Summary of Part B and Part D Inflation Rebate Programs

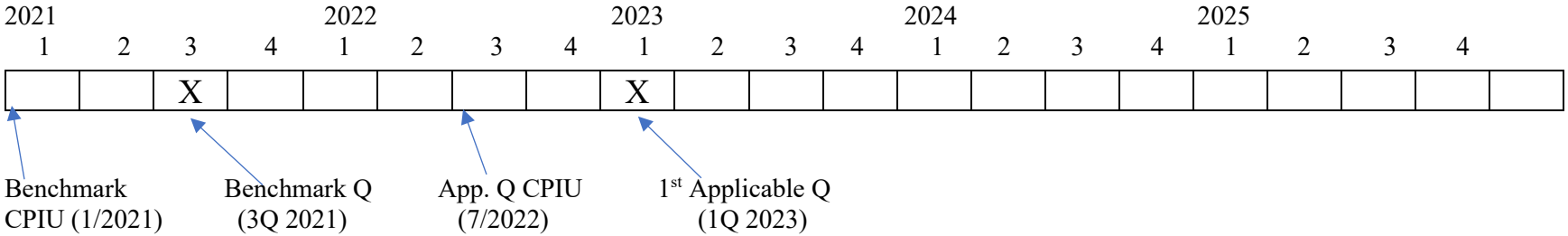
Feature	Part B	Part D
Drugs covered	NDA, BLA (including biosimilars)	NDA, BLA (including biosimilar), sole source ANDA[1]
Per-unit rebate amount	Rebate = (specified amount for applicable Q) – (benchmark Q payment amount x CPIU change)	Rebate = (AnMP for applicable period) – (benchmark period mfr. price x CPIU change)
First applicable period (for which rebates are due)	First applicable quarter = later of 1Q 2023 or 3rd Q after benchmark Q	Drug approved ≤ 10/1/2021: first applicable period = FY 2023[2] Drug approved > 10/1/2021: first applicable period = 1st FY after benchmark period
Benchmark period	Drug approved ≤ 12/1/2020: 3Q 2021 Drug approved > 12/1/2020: 3rd full Q after First Marketed Date	Drug approved ≤ 10/1/2021: 1Q–3Q 2021 Drug approved > 10/1/2021: 1st CY[3] after First Marketed Date
First Marketed Date	Date of first sale of any NDC-11 among all NDC-11s within a billing and payment code and approved under same application	Date of first sale by any manufacturer.
Prices that are compared	Applicable Q specified amount = For single source drug or biological: ASP+6% For biosimilar: ASP+6% of reference biological ASP Benchmark Q payment amount = published Part B payment limit for the quarter	Applicable period AnMP = weighted average of the 4 qAMPs in the applicable period Benchmark period mfr. price = weighted average of the 3 or 4 qAMPs in the benchmark period.
Applicable period CPIU	CPIU for 1st month of second Q before applicable quarter	CPIU for October of the applicable period
Benchmark period CPIU	Drug approved ≤ 12/1/2020: CPIU for January 2021 Drug approved > 12/1/2020: CPIU for 1st month of 1st full Q after First Marketed Date	Drug approved ≤ 10/1/2020: CPIU for January 2021 Drug approved > 10/1/2020: CPIU for January of benchmark period
Rebate reports (invoices)	2023 and 2024: by 9/30/2025 Subsequent years: 6 months after end of applicable Q.	FY 2023 and FY 2024: by 12/31/2025 Subsequent FYs: 9 months after applicable period
Reductions available	Currently in shortage; severe supply chain disruption	Currently in shortage; severe supply chain disruption of a generic or biosimilar; generic drug likely to be in shortage

[1] "Sole source ANDA" means that the reference listed drug (or any authorized generic of it) is no longer being marketed, no A-rated therapeutic equivalent is being marketed, and the ANDA drug has no exclusivity.
[2] "FY" = October 1 through September 30 of the following year (federal government fiscal year).
[3] "CY" = calendar year.

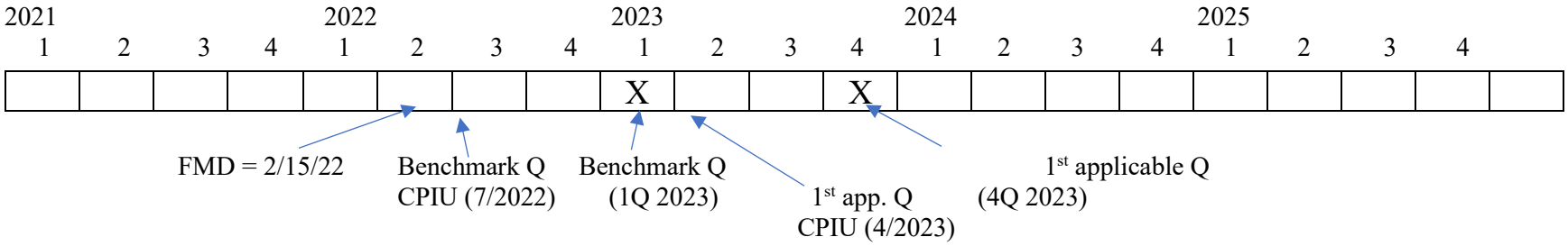
EXAMPLES

Part B

Drug approved on or before 12/1/2020:

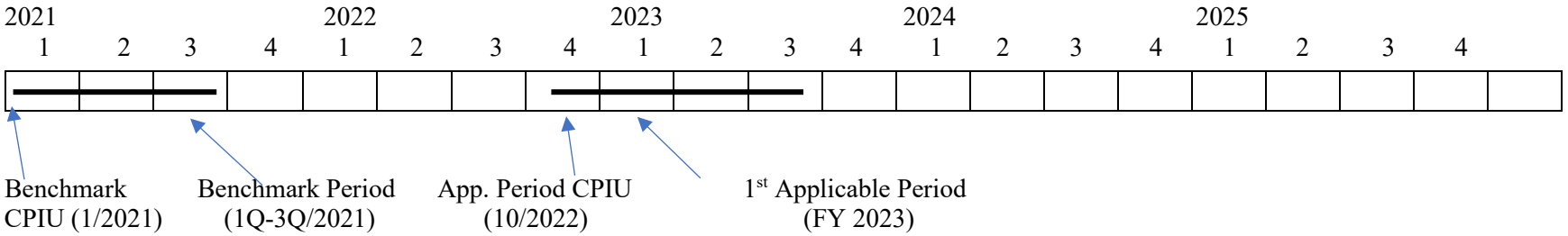


Drug approved after 12/1/2020:



Part D

Drug approved on or before 10/1/2021:



Drug approved after 10/1/2021: