From Tokyo to Washington: Impact of Japan's HTA Environment on U.S. MFN Pricing and Launch Strategy

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Introduction

Japan's multiple drug repricing mechanisms, such as cost-effectiveness assessment (CEA), the biennial drug price survey, market expansion repricing (MER), and similar efficacy comparison, are defining features of its national pricing environment. Together, these mechanisms create structured but sometimes unpredictable post-launch list price reductions, lowering manufacturer confidence in long-term price stability and putting them at risk of future price cuts (1).

The U.S. Most Favored Nation (MFN) policy aims to align U.S. drug prices with the lowest levels observed across a basket of comparable high-income markets, including Japan (2). As a result, Japan's repeated and multi-layered price revisions directly influence MFN benchmarks. Understanding how Japan's downward pricing pressure interacts with MFN policy is therefore critical for anticipating U.S. price ceilings and guiding manufacturers' global launch and pricing strategies.

Objectives

1 **Japan focus**
To evaluate how Japan's multi-layered repricing system affects post-launch list prices and long-term price stability.

2 **U.S. MFN implications**
To assess how Japan's repricing mechanisms may lower the MFN international benchmark under the GENErating cost Reductions fOr U.S. Medicaid (GENEROUS) Model, a voluntary Centers for Medicare & Medicaid Services (CMS) initiative, which applies MFN pricing principles to U.S. Medicaid.

Methods

Key parameters were extracted from all published Center for Outcomes Research and Economic Evaluation for Health (C2H) CEA decisions (2019–2023). Variables included:

- Classification category (H1–H5)
- Magnitude of price adjustments (%)
- Incremental cost-effectiveness ratios (ICERs)

Price adjustments were categorized into Japan's recognized ICER intervals, and a correlation analysis between ICER and price adjustment was conducted (3). Evidence related to biennial price survey revisions, MER, and similar efficacy comparison-based adjustments were also reviewed (4-8).

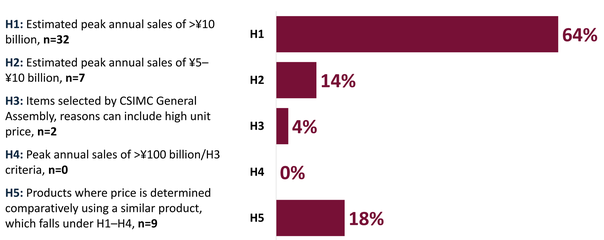
Finally, relevant CMS guidance was assessed to understand how Japan's repricing patterns may shape expectations under the GENEROUS Model (2). While other MFN-style models have been proposed for Medicare (Global Benchmark for Efficient Drug Pricing [GLOBE] for Part B and Guarding U.S. Medicare Against Rising Drug Costs [GUARD] for Part D), this analysis focused specifically on GENEROUS.

Results

CEA product selection

Product choice is based primarily on revenue and unit price. Our review shows that the process prioritizes new, high-impact launches, rather than retrospective assessments (Figure 1).

Figure 1: Retrospective view of product categories selected for CEA (H1–H5)



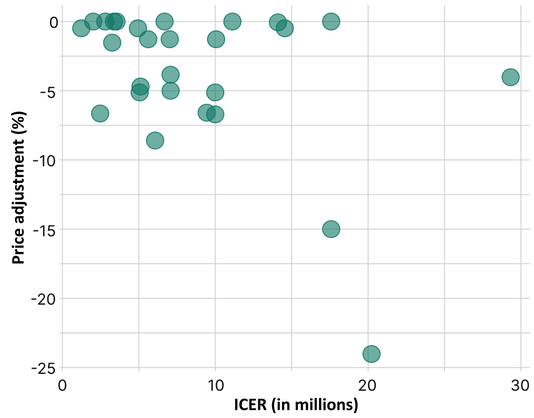
CEA-based repricing

Among products with a reported list price adjustment, the mean CEA-driven price change was −4.7% (median: −4.1%; range: −0.1–9.0%).

The mean percentage price change per ICER interval was:
- <5 million JPY/QALY (n=9) – mean: −2.9%
- 5–7.5 million JPY/QALY (n=10) – mean: −3.8%
- 7.5–10 million JPY/QALY (n=3) – mean: −6.1%
- >10 million JPY/QALY (n=12) – mean: −6.6%

After excluding two outliers, no meaningful ICER price adjustment relationship remained (r=−0.4) (Figure 2).

Figure 2: Correlation between ICER (JPY/QALY) and price adjustment (%)



Japan repricing mechanisms

Biennial survey

Routine National Health Insurance (NHI) price surveys identified a **7.0–8.0% deviation** between list and real-world transaction prices (2019–2022), leading to systematic downward list price revisions to align prices with actual market levels (5).

MER

Japan's market expansion repricing mechanism triggered out-of-cycle **price cuts of 7.0–50.0%** for products whose sales exceeded forecasts, introducing sudden and substantial downward pressure on list prices (6-8).

Similar efficacy repricing

Comparator-based repricing aligns products to lower priced clinical comparators, resulting in directionally downward price revisions. Although no quantitative estimate has been published, the size of these cuts depends entirely on the comparator's price level (3,4).

MFN implication

Table 1: Key trends found in research and implications under new MFN policy

Mechanism	Effect on Japan's price	MFN impact
CEA repricing	High-forecast (H1–H3) products more likely to be selected	High-revenue products face greater risk of price reduction and therefore impact on potential MFN price
	Moderate post-CEA list price cuts (4.7% average)	Lowers MFN benchmark
Biennial survey	Regular downward revisions based on list-to-market deviation (7.0–8.0%)	Repeated erosion of the MFN ceiling
MER	Larger out-of-cycle cuts for high sales products (approximately 7.0–50.0%)	Sudden MFN exposure due to abrupt price drops
Similar efficacy repricing	Prices aligned to lower priced comparators causing directional downward cuts	Inherits lower comparator price in MFN benchmark
Cumulative impact of mechanisms†	**Multiple repricing mechanisms applied across time causes repeated downward price resets**	**Amplifies MFN exposure as Japan becomes a structurally low-price reference**

† Key pricing effect found in the research and its predicted impact.

Key takeaway Japan's multi-layer and iterative price revision system results in repeated downward pressure on NHI list prices. As MFN benchmarks rely on international price comparisons, these cumulative reductions directly lower the MFN ceiling in Japan and increase US price-risk exposure.

Conclusion

Japan's multi-level repricing mechanisms create repeated downward pressure on NHI list prices, increasing the likelihood that Japan becomes a low-price anchor under MFN-style policies. This dynamic may prompt manufacturers to reconsider global launch timing and portfolio sequencing.

To anticipate MFN exposure, manufacturers should incorporate all Japan repricing pathways including CEA reviews, biennial survey adjustment, MER cuts, and comparator-based repricing into MFN pricing simulations. Mitigation strategies, such as pursuing Price Maintenance Premiums, monitoring policy changes to off-year revisions, and planning for potential reversals in expenditure control measures, could help stabilize price corridors and reduce downstream MFN risk.

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Abbreviations

C2H – Center for Outcomes Research and Economic Evaluation for Health
CEA – Cost-effectiveness analysis
CMS – Centers for Medicare & Medicaid Services
CSIMC – Central Social Insurance Medical Council
GENEROUS – GENErating cost Reductions fOr U.S. Medicaid
GLOBE – Global Benchmark for Efficient Drug Pricing
GUARD - Guarding U.S. Medicare Against Rising Drug Costs
HTA – Health technology assessment
ICER – Incremental cost-effectiveness ratio
MER – Market expansion repricing
MFN – Most Favored Nation
NHI – National Health Insurance
QALY – Quality-adjusted life year

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