

§ 416.173

42 CFR Ch. IV (10–1–24 Edition)

this section, CMS calculates the payment for code combinations that meet the eligibility requirements in paragraph (h)(1) of this section by applying the methodology specified in § 416.171(a) to the OPPS C-APC complexity-adjusted relative weights.

(ii) For primary procedures assigned device-intensive status that are a component of a code combination that is eligible for payment under paragraph (h)(2) of this section, the primary procedure of the code combination retains its device-intensive status, and—

(A) The device portion is equivalent to the device portion of the device-intensive APC under the OPPS (§ 419.44(b) of this subchapter); and

(B) The non-device portion is calculated in accordance with the methodology specified in § 416.171(a).

[72 FR 42545, Aug. 2, 2007, as amended at 80 FR 70604, Nov. 13, 2015; 87 FR 72291, Nov. 23, 2022; 88 FR 82179, Nov. 22, 2023]

§ 416.173 Publication of revised payment methodologies and payment rates.

CMS publishes annually, through notice and comment rulemaking in the FEDERAL REGISTER and/or via the Internet on the CMS Web site, the payment methodologies and payment rates for ASC services and designates the covered surgical procedures and covered ancillary services for which CMS will make an ASC payment and other revisions as appropriate.

[76 FR 74582, Nov. 30, 2011]

§ 416.174 Payment for non-opioid pain management drugs and biologicals that function as supplies in surgical procedures.

(a) *Eligibility for separate payment for non-opioid pain management drugs and biologicals.* Beginning on or after January 1, 2022, a non-opioid pain management drug or biological that functions as a surgical supply is eligible for separate payment for an applicable calendar year if CMS determines it meets the following requirements through that year's rulemaking:

(1) The drug is approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), under an abbreviated new drug application under section 505(j),

or, in the case of a biological product, is licensed under section 351 of the Public Health Service Act. The product has an FDA approved indication for pain management or analgesia.

(2) The per-day cost of the drug or biological estimated by CMS for the year exceeds the OPPS drug packaging threshold set for such year through notice and comment rulemaking.

(3) The drug or biological does not have transitional pass-through payment status under § 419.64 of this subchapter. In the case where a drug or biological otherwise meets the requirements under this section and has transitional pass-through payment status that expires during the calendar year, the drug or biological will qualify for separate payment as specified in this paragraph (a) during such calendar year on the first day of the next calendar year quarter following the expiration of its pass-through status.

(4) The drug or biological is not already separately payable in the OPPS or ASC payment system under a policy other than the one specified in this section.

(b) [Reserved]

[86 FR 63993, Nov. 16, 2021, as amended at 87 FR 72291, Nov. 23, 2022]

§ 416.178 Limitations on administrative and judicial review.

There is no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following:

- (a) The classification system;
- (b) Relative weights;
- (c) Payment amounts; and
- (d) Geographic adjustment factors.

§ 416.179 Payment and coinsurance reduction for devices replaced without cost or when full or partial credit is received.

(a) *General rule.* CMS reduces the amount of payment for a covered surgical procedure for which CMS determines that a significant portion of the payment is attributable to the cost of an implanted device not on pass-through status under subpart G of part 419 of this subchapter when one of the following situations occur:

(1) The device is replaced without cost to the ASC or the beneficiary;