CAPITOL STREET

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CMS Names 7 Products for No PAIN in 2025

Positive for Radiopharmaceuticals Being Paid Separately

Relevant Companies

Our Take & Next Up

The proposed rule is in line for non-opioid manufacturers (*NO PAIN)* and represents a reasonable, positive approach for radiopharmaceutical manufacturers. Recall that CMS is implementing *NO PAIN* (here) and CMS's approach to separate diagnostic radiopharma payment reflects what Congress is asking CMS to do i.e. unbundle where appropriate instead of having to pass *FIND Act*, which is extremely unlikely to pass in 2024. As we previewed these policies (here), CMS is strictly defining non-opioid pain treatment payments with only 6 drugs and 1 device qualifying in the proposed rule. For radiopharma unbundling, the additional payment relies on a higher threshold ($630) compared to what is legislatively proposed ($500) under the *FIND Act* (here). Comments are due by Sept. 9, 2024, and the final rule is due on or around Nov 1, with new payments and policies that start Jan 1, 2025. See below for details.

Key Points

NO PAIN

***NO PAIN Act* implementation starts in 2025 (for three years).** CMS is limiting qualifying therapies to those that have an FDA approved indication "to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body's opioid receptors." For a medical device to qualify, it must be "used to deliver a therapy to reduce postoperative pain or produce post-surgical or regional analgesia" and replace, reduce, or avoid intraoperative or postoperative opioid through evidence in a clinical trial or through data published in a peer-reviewed journal.

Six drugs and one medical device qualify as non-opioid treatments for pain relief. CMS is soliciting comment on whether there are any additional drugs, biologicals, or medical devices that meet the requirements.

These products will be paid for separately in both the HOPD & ASC settings at the same amount that is not yet finalized. The drugs & devices are as follows.

- Zynrelef (HRTX);
- Xaracoll (Innocoll Biotherapeutics);
- Exparel (PCRX);
- Dextenza (OCUL);
- Omidria (Rayner);
- Ketorolac tromethamine injection (PFE); and
- ON-Q Pump (AVNS) (NOTE: this is the one medical device defined; CMS asks for other products in the proposal for inclusion)

CMS is proposing to utilize the top five OPPS procedures by volume for each nonopioid drug or device to calculate the payment limitation. The additional payment must not exceed the estimated average of 18% of the relevant OPPS payment for OPPS service or group of services. CMS is proposing to apply the 18% payment limitation per date of service billed, rather than per HCPCS dosage unit. The agency is also proposing to create new status indicators for non-opioid drugs and devices to implement this payment limitation.

See chart below for values provided by CMS. The additional payment rate (per billing unit) ranges from $0.70 (Ketorolac tromethamine injection, PFE) to $117.01 (Dextenza, OCUL) with several falling under $1.50 per billing unit.

INCREMENTAL MEDICARE PAYMENT (CY25) PROPOSED*

Non-Opioid Drug	CY 2025 Procedure Payment Rate	Payment Limitation Applied Per Date of Service Volume Weighted Average of 18% of Procedure Payment Rate	Separate Payment Rate (Per Billing Unit)
Zynrelef (C9088)	$13,048.08 $86.88 $13,048.08 $42.37 $116.11	$1,206.16	$0.73
Xaracoll (C9089)	$3,541.93 $324.11 $24.96 $50.14 $3,541.93	$388.53	$0.85
Exparel (C9290)	$13,048.08 $42.37 $324.11 $116.11 $86.88	$583.29	$1.41

Non-Opioid Drug	CY 2025 Procedure Payment Rate	Payment Limitation Applied Per Date of Service Volume Weighted Average of 18% of Procedure Payment Rate	Separate Payment Rate (Per Billing Unit)
Dextenza (J1096)	$2,159.44 $2,114.22 $2,159.44 $4,250.50 $24.96	$386.39	$117.01
Omidria (J1097)	$2,159.44 $2,159.44 $2,114.22 $24.96 $4,250.50	$383.59	$97.12
Ketorolac tromethamine Injection (J1885)	$42.37 $42.37 $206.57 $67.47 $116.11	$22.82	$0.70

Source: CMS, CY 2025 HOPPS Proposed Rule, 2024 here, page 594 & Capitol Street
* Having trouble viewing this table? View in browser

CMS is proposing to initially assign a payment offset of $0 for the qualifying non-opioid products to maintain the non-opioid portion of the procedure payment. A zero offset means that CMS would not offset or remove the amount that the non-opioid product represents from the procedure payment rate when setting payment rates.

RADIOPHARMACEUTICALS

CMS is proposing in CY25 to pay separately for diagnostic radiopharmaceuticals with per day costs above a threshold of $630, which is generally positive news. Under the OPPS, the costs associated with diagnostic radiopharmaceuticals are packaged into the payment for the nuclear medicine tests they are used with. CMS is allowing for separate payment for when the packaged payment amount may not adequately account for the cost of a diagnostic radiopharmaceutical that has a significantly higher cost, but lower utilization.

This threshold ($630) is 2x the volume weighted average cost amount currently associated with diagnostic radiopharmaceuticals. Any diagnostic radiopharmaceutical with a per-day cost equal to or below that threshold would continue to be policy-packaged, with costs incorporated into the payment rates for the nuclear medicine tests. This threshold would be updated in CY 2026 by the Producer Price Index (PPI) for Pharmaceutical Preparations. This is the same as the update factor used for the OPPS drug packaging threshold.

- **This threshold may be lower in the future as CMS seeks feedback on the alternatives of using 1.75x the volume weighted average amount as the threshold**. This approach to multiply the average

offset amount by two is consistent with the OPPS outlier policy for high-cost procedures, where costs greater than 1.75 times the ambulatory payment classification (APC) trigger an additional outlier payment.

- **Another alternative considered by CMS is using the standard drug packaging threshold, proposed to be $140 for CY 2025.** CMS believes diagnostic radiopharmaceuticals are functioning as supplies to the nuclear medicine procedure. As a result, CMS determined that radiopharma have a different usage clinically compared to therapeutic drugs, biologicals, and therapeutic radiopharmaceuticals that are typically packaged under the standard drug packaging threshold. The agency requests feedback on this assessment.

Per day costs would be based on their Mean Unit Cost (MUC) derived from OPPS claims. This may be changed to ASP for payment in future years as the agency is encouraging ASP reporting by manufacturers. CMS is proposing to make an annual packaging determination for each diagnostic radiopharmaceutical HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year. Once a radiopharma exceeds the threshold, CMS is proposing to assign that radiopharmaceutical to an APC, making it a specified covered outpatient drug (SCOD).

There are 26 proposed qualifying diagnostic radiopharmaceuticals. These encompass a variety of diagnostics including those for cancer, strokes, and diagnostics for infections. Proposed diagnostics include (but are not limited to):

- **Cancer diagnostics include:** Choline c-11 (Mayo Clinic, Precision Nuclear) ; In111 ibritumomab, dx (Acrotech Biopharma); indium in-111 pentetreotide (Curium, Mallinckrodt); iodine i-123 iobenguane (GEHC); gallium ga-68 (AAAP); fluciclovine f-18 (Blue Earth Diagnostics); fluoroestradiol f 18 (GEHC); copper cu 64 dotatate diag (RadioMedix, Curium); Gallium ga-68 psma-11 (UCSF Radiopharmaceutical Facility, UCLA Biomedical Cyclotron); Piflu f-18 (PGNX, Curium).
- **Noncancer diagnostics include:** Tc99m exametazime (GEHC); In111 pentetate (AnazaoHealth, GEHC); Tc99m bicisate (AnazaoHealth, LNTH); iodine i-123 ioflupane (GEHC); florbetapir f18 (LLY); Fluorodopa f-18 diag per mci (The Feinstein Institutes for Medical Research); Flutemetamol f18 diagnostic (GEHC); Florbetaben f18 diagnostic (Life Molecular Imaging).

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
