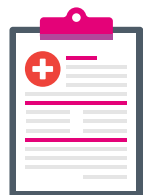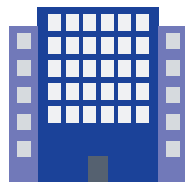# MEDICARE PART B REIMBURSEMENT CONSIDERATIONS FOR BIOSIMILARS WITH AN ASP

Enhance your understanding about the Medicare Part B reimbursement methodology for biosimilar products with an ASP[a]

STANDARD REIMBURSEMENT METHODOLOGY FOR BIOSIMILARS

- The reimbursement methodology for biosimilars with an ASP is calculated as **ASP + statutory uplift.** The statutory uplift is a percentage of the originator product's ASP[1,2]
- The originator product and the biosimilar product will each have an ASP that is calculated specific to the individual product[2]
- The statutory uplift is a percentage of the ASP that is added to the ASP to determine the maximum reimbursement payment limit for Medicare Part B drugs. For the originator product, the statutory uplift is calculated based on the originator product's ASP. For biosimilars with an ASP, the statutory uplift is also calculated based on the originator product's ASP. This means that the statutory uplift for the originator product and the biosimilar product will be the same amount[2]
- For more information about the reimbursement methodology, please refer to the **Medicare Claims Processing Manual, Chapter 17**

INFLATION REDUCTION ACT: TEMPORARY PAYMENT INCREASE FOR BIOSIMILARS

- **Inflation Reduction Act of 2022** 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 at **ASP plus a statutory uplift** of 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[3]
- 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[3]
- 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)[3]
- For more information related to the impact the Inflation Reduction Act of 2022 has on biosimilars, please refer to **Frequently Asked Questions (cms.gov)**

CMS ASP DRUG PRICING FILE

- CMS publishes an ASP Drug Pricing File that provides the **ASP + the maximum statutory uplift** for each Medicare Part B drug. The payment limit in the ASP Drug Pricing File reflects the maximum allowable payment limit, but does not necessarily reflect the actual reimbursement amount for the product[1,2]
- The ASP Drug Pricing File is published by CMS on a quarterly basis and can be found on the **CMS website**

ASP, average sales price; CMS, Centers for Medicare & Medicaid Services.

[a]Note that the reimbursement methodologies will be different for biosimilar products that do not have an ASP. This flashcard is not intended to address reimbursement methodologies for biosimilar products that do not have an ASP.

The information in this flashcard pertains to reimbursement methodologies for Medicare Part B only. Commercial reimbursement methodologies will vary by plan. This flashcard is not intended to address reimbursement methodologies for commercial plans.

The information in this flashcard is general in nature and is subject to change. It is not intended to be exhaustive, or to replace the guidance of a qualified reimbursement advisor, and does not constitute legal or reimbursement advice.

References: 1. Centers for Medicare & Medicaid Services (CMS). Drugs and biologicals. In: Medicare Claims Processing Manual. Rev. 11764. CMS; 2020. Accessed January 31, 2023. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf **2.** Statute 42 U.S.C. §1395w-3a(b)(8) US Government Publishing Office. Accessed February 1, 2023. https://www.govinfo.gov/content/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap7-subchapXVIII-partB-sec1395w-3a.htm **3.** Frequently asked questions: inflation reduction act biosimilars temporary payment increase. Centers for Medicare & Medicaid Services (CMS). Accessed January 31, 2023. https://www.cms.gov/files/document/biosimilar-faqs.pdf

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