

42 C.F.R. § 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.

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