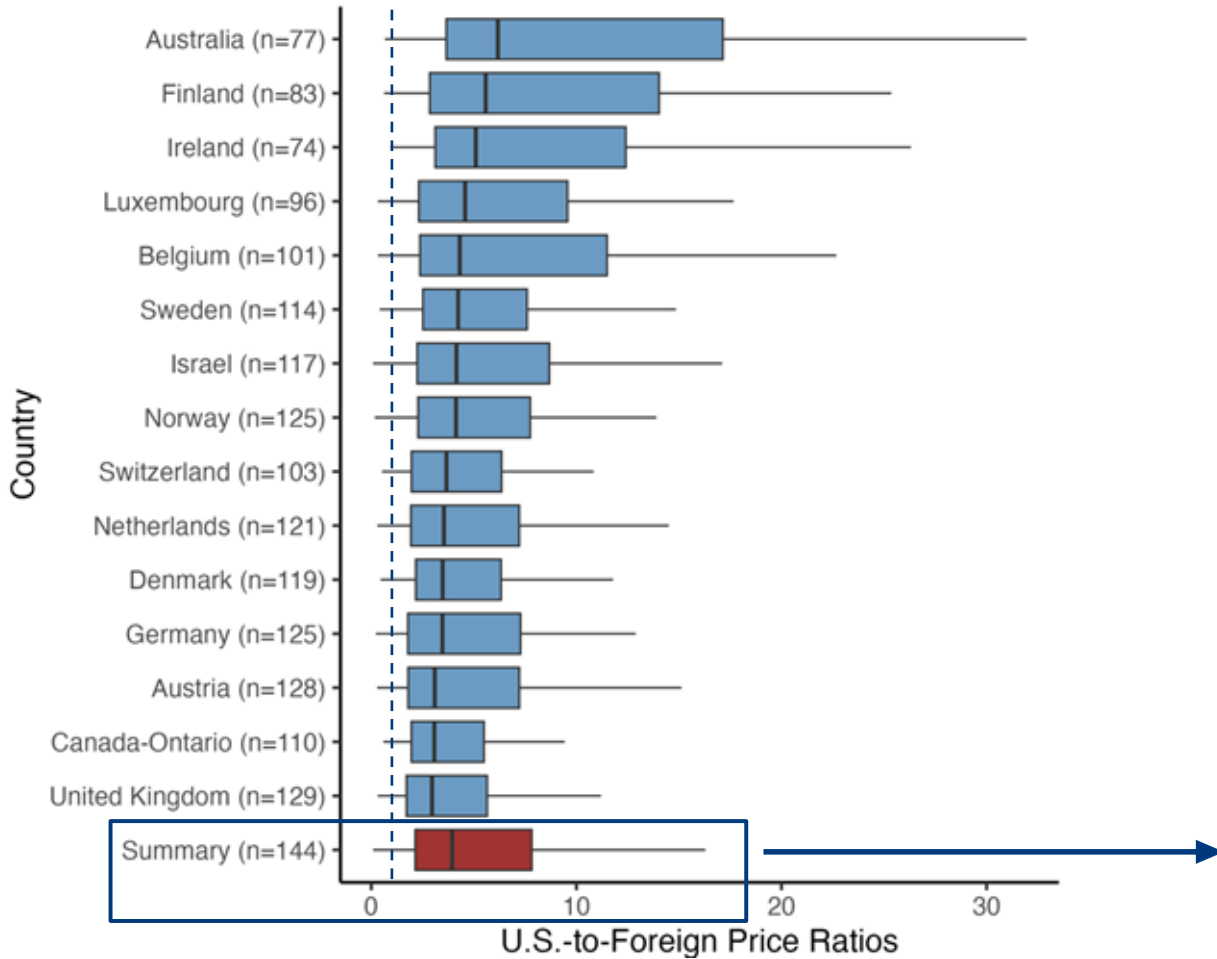
- **84% orphan** designated or indicated
- **35% antineoplastic agents**; 11.2 % immunosuppressants; 11.2% alimentary tract and metabolism products
- **27% biologics**

# Availability of ultra-expensive drugs in industrialized countries.

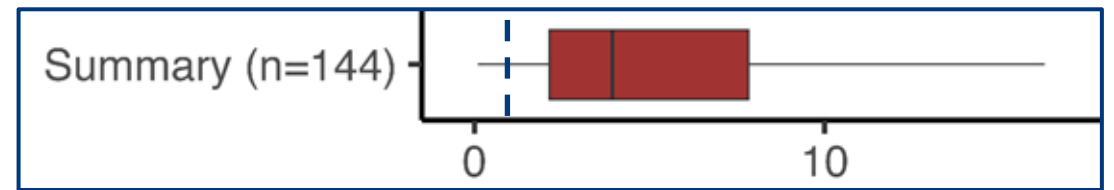


- Availability varied from **12 to 130 (median 100)** ultra-expensive drugs across countries
- 146 of 161 drugs (91%) available in at least one reference country; **15 drugs (9%)** have no international availability
- **54 drugs (34%)** available in fewer than 19 countries - MFN reference basket size

# Distribution of U.S.-to-reference country list price ratios across reference countries.



- U.S. prices exceeded reference country prices in an overwhelming majority of drug-country pairs
- Median U.S.-to-reference country list price ratio was **4.13 (IQR 2.24 to 7.60)**



# Limitations

- List prices used in our analysis did not reflect confidential rebates, likely overstating the true U.S.-to-foreign price ratio.
- Our analysis provides a static snapshot of availability and prices using January 2026 data and exchange rates, and does not capture changes over time, such as normal launch lags.
- We did not include drugs covered under Part B or other programs, which limits the generalizability of our findings.

# Summary of Findings

- **Question:** How feasible is MFN pricing for the highest cost drugs in Medicare Part D?
- **Findings:** In this retrospective analysis of 161 ultra-expensive Part D drugs,
  - These drugs represented a growing share of covered drugs and spending
  - **A meaningful subset lacked full international benchmarks** under current MFN criteria: 9% had no international list price available, and 34% were available in fewer than 19 reference countries
  - Where benchmarks existed, U.S. list prices were a median of **4.13 times higher** than international prices

# Implications for Policy or Practice

- Amid renewed interest in policies (such as most favored nation pricing) that rely on external reference pricing...
- These findings highlight an unresolved practical question for current MFN policies: how to set benchmarks when reference prices are missing or limited.
- They show the need for further consideration of drugs that rely heavily on the U.S. market.



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### Introduction

The growing use of high-cost specialty drugs has raised affordability concerns for policymakers and patients. In particular, ultraexpensive drugs (UEDs) account for a disproportionate share of Medicare Part D spending and are expected to further increase financial burdens on the program, especially given recent caps on patient cost-sharing.<sup>1,2</sup> Recent policy proposals, including most-favored-nation (MFN) pricing initiatives, have considered external reference pricing to address high prices.<sup>3-6</sup> However, limited evidence on international availability and pricing constrains assessments of these approaches. This study characterizes UEDs in Medicare Part D and examines their availability and relative prices across industrialized countries.

### + Supplemental content

Author affiliations and article information are listed at the end of this article.



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# Thank You

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