CAPITOL STREET

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Biopharma Policies in 2026 Fee Schedule

ASP Modifications, Skin Sub Policies Address Fraud & Abuse, MFP in 2028 (Due to IRA), Cell & Gene Therapy Bundling

Relevant Companies

Our Take & Next Up

CMS finalized on Halloween a majority of the proposed physician fee policies impacting biopharmaceuticals. ASP prices will be lower, cell & gene as well as skin substitute reimbursement will also be reduced. CMS released its final 2026 physician fee schedule (PFS) after the close on October 31 (here). In line with the administration's concern on excessive spending, there are several proposals aimed at reining in Part B spend. New policies and payment rates start Jan 1, 2026.

Key Points

PART B DRUG ASP NEGATIVELY IMPACTS HOSPITALS & PHYSICIANS

In a negative for providers, CMS is finalizing several changes – services fees, price concessions, bundling – that will impact ASP prices. Currently for ASP, manufacturers must deduct price concessions such as volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (which lowers ASP prices).

CMS decided not to finalize changes to bona fide service fees or the definition of fair market value, due to significant stakeholder opposition. CMS finalized the proposals on bundling and reporting requirements. On value-based purchasing, CMS continues to evaluate these arrangements for Part B drugs and we could see a policy proposal in the future.

- **CMS is not finalizing the revised definition of bona fide service fees nor the standards and methodology on determining fair market value (good for manufacturers)**. CMS proposed (1) specifying the methodologies that should be used to calculate fair market value in certain circumstances and (2) specifying that if fees paid by a manufacturer to an entity vary directly with the amount or price of a manufacturer’s drugs, they are presumed to be price concessions to be deducted from the ASP.
- **CMS finalizes guidance on how manufacturers should allocate pricing for drugs sold under a bundled arrangement.** CMS is finalizing its proposal to provide clarity to manufacturers on how to account for bundled price concessions when calculating the manufacturer’s ASP. CMS is finalizing as

proposed that discounts in a bundled arrangement are allocated proportionately to the dollar value of the units of all drugs or products sold under a bundled arrangement.

- **CMS finalizes its proposal that manufacturers be required to submit any reasonable assumptions they utilize for manufacturer's ASP calculations (which is currently voluntary).** This would include documentation of the methodology used to determine fair market value and periodic reviews of fair market value.

MFP (Maximum Fair Price) will be included in ASP (negative for manufacturers) in 2028. This policy is likely to impact providers' ASP+6% when Part B MFPs go into effect in 2028. CMS clarifies that units of negotiated drugs sold at MFP are included in the calculation of the manufacturer's ASP. For Medicare Part B drugs selected for negotiation, the MFP will replace ASP in the quarterly payment files.

CELL & GENE ASP TO INCLUDE PREP PROCEDURES

CMS finalizes the bundled payment policy on cost of preparatory procedures for cell & gene therapies in ASP calculations, slightly lowering the price for these therapies. This is expected to minimally lower Medicare reimbursement for cell & gene therapies overall (NVS, GILD, BMY, JNJ, AUTL) with the cost of preparatory work being included in the payment of the product itself. However, CMS is not finalizing the proposal to prevent these payments from qualifying as BFSFs or to require their inclusion in ASP beginning January 1, 2026.

CMS is not finalizing its proposal to include tissue procurement in ASP. Instead the agency will allow manufacturer-paid preparatory services to be treated as bona fide service fees (BFSFs) if it meets the criteria. CMS proposed that any preparatory procedures for tissue procurement for CAR-T therapies or gene therapy paid by the manufacturer be included in the calculation of the manufacturer's ASP.

DRUG AS A PREVENTATIVE SERVICE: PrEP

CMS finalizes classifying drugs covered as additional preventive services (DCAPS), PrEP drugs (GSK, GILD), as Part B rebatable drugs. CMS will determine the payment limit for a DCAPS drug by applying the ASP methodology or by National Average Drug Acquisition Cost (NADAC) prices.

CMS covers PrEP drugs and certain vaccines as additional preventive services. Medicare Part B covers "additional preventive services" (including drugs) that are (A) reasonable and necessary for the prevention or early detection of an illness or disability; (B) recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF); and (C) appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

SKIN SUBSTITUTES

For CY 2026, CMS finalizes its proposal to pay for certain skin substitute products as supplies when they are used as part of a covered application procedure (saves $19.6 B). CMS is looking to rein in Part B spending for skin substitute products. The agency is proposing to set payment rates using three CMS payment categories based on FDA regulatory pathways (PMAs, 510(k)s, and 361 HCT/Ps).

Skin subs: this is a significant fraud and abuse area that Dr. Oz addressed at a recent MA conference. For 2026, CMS is finalizing the use of a single payment rate ($127.28) to reflect the highest average for the three categories of skin substitute products. CMS will propose different payment rates in future years.

SINGLE USE VIALS

CMS reviewed two applications (Partner Therapeutics, URGN) for increased applicable % for specific products for 2026, but the agency will not increase applicable percentages for either drug. By statute, single dose containers or single use packages which are separately payable Part B are required to provide the CMS a refund for unused portions of specified drugs.

IRA – INFLATIONARY REBATES

CMS finalizes its proposal to codify policies for the Medicare Part B & Part D Drug Inflation Rebate Program (as expected). The IRA established requirements for drug manufacturers to pay inflation rebates if they raise their prices for Part B/D drugs faster than the rate of inflation. CMS finalized:

- Methods to identify a Part B payment amount benchmark quarter if benchmark quarter data is not available
- Establishing a claims-based methodology to remove 340B units from Part D rebate calculations starting on January 1, 2026.
- Establishing a Medicare Part D Claims Data 340B Repository for voluntary submissions by covered entities for Part D claims to allow CMS to begin usability testing for the 340B repository.

Ipsita Smolinski
Managing Director I Capitol Street
ipsita@capitol-street.com

202.250.3741 I www.capitol-street.com

900 19th St NW 6th Fl
Washington, D.C. 20006

CAPITOL STREET
