

Nationwide Serial Cross-sectional Analysis of Biosimilar Utilization Following Policy Interventions in Japan

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Conflict of Interest: Takehiro Ishida is an employee of Daiichi Sankyo Company, Limited. Satoshi Yamaguchi is an employee of Accenture.

This research was conducted independently of these institutions.



INTRODUCTION

The World Health Organization (WHO): Definition of Biosimilar

- Biosimilars are “products with quality, safety, and efficacy highly similar to those of the reference biologic,” and are regarded as an important way to reduce healthcare costs and improve access to medicines.

Japan's Policy Direction and Goals

- The Ministry of Health, Labour and Welfare (MHLW) actively promotes biosimilars use to optimize healthcare costs.
- Target (by end of FY2029): At least 60% of eligible components achieve a biosimilar substitution rate of 80% or higher.

National Biosimilar Promotion Policy in Japan

- April 2020: Introduced ¥1,500 (\$9.5) incentives for hospitals and clinics initiating biosimilars for home care patients.
- April 2022: The incentive (¥1,500/\$9.5) was expanded to outpatient care.
- April 2024: Introduced ¥1,000 (\$6.3) incentives for hospitals and clinics initiating biosimilars for inpatients.

METHODS

【Study Design】 Nationwide Serial Cross-Sectional Study (FY2019–FY2024)

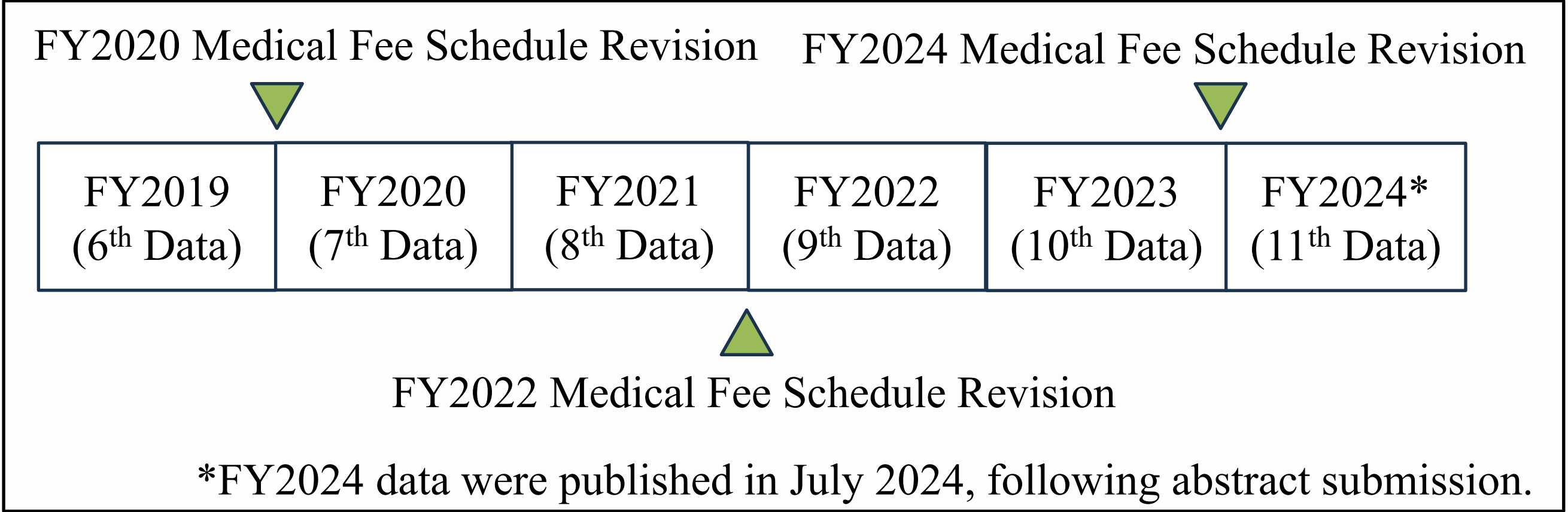
【Data Source】

- NDB Open Data** — an aggregated national reimbursement claims database published by MHLW, covering nearly all health insurance claims in Japan.
 - Annual nationwide health insurance claims data
 - Prefecture-level biosimilar prescription data

	NDB	NDB Open Data
Data	Individual-level insurance claims & health-checkup data	Aggregated statistical data (by age, sex, drug, etc.)
Access	Strict expert review & approval required	Publicly available; no restriction
Personal Info	Included (anonymized)	Individuals cannot be identified; no hospital-level data

【Data Selection】

- Biosimilars and corresponding reference biologics were identified based on MHLW criteria and categorized by **therapeutic categories and care setting**.
- Included prescription data from **all 47 prefectures** in Japan.



【Outcome】

- Annual biosimilar prescription units per 100,000 population

Annual Biosimilar Prescription Units

Prefectural Population

 × 100

Expenditure analysis included three outcomes:

- Annual expenditure:** $\sum \{(\text{Prescription Units}) \times (\text{Official Drug Price} / \text{Unit})\}$
- Annual prescribed units:** $\sum (\text{Prescription Units})$
- Average expenditure per prescribed unit:**
 $(\text{Annual Expenditure}) \div (\text{Annual Prescribed Units})$

【Statistical Analysis】

- Mean and 95% confidence intervals (95% CI) across 47 prefectures.
- Differences between FY2019 and FY2024 using paired t-tests.
- Two-sided $P < 0.05$ was considered statistically significant.

AIM

To describe nationwide trends in biosimilar utilization and biologic expenditures during a period of policy interventions in Japan.

RESULTS

Table 1: Number of Biosimilar Prescriptions per 100,000 Population by Therapeutic Categories

	FY2019	FY2020	FY2021	FY2022	FY2023	FY2024	Change
249	2,463 (2,292–2,634)	2,976 (2,767–3,184)	4,011 (3,688–4,333)	4,671 (4,276–5,066)	4,883 (4,493–5,273)	5,936 (5,460–6,411)	+141.0%
399	774 (707–841)	1,626 (1,514–1,737)	1,602 (1,483–1,721)	1,644 (1,527–1,760)	1,742 (1,620–1,863)	1,921 (1,768–2,073)	+148.2%
429	177 (150–203)	514 (458–569)	758 (686–830)	972 (895–1,049)	1,273 (1,186–1,359)	1,335 (1,256–1,415)	+655.8%
Other	770 (701–840)	971 (892–1,051)	1,101 (1,028–1,174)	1,301 (1,221–1,380)	1,674 (1,585–1,764)	1,722 (1,635–1,809)	+123.6%
Total	4,184 (3,955–4,412)	6,086 (5,779–6,393)	7,472 (7,060–7,884)	8,587 (8,128–9,046)	9,571 (9,117–10,025)	10,914 (10,356–11,472)	+160.9%

249 Diabetes; 399 Rheumatoid Arthritis; 429 Cancer

Key Finding: Biosimilar prescriptions increased across all analyzed therapeutic categories, with the largest increase observed in cancer.

Table 2: Changes in Biosimilar Prescriptions by Care Setting (Mean 95% CI)

	Care Setting	FY2019	FY2024	Difference (FY2019–2024)	P-value	Change
Biosimilar	Outpatient	3,302 (3,105–3,498)	9,163 (8,674–9,652)	+5,861 (5,496–6,227)	<0.001	+177.5%
	Inpatient	882 (813–951)	1,766 (1,593–1,938)	+884 (727–1,040)	<0.001	+100.2%
	Total	4,184 (3,955–4,412)	10,929 (10,369–11,489)	+6,745 (6,308–7,183)	<0.001	+161.2%
Reference Biologics	Outpatient	20,310 (19,711–20,909)	17,615 (16,955–18,276)	–2,695 (–3,172– –2,219)	<0.001	–13.3%
	Inpatient	1,843 (1,646–2,039)	683 (590–777)	–1,159 (–1,319– –999)	<0.001	–62.9%
	Total	22,153 (21,462–22,845)	18,299 (17,612–18,985)	–3,855 (–4,346– –3,363)	<0.001	–17.4%

Key Finding: Biosimilar prescriptions increased while prescriptions of reference biologics declined, with a particularly large increase in outpatient biosimilar use.

Table 3: Expenditure Analysis for Biologics

	Annual Expenditure (million JPY)	Annual Prescribed Units (million)	Average Expenditure per Prescribed Unit (JPY)
	FY2019–FY2024 (Change %)	FY2019–FY2024 (Change %)	FY2019–FY2024 (Change %)
Biosimilar	38,527 → 88,260 (+126.5%)	5.3 → 13.6 (+158.9%)	7,332 → 6,405 (–12.6%)
Reference Biologics	603,887 → 375,449 (–37.8%)	27.8 → 22.8 (–17.7%)	21,687 → 16,435 (–24.2%)
Total	642,413 → 462,709 (–28.0%)	33.1 → 36.5 (+10.2%)	19,408 → 12,687 (–34.6%)

Key Finding: Total biologic expenditure decreased despite an overall increase in prescribed units, alongside a marked decline in average expenditure per prescribed unit.

CONCLUSION

Biosimilar utilization increased nationwide from FY2019 to FY2024, alongside declining reference biologic use and lower estimated biologic expenditures. These trends occurred during a period of evolving biosimilar policies in Japan.



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