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

§ 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 approved by the FDA.

(2) Claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison...
to currently available IOLs are approved by the FDA for use in labeling and advertising.

(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) Evidence demonstrates that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs. Superior 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.

§ 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 CMS to receive the new technology IOL payment adjustment.

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

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