

# CAPITOL STREET

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November 3, 2024

## Biopharmaceutical & MedTech Policies in Final CMS Rules

Cell & Gene Pay, Unbundled Radiopharmaceuticals, Non-Opioid Therapy List Expansion

Relevant Companies



### »» Our Take & Next Up

**CMS finalized policies for CY25 that benefit a wide variety of therapies: vaccines, non-opioid abuse therapies, radiopharmaceuticals, compounded immunosuppressants & other drugs.** CMS released its final 2025 physician fee schedule (PFS) and hospital outpatient payment system late Friday. The final physician fee rule can be found [here](#). Our analysis can be found [here](#). The final hospital outpatient final rule can be found [here](#). The final rules largely reflect what was proposed with new policies and payment rates starting Jan 1, 2025.

### »» Key Points

#### IRA INFLATIONARY REBATES

**CMS finalizes IRA Part B & D inflationary rebate guidance.** CMS is codifying policies established in the revised guidance for the Medicare Part B & Part D Drug Inflation Rebate Program. These policies include the method and process for reconciliation of a rebate amount for the rebatable drug, establishing a civil money penalty process for when a manufacturer fails to pay the rebate amount, and clarifying rebate calculations in specific circumstances, including exclusion of Part B units of single-dose container or single-use package drugs that are subject to discarded drug refunds.

**CMS did not finalize its proposed methodology of removing Part D 340B units from rebate calculation.** The agency states they will continue to work on ways to remove 340B rebates from calculations. As a reminder, CMS has until January 1, 2026 to exclude 340B units.

**We note that Congressional 340 B reform is nowhere in sight.** See our most recent analysis ([here](#)) for more on the Gang of 6 and other proposals.

#### RADIOPHARMACEUTICALS

**Positively, payments for radiopharmaceuticals get an overall boost with the separate payment for high-cost diagnostics in the HOPD setting (NVS, BMY, LNTH, Bayer AG).** In the hospital outpatient final rule, CMS will pay separately for diagnostic radiopharmaceuticals with per day costs above a threshold of \$630. CMS will update the \$630 threshold in subsequent years by the Producer Price Index (PPI). Payment will be based on their Mean Unit Cost (MUC) derived from OPPS claims for CY 2025. Previously, radiopharm was packaged with payment for the accompanying nuclear medicine test.

**MACs (local Medicare contractors) may determine Part B pay limits for physician administered radiopharmaceuticals finalized.** CMS is finalizing a clarification that, for radiopharmaceuticals furnished in a setting other than a hospital outpatient department, MACs shall determine Part B pay limits for radiopharmaceuticals based on any methodology used to determine payment limits for radiopharmaceuticals in place on or prior to November 2003. These methods may include the use of invoice-based pricing.

#### CELL & GENE THERAPIES

**CMS clarifies that gene therapies are not clotting factors and are only eligible for the administration fee, to avoid mispayment.** Hemophilia gene therapies only qualify for Part B administration fee (not the clotting factor furnish fee). This change aims to prevent double payment of administration fees under Part B for gene therapies. (CSL Behring, Pfizer, BioMarin)

**Blood clotting factor treatments are covered under Part B regardless of administration.** Clotting factor furnishing fees are paid when self-infused products are furnished. In contrast, when administered in health care settings, administration fees are paid.

#### PREVENTION & DIAGNOSTICS (CANCER, HIV, HEP B)

**Expanded colorectal cancer screening is finalized (positive for diagnostics).** CMS is expanding coverage for CRC screening to include computed tomography colonography (CTC) and Medicare covered blood-based biomarker CRC screening tests as part of the continuum of screening. A blood-based biomarker test with a positive result will lead to a follow-on screening colonoscopy (with no beneficiary cost-sharing).

**CMS finalizes the fee schedule for drugs covered as additional preventive services (DCAPS), a positive for PrEP makers Gilead & GSK.** On September 30, 2024, CMS finalized the NCD which established coverage of HIV PrEP drugs as additional preventive services under Part B. A payment limit for these drugs and supplying and administration would be determined based on the ASP or through an alternative payment mechanism if ASP data is not available.

**CMS finalizes coverage of Hepatitis B vaccines (Dynavax, MRK, GSK).** CMS clarifies that a physician's order will no longer be required for the administration of a hepatitis B vaccine. CMS is also aiming to improve vaccination at rural health centers (RHCs) and federally qualified health centers (FQHCs) by finalizing payment for hepatitis B vaccines and their administration at 100% of reasonable cost in RHCs and FQHCs, separate from their rate setting methodologies.

#### NON-OPIOID PAY LIMITS (NO PAIN)

**CMS finalizes the non-opioid pain treatment payment limit to the estimated average 18% of the OPPS payment for the service(s) which it is furnished with.** CMS will utilize the top five OPPS procedures by volume, for each non-opioid drug or device, to calculate the payment limitation. CMS also finalized the policy to create new OPPS status indicators for non-opioid drugs and devices to implement this payment limitation for CY 2025. Final drugs & devices are below.

- Zynrelef (**HRTX**);
- Xaracoll (**Innocoll Biotherapeutics**);
- Exparel (**PCRX**);
- Dextenza (**OCUL**);
- Omidria (**Rayner**);
- Ketorolac tromethamine injection (**PFE**);
- ON-Q Pump (**AVNS**)
- ambIT Electronic Infusion Pump (**AVNS**) *NEW*
- Cryo Nerve Block Therapy (**ATRC**) *NEW*
- Ilovera System (**PCRX**) *NEW*
- SPRINT Peripheral Nerve Stimulator System (**SPR Therapeutics**) *NEW*

**CMS adds several medical devices to the finalized list as suggested by comments (AVNS, ATRC, PCRX, SPR Therapeutics).** Final products (5 medical devices and 6 drug products) will be paid for separately in both the HOPD & ASC settings at the same amount. Final medical devices must have met the statutory criteria and generated literature that demonstrates that the device can replace, reduce, or avoid intraoperative or postoperative opioid use. See below for CY 2025 payment limits.

Non-Opioid Drug or Device	CY 2025 Payment Limit (Volume Weighted Average of 18 % of Primary Procedure Payment Rate)
Zynrelef (C9088)	\$2,267.26
Xaracoll (C9089)	\$700.48
Exparel (J0666; C9290)	\$2,368.14
Dextenza (J1096)	\$427.57
Omidria (J1097)	\$425.89
Ketorolac tromethamine Injection (J1885)	\$1,214.30
ON-Q Elastomeric Infusion Pump (C9804)	\$2,284.98
ambIT Electronic Infusion Pump (C9806)	\$2,284.98
Cryo Nerve Block Therapy (C9808)	\$985.94

Non-Opioid Drug or Device	CY 2025 Payment Limit (Volume Weighted Average of 18 % of Primary Procedure Payment Rate)
Iovera System (C9809)	\$255.85
SPRINT Peripheral Nerve Stimulator System (C9807)	\$2,483.16

Source: CMS CY 2025 HOPPS Final Rule [here](#), & Capitol Street, 2024

## SPECIALTY CARE

**Expanded coverage of compounded immunosuppressive drugs were also finalized, along with policies that improve access.** Compounded formulations with active ingredients derived only from FDA-approved drugs that have immunosuppressive indications or FDA-approved drugs that have been determined to be reasonable and necessary for a specific purpose in immunosuppressive treatment may be covered. CMS will also provide supply fee payment for a supply of up to 90 days and allow prescriptions for immunosuppressive drugs to be refillable.

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

- A new add-on code for a nalmeferne hydrochloride nasal spray product (Opvee, **INDV**) indicated for the emergency treatment of known or suspected opioid overdose.
- 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.

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