External FAQs
Inflation Reduction Act
Biosimilars temporary payment increase

Q. What policy is CMS implementing?
CMS is implementing a temporary payment increase for qualifying biosimilars under Medicare Part B. For biosimilars, Medicare Part B generally pays Average Sales Price (ASP) plus 6% of the reference biological product's ASP when the biosimilar is separately payable in physician offices, hospital outpatient departments (HOPDs), and ambulatory surgical centers (ASCs).

Section 11403 of the Inflation Reduction Act includes a temporary increase in Medicare Part B payment for certain biosimilars. Starting October 1, 2022, existing qualifying biosimilars will be paid ASP plus 8% of the reference biological product's ASP. The temporary payment increase remains in effect for five years. A qualifying biosimilar biological product is defined as a biosimilar with an ASP that is not more than the ASP of the reference biological.

For existing qualifying biosimilars for which payment was made using ASP as of September 30, 2022, the five-year period begins on October 1, 2022. For new qualifying biosimilars for which payment is first made using ASP between October 1, 2022, and December 31, 2027, the applicable 5-year period begins on the first day of the calendar quarter during which such payment is made.

Q: Why is Medicare payment for certain qualifying biosimilars in Medicare Part B changing from ASP plus 6% to ASP plus 8%?
A: Section 11403 of the Inflation Reduction Act requires a temporary, 5-year increase in the Medicare Part B payment for certain qualifying biosimilars that have an ASP that is not more than the ASP of the reference biological product. Such qualifying biosimilars will be paid ASP plus 8% (rather than plus 6%) of the reference biological product's ASP. This temporary add-on payment is intended to increase access to and utilization of biosimilars and promote competition in the marketplace.

Q: Will this payment change cost sharing for Part B biosimilars for people with Medicare?
A: For most Part B drugs, beneficiary cost-sharing is 20% of the Medicare allowed charge. Section 11403 of the Inflation Reduction Act did not change the cost-sharing percentage. Since beneficiary cost-sharing is calculated using these payments, there may be a nominal increase in beneficiary cost-sharing. However, the increase for some beneficiaries may be mitigated by other factors, such as normal fluctuations in drug prices and supplemental coverage.

ASP for Part B drugs and biologicals fluctuates quarterly, and it is common for beneficiaries to experience slight changes in cost-sharing obligations every quarter. CMS anticipates that any increase in cost sharing for qualifying biosimilars will be relatively small. For example, if the qualifying biosimilar's ASP plus 6% of its reference biological product's ASP was $1,060, then cost sharing would be $212. With the temporary add-on payment, cost sharing would increase to

$216 when the biosimilar's add-on is increased to 8% of the reference biological product (a total increase of $4).

In addition, many beneficiaries have financial safeguards in place, including wrap-around coverage, such as a Medigap. These safeguards often cover some or all of the cost-sharing on Part B drugs, so beneficiaries do not have to pay the full 20% coinsurance.

This policy is intended to increase competition in the market, and price competition between products may lead to lower prices.

Q: In which settings will this temporary increase in the Medicare Part B payment add-on for qualifying biosimilars apply?
A: The temporary increase in the Medicare Part B payment add-on for qualifying biosimilars will apply for qualifying biosimilars administered in physician offices, hospital outpatient departments (HOPDs), and ambulatory surgical centers (ASCs).

Q: How many drugs will this temporary payment increase apply to?
A: Qualifying biosimilars are those that have an ASP that is not more than the ASP of the reference biological product. Since ASPs are updated on a quarterly basis, the number of qualifying biosimilars may vary from quarter to quarter. For the initial implementation period (Q4 of 2022), there are 15 qualifying biosimilars.

Q: How will this policy help lower overall health care costs for consumers?
The goal of the temporary add-on payment for providers is to increase access to biosimilars, as well as to encourage competition between biosimilars and reference biological products, which may, over time, lower drug costs and lead to savings to beneficiaries and Medicare.

Q: Will biologicals (both biosimilars and their associated biological reference products) continue to be covered by Medicare, and will beneficiaries continue to have access to them?
A: Yes; this provision does not change coverage rules under Part B. It makes a temporary change to increase payment limits for qualifying biosimilars, and is expected to drive competition and reduce prices of biosimilars and other biologicals, which could help expand access over time.

Q5: How is CMS selecting "qualifying biosimilar biological products" that will be paid at ASP plus 8% of the reference biological product's ASP, while others will continue to be paid at ASP plus 6% of the reference biological product's ASP?
A: In accordance with section 11403 of the Inflation Reduction Act, Medicare will pay ASP plus 8% of the reference biological product's ASP only for biosimilars that have an ASP that is not more than that of its reference biological product. Other biosimilars will continue to be paid a rate of ASP plus 6% of its reference biological product's ASP.

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CMS STATEMENT

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HHS Secretary Xavier Becerra, CMS Administrator Chiquita Brooks-LaSure Remark on Implementation of Inflation Reduction Act Provision Addressing Medicare Payments for Biosimilars

Today, U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra and Centers for Medicare & Medicaid Services (CMS) Administrator Chiquita Brooks-LaSure issued the following statements on the implementation of Medicare Part B payment changes for certain biosimilars, one of the first Medicare provisions of the Inflation Reduction Act to go into effect.

Secretary Xavier Becerra: "Today's action marks a critical step toward reducing health care costs for American families and increasing competition. We're moving full-speed ahead on Inflation Reduction Act implementation to deliver results for millions of Americans."

CMS Administrator Chiquita Brooks-LaSure: "CMS is swiftly implementing the historic Inflation Reduction Act to make the new law and the benefits it provides a reality for the people we serve. The temporary Medicare Part B payment increase for qualifying biosimilars that is now in effect will foster competition in the drug marketplace for conditions such as diabetes, cancer, and immune disorders, and will improve access to these life-saving medicines that help keep people with Medicare healthy."

Additional Background:
According to the United States Food & Drug Administration (FDA), biosimilars are a diverse category of products and are generally large, complex molecules. Biological products may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and represent the fastest growing segment of the pharmaceutical industry.

In accordance with section 11403 of the Inflation Reduction Act, CMS is implementing a temporary increase in payment under Medicare for qualifying biosimilars. The new law provides for a temporary increase in the add-on payment for qualifying biosimilars whose average sales price (ASP) is not more than the price of the associated reference biological product. This provision encourages the creation and utilization of biosimilars to compete with original biologic

products and incentivizes innovation for less costly access to these important therapies in the United States.

By statute, Medicare Part B generally pays 106% of ASP (ASP plus 6%) for separately payable drugs and biologicals furnished in physician offices, hospital outpatient departments, and ambulatory surgical centers, with some exceptions. ASP is calculated based on manufacturers' sales to all U.S. purchasers minus manufacturer rebates, discounts, and price concessions (with certain exceptions). Manufacturers report ASP data to CMS quarterly.

Prior to the implementation of the provisions in section 11403 of the Inflation Reduction Act, CMS paid biosimilars a rate of the biosimilar's ASP plus an add-on of 6% of the reference biological product's ASP. Under section 11403 of the Inflation Reduction Act, qualifying biosimilars will temporarily be paid ASP plus 8% (rather than plus 6%) of the reference biological product's ASP for a 5-year period. For existing qualifying biosimilars for which payment was made using ASP as of September 30, 2022, the 5-year period begins on October 1, 2022. For new qualifying biosimilars for which payment is first made using ASP between October 1, 2022, and December 31, 2027, the applicable 5-year period begins on the first day of the calendar quarter during which such payment is made.

The goal of the temporary add-on payment for providers is to increase access to biosimilars, as well as to encourage competition between biosimilars and reference biological products, which may, over time, lower drug costs and lead to savings to beneficiaries and Medicare.

CMS has posted the quarterly Medicare Part B drug pricing file that reflects the temporary increased amount for qualifying biosimilar biological products. The October 2022 Medicare Part B quarterly drug pricing file can be accessed at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice.

Public payment files for biosimilars in the hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs) can be found at the following links:

- HOPD: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates

- ASC: https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/11_addenda_updates

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