Payment Limit Calculation when Manufacturers Report Negative ASPs

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AMGEN

Amgen Supports a Level Playing Field for Biosimilars and Reference Products

Amgen is committed to bringing U.S. consumers one of the largest portfolios of biosimilars

Four decades of experience developing, manufacturing and delivering biologic medicines to patients across the globe	We have **invested over $2B** across a portfolio of **11 biosimilar medicines**, focusing primarily on oncology, hematology and chronic inflammatory diseases	**11 of our biosimilars are FDA-approved**, and **5 are commercially available** for patients

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Recommendations for Payment Limit Calculation when Manufacturers Report Negative ASPs

1. CMS should ***not finalize*** its proposal to create a blended payment rate using ASP data from other biosimilars when a biosimilar manufacturer reports negative or zero ASPs.

2. The base ASP payment limit for a biosimilar or biologic should be calculated using only the ASP data for the NDCs that are attributed to that biosimilar's or biologic's HCPCS billing code.

3. CMS should instead use the most recent positive ASP data from all NDCs attributed to the HCPCS billing code for single source drugs and biologicals, including biosimilars.

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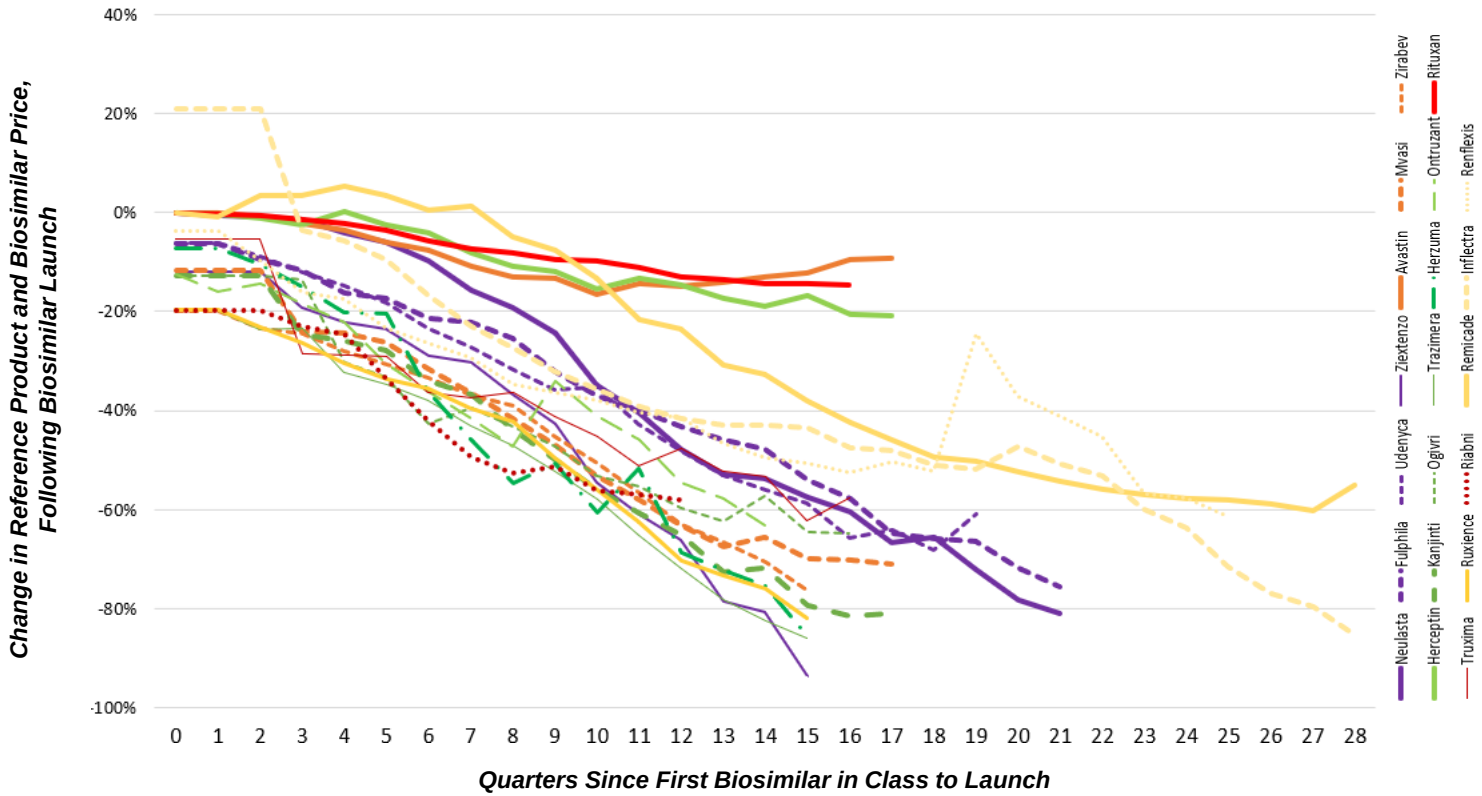
CMS' Policy For Separate Coding and Reimbursement of Biosimilars Has Fostered a Competitive Market

ASPs are declining for both reference and biosimilar products

Average sale price (ASP) for biosimilars and reference products over time[1]



The prices of biosimilars have decreased at a compound annual growth rate (CAGR) of

-11% to -28%[1]

Meanwhile, the prices of most reference products have decreased at a negative CAGR of

-2.2% to -26%[1]

Reference:

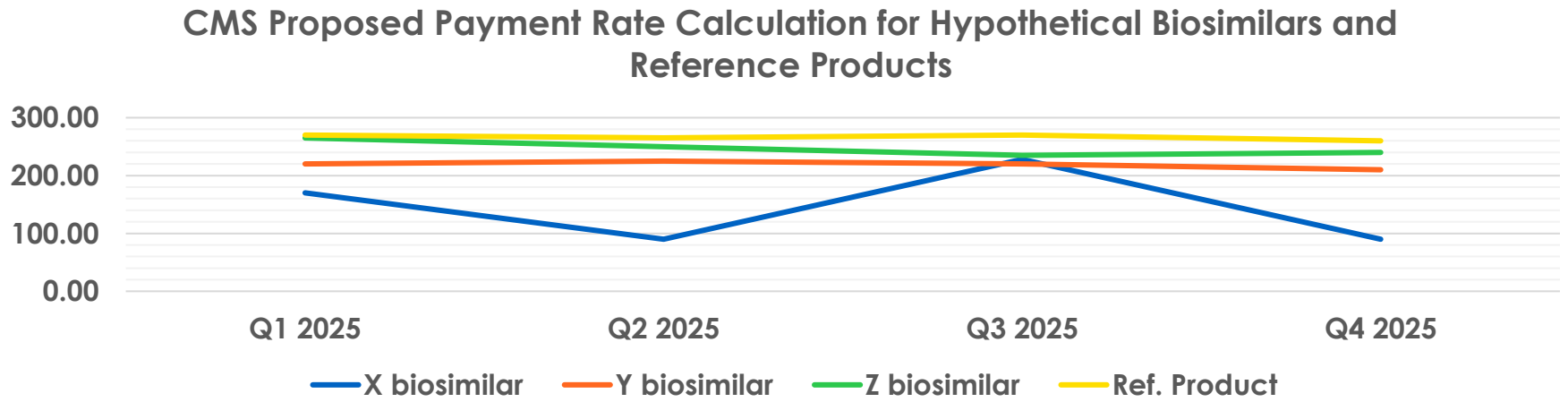
1. CMS ASP Pricing Files through Q4 2023. Dec. 2023.

CMS Should Not Finalize Its Proposal to Blend Reimbursement of Biosimilars with Negative or Zero ASPs

Illustrative Example of Unintended Consequences of CMS' Proposed Negative ASP Methodology for Biosimilars

ASP data	Q1 2025	Q2 2025	Q3 2025	Q4 2025
X Biosimilar	$150	$70	$(10)	$70
Y Biosimilar	$200	$205	$200	$190
Z Biosimilar	$245	$230	$215	$220
Ref. product	$255	$250	$255	$245

In this hypothetical scenario of a competitive market, the resulting calculated CMS payment rate for Biosimilar X will swing between quarters and also does not reflect the product's sales and discounts.



Note: In this hypothetical example, we assumed each product had only 1 NDC and the reported NDC units sold stayed static across quarters for simplicity. Calculated payment rates do not yet reflect Medicare sequestration and are either ASP+6% or biosimilar ASP + 8% of Ref. Product ASP

CMS' Rationale for its 2018 HCPCS Policy for Biosimilars Underscores Why CMS Should Not Proceed with its Proposal or Alternative 1

- "[W]e seek ***to promote innovation, to provide more options to patients and physicians, and to encourage competition*** to drive prices down . . . ."
- "We believe that this policy change will ***encourage greater manufacturer participation in the marketplace and the introduction of more biosimilar products***, thus creating a stable and robust market, driving competition and decreasing uncertainty about access and payment."
- "[W]e anticipate that this policy change will ***provide physicians with greater certainty about biosimilar payment***. We are persuaded that, in turn, this will affect utilization of these products, creating more demand that would help increase competition (compared to the policy that is currently in place)
- "[W]e anticipate ***greater access to biosimilar biological products*** and we anticipate that ***more price competition between more products will occur*** because there will be more products available."
- ***"***The change in policy could lead to ***additional savings for Medicare and its beneficiaries over the long-term*** by increasing the utilization of products that are less expensive than reference biologicals."

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