

Attorneys at Law



MEMORANDUM				
To:	American Association of Hip and Knee Surgeons			
From:	Epstein Becker & Green			
Date:	January 7, 2025			
Re:	UPDATE: NOPAIN Act and 2025 Rates for Non-Opioid Pain Relief			

Background

Congress enacted the NOPAIN (Non-Opioids Prevent Addiction in the Nation) Act on December 29, 2022 in order to minimize financial barriers to the provision of branded non-opioids to Medicare surgical patients for improved management of postsurgical pain. The law was a bipartisan effort led by Congressional members from states hardest hit by the opioid crisis to make non-opioid-pain management options more available.

CMS took several steps for the provisions of the NOPAIN Act to go into effect on January 1, 2025: (1) the new law directs CMS to make a separate payment for certain non-opioid pain relief treatments beginning in 2025. This new reimbursement scheme is explained and implemented in the 2025 OPPS and ASC final rules. (2) CMS recently approved assigning a new J-code to one of the most commonly prescribed non-opioid pain management products, which will have a favorable impact on coverage and reimbursement.

Establishing Temporary Separate Medicare Payments

The new law directs CMS to make a "separate" payment under the OPPS for certain non-opioid pain relief in the hospital outpatient department (OPD) setting only between January 1, 2025 and December 31, 2027¹:

- The new payments must be *separate* and *in addition to* the payment to the facility for the underlying procedure. CMS may not bundle payment for non-opioid pain relief into the underlying procedure payment. CMS may not reduce the payment level of the underlying procedure to offset the separate payment.
- The separate payment must be budget neutral. This means that the national Medicare Conversion Factor for 2025 will be slightly decreased to offset the increased payments for non-opioid pain relief.

¹ 89 Fed. Reg. 94343 (Nov. 27, 2024).

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- The NOPAIN Act states that the separate payment amount shall not exceed the estimated average of 18% of the OPPS fee schedule amount for the OPD service with which the nonopioid treatment for pain relief is furnished. CMS finalized a policy wherein the 18% limitation is based on the volume weighted average of the 2025 payment rates of the top five primary procedures by volume into which a non-opioid treatment for pain relief would have its payment packaged, absent the NOPAIN Act.
- Payment is limited to non-opioid pain drugs, biologics, or devices with an FDA-approved indication to reduce post-operative pain or produce post-surgical or regional analgesia.
- Of 5 non-opioid pain drugs approved by CMS for separate payment in 2025 in the OPD setting, only 2 are approved for use with TJA:
 - Exparel (C9290, injection, bupivacaine liposome, 1mg) for TKA & THA²
 - o Zynrelef (C9088, instillation, bupivacaine and meloxicam, 1mg) for TKA & THA
 - On Jan. 1, 2028, without Congressional action, reimbursement for these non-opioid pain treatments will revert back into the bundled procedure payment.

New J Code for Exparel Approved

In 2024, Exparel and Zynrelef were identified by "C codes", temporary Level II HCPCS codes for outpatient, separate payment drugs and devices. Earlier in 2024, Pacira, the manufacturer of Exparel, submitted a proposal to the CMS HCPCS Working Group to convert Exparel from a temporary C-code to a permanent J-code.

On Oct. 9, 2024, as a part of the 2024 Q3 HCPCS Coding Cycle, CMS approved assignment of Exparel to new J-code J0666.³ As permanent codes, J-codes facilitate wider coverage and payment by commercial payers in addition to Medicare, Medicare Advantage, and other government payers.⁴

Treatment	2024 Separate Payment	Proposed 2025 Separate	Final 2025 Separate Payment	
	Rate (Per billing unit)	Payment Rate (Per billing unit)	Rate (Per billing unit)	
Zynrelef, 1mg (C9088)	Not Covered	\$0.73	\$0.7 7	
Exparel, 1mg (J0666)⁵	\$1.42 (ASC locations only)	\$1.41	\$1.45	

Medicare Separate Payment Rates for Non-Opioid Relief Approved for TKA & THA

² Exparel has already been covered for separate payments in the ASC-setting since 2019.

³ CMS, Third Quarter, 2024 HCPCS Coding Cycle, pg. 28 (Oct. 9, 2024); available at:

https://www.cms.gov/files/document/2024-hcpcs-application-summary-quarter-3-2024-drugs-and-biologicals.pdf.

⁴ <u>Pacira Biosciences Announces New Product-Specific J-Code for Exparel Effective January 1, 2025</u>

⁵ Pacira packages Exparel in 133mg (10 mL) or 266 mg (20mL) doses. See <u>https://www.exparelpro.com/reimbursement</u>

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Subsequent Congressional Report

No Later than Jan. 1, 2028 a CMS Report is due to Congress⁶ that must:

- "Identify limitations, gaps, barriers to access, or deficits in Medicare coverage or reimbursement for restorative therapies, behavioral approaches, and complementary and integrative health services that are identified in the Pain Management Best Practices Inter-Agency Task Force Report and that have demonstrated the ability to replace or reduce opioid consumption"
- Recommend actions to address limitations, gaps, barriers to access and deficits.
- Compare the quantity of opioids administered, dispensed, and prescribed for the same covered OPD service, including postoperative management; and the Medicare beneficiaries who did not receive a non-opioid treatment for pain relief as part of the same covered OPD service in clause the quantity of opioids administered, dispensed, and prescribed for the same covered OPD service, including postoperative management. The data for this will be collected in the 12-month period following the first 6 months in which additional payment for non-opioid treatments for pain relief is implemented.
- The report will compare results from nationally represented samples of beneficiaries.

⁶ <u>https://www.congress.gov/117/plaws/publ328/PLAW-117publ328.pdf</u>