

§ 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;

(2) The ASC receives full credit for the cost of a replaced device; or

(3) The ASC receives partial credit for the cost of a replaced device but only where the amount of the device credit is greater than or equal to 50 percent of the cost of the new replacement device being implanted.

(b) *Amount of reduction to the ASC payment for the covered surgical procedure.* (1) The amount of the reduction to the ASC payment made under paragraphs (a)(1) and (a)(2) of this section is calculated in the same manner as the device payment reduction that would be applied to the ASC payment for the covered surgical procedure in order to remove predecessor device costs so that the ASC payment amount for a device with pass-through status under §419.66 of this subchapter represents the full cost of the device, and no packaged device payment is provided through the ASC payment for the covered surgical procedure.

(2) The amount of the reduction to the ASC payment made under paragraph (a)(3) of this section is 50 percent of the payment reduction that would be calculated under paragraph (b)(1) of this section.

(c) *Amount of beneficiary coinsurance.* The beneficiary coinsurance is calculated based on the ASC payment for the covered surgical procedure after application of the reduction under paragraph (b) of this section.

[72 FR 42545, Aug. 2, 2007, as amended at 72 FR 66932, No. 27, 2007]

Subpart G—Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Service Centers

SOURCE: 71 FR 68226, Nov. 24, 2006, unless otherwise noted.

§416.180 Basis and scope.

(a) *Basis.* This subpart implements section 141 of Public Law 103-432, which provides for adjustments to payment amounts for new technology intraocular lenses (IOLs) furnished at ambulatory surgical centers (ASCs).

(b) *Scope.* This subpart sets forth—

(1) The process for interested parties to request that CMS review the appropriateness of the ASC facility fee for insertion of an IOL. This process includes a review of whether that payment is reasonable and related to the cost of acquiring a lens determined by CMS as belonging to a class of new technology IOLs;

(2) Factors that CMS considers for determination of a new class of new technology IOLs; and

(3) Application of the payment adjustment.

§416.185 Process for establishing a new class of new technology IOLs.

(a) *Announcement of deadline for requests for review.* CMS announces the deadline for each year's requests for review of a new class of new technology IOLs in the final rule updating the ASC payment rates for that calendar year.

(b) *Announcement of new classes of new technology IOLs for which review requests have been made and solicitation of public comments.* CMS announces the requests for review received in a calendar year and the deadline for public comments regarding the requests in the proposed rule updating the ASC payment rates for the following calendar year. The deadline for submission of public comments is 30 days following the date of the publication of the proposed rule.

(c) *Announcement of determinations regarding requests for review.* CMS announces its determinations for a calendar year in the final rule updating the ASC payment rates for the following calendar year. CMS publishes the codes and effective dates allowed for those lenses recognized by CMS as belonging to a class of new technology IOLs. New classes of new technology IOLs are effective 30 days following the date of publication of the final rule.

§416.190 Request for review of payment amount.

(a) *When requests can be submitted.* A request for review of the appropriateness of ASC payment for insertion of an IOL that might qualify for a payment adjustment as belonging to a new class of new technology IOLs must be submitted to CMS in accordance with the annual published deadline.

(b) *Who may submit a request.* Any individual, partnership, corporation, association, society, scientific or academic establishment, or professional or trade organization able to furnish the information required in paragraph (c) of this section may request that CMS review the appropriateness of the payment amount provided under section 1833(i)(2)(A)(iii) of the Act with respect to an IOL that meets the criteria of a new technology IOL under § 416.195.

(c) *Content of a request.* In order to be accepted by CMS for review, a request for review of the ASC payment amount for insertion of an IOL must include all the information as specified by CMS.

(d) *Confidential information.* In order for CMS to invoke the protection allowed under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and, with respect to trade secrets, the Trade Secrets Act (18 U.S.C. 1905), the requestor must clearly identify all information that is to be characterized as confidential.

§ 416.195 Determination of membership in new classes of new technology IOLs.

(a) *Factors to be considered.* CMS uses the following criteria to determine whether an IOL qualifies for a payment adjustment as a member of a new class of new technology IOLs when inserted at an ASC:

(1) The IOL is considered new. CMS will evaluate an application for a new technology IOL only if the IOL type has received initial FDA premarket approval within the 3 years prior to the new technology IOL application submission date.

(2) The IOL shall have a new lens characteristic in comparison to currently available IOLs. The labeling, which must be approved by FDA, shall contain a claim of a specific clinical benefit imparted by the new lens characteristic.

(3) The IOL is not described by an active or expired class of new technology IOLs; that is, it does not share a predominant, class-defining characteristic associated with improved clinical outcomes with members of an active or expired class.

(4) Any specific clinical benefit referred to in paragraph (a)(2) of this sec-

tion must be supported by evidence that demonstrates that the IOL results in a measurable, clinically meaningful, improved outcome. Improved outcomes include:

- (i) Reduced risk of intraoperative or postoperative complication or trauma;
- (ii) Accelerated postoperative recovery;
- (iii) Reduced induced astigmatism;
- (iv) Improved postoperative visual acuity;
- (v) More stable postoperative vision;
- (vi) Other comparable clinical advantages.

(b) *CMS determination of eligibility for payment adjustment.* CMS reviews the information submitted with a completed request for review, public comments submitted timely, and other pertinent information and makes a determination as follows:

(1) The IOL is eligible for a payment adjustment as a member of a new class of new technology IOLs.

(2) The IOL is a member of an active class of new technology IOLs and is eligible for a payment adjustment for the remainder of the period established for that class.

(3) The IOL does not meet the criteria for designation as a new technology IOL and a payment adjustment is not appropriate.

[71 FR 68226, Nov. 24, 2006, as amended at 77 FR 68558, Nov. 15, 2012; 80 FR 70604, Nov. 13, 2015]

§ 416.200 Payment adjustment.

(a) CMS establishes the amount of the payment adjustment for classes of new technology IOLs through proposed and final rulemaking in connection with ASC facility services.

(b) CMS adjusts the payment for insertion of an IOL approved as belonging to a class of new technology IOLs for the 5-year period of time established for that class.

(c) Upon expiration of the 5-year period of the payment adjustment, payment reverts to the standard rate for IOL insertion procedures performed in ASCs.

(d) ASCs that furnish an IOL designated by CMS as belonging to a class of new technology IOLs must submit claims using billing codes specified by