

Non-Opioid Quarterly Implementation Process

OPPS (Outpatient Prospective Payment System) & ASC (Ambulatory Surgical Center)

This guidance outlines how to alert and engage with CMS regarding new non-opioid treatments for pain relief. Refer to the [CY 2026 OPPS/ASC final rule with comment period](#) (90 FR 53448) discussion for the full criteria and information needed for a product to qualify as a non-opioid treatment for pain relief.

Payment Policy Overview

- Section 4135 of the Consolidated Appropriations Act (CAA), 2023 was signed into law on December 29, 2022.
- Section 4135 amended section 1833(t)(16) and section 1833(i) of the Social Security Act to provide for temporary additional payments for certain non-opioid treatments for pain relief in both the hospital outpatient department (HOPD) and the ASC setting.
- These temporary additional payments will be provided for certain non-opioid treatments for pain relief furnished from January 1, 2025, through December 31, 2027, in both the OPPS and ASC payment systems.

CY 2026 Updates

- For CY 2026, CMS is maintaining the policy codified at 42 CFR 419.43(k) and 416.174, which adheres closely to the statutory requirements of section 4135 of the Consolidated Appropriations Act, 2023, with a minor modification to permit more timely consideration of payment requests.
- Based on the comments received on the CY 2026 OPPS/ASC proposed rule, we believe it is reasonable to consider a pathway to approve new products, or products newly meeting the established criteria, on a more frequent basis than annually.
- The qualifying criteria did not change for CY 2026, only the frequency in which CMS can approve qualifying non-opioid treatments for pain relief.

How to Engage with CMS

CMS welcomes engagement from the public on products that newly meet the qualifying criteria and should be paid according to the statute under this policy.

Please contact OutpatientPPS@cms.hhs.gov if there is a product you believe qualifies as a non-opioid treatment for pain relief along with any necessary supporting information. In the subject line of your email, please include “Non-Opioid Treatment for Pain Relief Supporting Documentation.”

Examples of engagement could include:

- Documentation verifying appropriate FDA status, including the required FDA-approved indication for drugs
- Qualifying peer-reviewed literature for medical devices and that the medical device is used to deliver a therapy to reduce postoperative pain or produce postsurgical or regional analgesia
- Suggestions for the top 5 most frequent procedures for purposes of calculating a payment limitation

- Verification that the product does not have transitional pass-through status
- Confirmation that the product has payment that is packaged into a payment for a covered OPD service
- The current HCPCS code describing the product or recommendations for a new HCPCS code to describe the product.¹

Please see 42 CFR 419.43(k) and 416.174 for the full established criteria.

CMS Review Process

- CMS will make payment, according to the statute and established regulation text, retroactively effective to the date that CMS determines that a product meets the criteria, with the earliest effective payment date being January 1, 2026.
- Once these determinations are made by CMS, they will be publicly available on the CMS OPPS website.²
- Payment will be effectuated in the applicable quarterly OPPS/ASC update.

Anticipated Timeline

- CMS will evaluate potentially qualifying non-opioid treatments for pain relief on a rolling basis, but we have included an anticipated review and implementation timeline to set expectations for the public. Note, lack of either clarity or information regarding how the product meets the established criteria, including the required payment limitation, could delay this evaluation.
- If approved, CMS will first post the approval on the CMS Hospital OPPS Website.
- If not approved, CMS will contact the submitter via email.
- Payment will be made retroactively effective to the date that CMS determines that a product meets the criteria (with the earliest effective payment date being January 1, 2026).. Note that the CMS determination date could be before the website posting date.

	2026 Engagement/ Submission Period (deadline in bold)	Earliest CMS Implementation Date	Effective Payment Date
	January 1 - February 1	April 1 (Q2 2026)	Retroactive to date CMS determines the product met the criteria (earliest: Jan 1, 2026)
	February 2 -- May 1	July 1 (Q3 2026)	Retroactive to date CMS determines the product met the criteria
	May 2 - August 1	October 1 (Q4 2026)	Retroactive to date CMS determines the product met the criteria
	August 2 - November 1	January 1 (Q1 2027)	Retroactive to date CMS determines the product met the criteria

¹ Please note, a separate HCPCS code application is not required for purposes of payment under this policy. It has been CMS's practice to create C-codes for qualifying products to facilitate payment in the OPPS and ASC payment systems.

² <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>