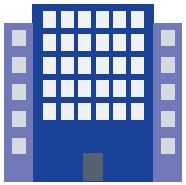
MEDICARE PART B REIMBURSEMENT CONSIDERATIONS FOR BIOSIMILARS WITH AN ASP

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**



340B REIMBURSEMENT METHODOLOGY FOR PRODUCTS WITH PASS-THROUGH STATUS

- For eligible 340B facilities, some products, including some biosimilars, have pass-through status. For biosimilars with pass-through status and with an ASP, the reimbursement methodology is **ASP + statutory uplift**. The statutory uplift is a percentage of the originator product's ASP[1]
- For biosimilars with pass-through status and with an ASP, the statutory uplift for eligible 340B facilities is calculated in the same manner as the standard methodology, described above[1]
- For a list of products with pass-through status, **click here**. Products with pass-through status are designated with a "G" in the column labeled "SI"

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**[1]

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. Medicare claims processing manual. Chapter 17: drugs and biologicals. Updated August 28, 2020. Accessed January 18, 2021. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf **2.** Statute 42 U.S.C. §1395w-3a(b)(8). Accessed January 15, 2021. https://www.govinfo.gov/content/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap7-subchapXVIII-partB-sec1395w-3a.htm

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