July 11, 2024

PFS: Biopharmaceutical Policies

Positive for Radiopharmaceuticals, HIV/HepB Vaccines, Compounded Drugs

Relevant Companies

GSK BIOMARIN GILEAD INDIVIOR DYNAVAX CSL Behring MERCK Biogen Lilly Pfizer

Our Take & Next Up

CMS proposed policies that benefit a wide variety of pharmaceuticals: vaccines, opioid abuse therapies, radiopharmaceuticals, compounded immunosuppressants & drugs. CMS released its proposed 2025 physician fee schedule (PFS) late yesterday. Full rule can be found here. While this is a proposal, we see these as potentially being largely finalized as proposed. Stakeholders have until September 9 to submit comments. The final rule will be out on or around Nov 1, with new policies and payment rates starting Jan 1, 2025.

Key Points

CELL & GENE

CMS is proposing to clarify that the furnishing fee for blood clotting factors only applies for self-administered treatments. This change aims to prevent double payment of administration fees for gene therapies for hemophilia (which are usually not self-administered). Approved gene therapies for hemophilia include Roctavian (BMRN), BEQVEZ (PFE), and HEMGENIX (CSL Behring).

Blood clotting factor treatments are covered under Part B (self-infused or provided in the physician office setting). Clotting factor furnishing fees are paid for self-infused products. In contrast, in the physician administered settings, administration fees are paid instead for clotting factor, reflecting the resources involved in administering the product.

PREVENTATIVE CARE (HIV, Hep. B)

CMS proposes coverage expansion for hepatitis B vaccinations (GSK, MRK, DVAX). Expanded no-cost coverage would include those who have not previously received a completed hepatitis B vaccination series or whose vaccination history is unknown. If finalized, Hep B vaccinations under Part B would no longer require physician orders and allow for pharmacies and mass immunizers to roster bill Medicare, consistent with current billing for flu, pneumococcal, and COVID-19 vaccines.

CMS is also proposing a fee schedule for Drugs Covered as Additional Preventive Services (DCAPS drugs), as legislatively required. This would be a fee schedule for drugs covered as additional preventive services as CMS has not yet covered or paid for any drugs under the category of additional preventive services. A payment limit for DCAPS drugs and supplying and administration would be determined based on the ASP.

- **A positive for PrEP (GSK, Gilead).** On July 12, 2023, CMS released a Proposed NCD for Pre-Exposure Prophylaxis (PrEP) for HIV Infection Prevention, which proposes to cover HIV PrEP drugs under Part B

as additional preventive services.

RADIOPHARMACETUICALS

CMS could allow Medicare Administrative Contractors (MACs) to have wide latitude in setting prices for radiopharmaceuticals in physician offices (allowing for invoices). MACs can use any pricing method that was used before Nov 2003, including invoice-based pricing, for radiopharmaceuticals provided outside of HOPDs. This presents a potential enhanced payment to physician offices which is likely to incentivize utilization of these diagnostics.

Payments for radiopharmaceuticals get an overall boost with the separate payment for high-cost diagnostics in the HOPD setting. In the Hospital Outpatient proposed rule, CMS is also proposing to pay separately for diagnostic radiopharmaceuticals with per day costs above a threshold of $630. See our analysis here. The boost in payment will benefit radiopharmaceuticals for cancer diagnostics, and particularly for Alzheimer's disease therapies (LLY, BIIB) as treatment and coverage start relies on diagnostic radiopharmaceuticals.

OPIOIDS

CMS is proposing to establish payment for new FDA approved opioid agonist and antagonist medications. These payments utilize CMS's existing authority to provide payment for injectable buprenorphine and nalmefene hydrochloride products furnished by OTPs.

- CMS is proposing a new add-on code for a nalmefene hydrochloride nasal spray product (Opvee, INDV) indicated for the emergency treatment of known or suspected opioid overdose.
- CMS is proposing payment for a new injectable buprenorphine product (Brixadi, Braeburn) via a new weekly bundled payment code for the weekly formulation, and by including payment for the monthly formulation of Brixadi into the existing code for monthly injectable buprenorphine.

IMMUNOSUPRESSIVE DRUGS

CMS is proposing changes to include certain compounded versions of FDA-approved drugs in the immunosuppressive drug benefit. These drugs, specifically orally or enterally administered ones, must have approved uses for preventing organ or tissues rejection or be considered necessary by a MAC. Additionally, the entire drug class benefits from proposed coverage for a 90-day supply fee and payment for refills of these prescriptions.

IRA INFLATIONARY REBATES

CMS is proposing to codify policies established in the revised guidance for the Medicare Part B & Part D Drug Inflation Rebate Program. See our analysis of revised guidance here. These policies include, but are not limited to, how CMS will identify Part B & D rebatable drugs, method to determine the inflation-adjusted coinsurance and Medicare payment amount, rebate calculation, adjustments for changes to billing and payment codes, and rebate amount for drugs in shortage.

Rebate invoicing will occur in late 2025 (as previously stated). CMS will invoice drug companies for rebates owed to Medicare for Part B drugs for all calendar quarters in 2023 and 2024 no later than September 30, 2025, and for rebates owed to Medicare for Part D drugs for the 12-month applicable periods beginning October 1, 2022, and October 1, 2023, no later than December 31, 2025.

CMS is also proposing policies that impact the calculation of rebates (340B units, single-dose drugs). Proposed policies include:

- Establishing the method and potential data sources to remove 340B units from the total number of units used to calculate the total rebate amount for a Part D rebatable drug.
- Establishing the method and process for reconciliation of a rebate amount for Part B and Part D rebatable drugs, including the circumstances that may trigger such a reconciliation.
- Establishing a civil money penalty process as directed by law to address when a manufacturer of a Part B or D rebatable drug fails to pay the rebate amount in full by the payment deadline
- Clarifying rebate calculations for Part B and Part D rebatable drugs in specific circumstances, including exclusion of Part B units of single-dose container or single-use package drugs subject to discarded drug refunds.

SINGLE-USE PACKAGE DRUGS

CMS is proposing to expand the definition of refundable single-dose container or single-use drug. Refundable drugs would potentially include products furnished from an ampule for which product labeling does not have discard statement or language indicating the package type term, and products furnished from a container with a total labeled volume 2 ml or less. CMS is also proposing to require the JW modifier if a billing supplier is not administering a drug, but there are discarded amounts discarded during the preparation process before supplying the drug to the patient.

On exclusions, CMS clarifies that they would use the date on which the drug is first paid under Part B if the date of first sale does not adequately approximate the first date of payment under an NCD. As a reminder, CMS excludes drugs for which payment has been made under Part B for fewer than 18 months from the definition of refundable single-dose container or single-use package drug.

Skin substitutes (MDXG, ORGO, SNN, Tissue Regenix) will also continue to be excluded from application of the refund. CMS will revisit discarded drug refund obligations for skin substitutes in future rulemaking.

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
