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Medicare Authorities To Reduce Payment for Covered Items or Services

	Least Costly Alternative	Inherent Reasonableness	Functional Equivalence
Description	CMS contractors determine that two or more covered items or services are clinically indistinguishable and announce, through a local coverage determination, that they will only pay for the least costly of the items.	CMS determines that the statutorily-determined payment amount for a covered item or service is "grossly excessive or deficient" and, therefore, not inherently reasonable. CMS can only invoke the authority to reduce payment for a covered item or service by 15%. If CMS wants to reduce payment by more than 15%, it must go through notice and comment rulemaking identifying the specific item or service, and engage in consultation with the affected industry.	CMS determines, for purposes of applying the transitional new drug or device pass-through under the Outpatient Prospective Payment System (OPPS), that a particular new drug or device applying for pass-through status is "functionally equivalent" to a drug or device that is already covered under OPPS outside of the pass-through. By making the functional equivalence determination, CMS is able to avoid paying for the item on a pass-through basis.
Examples of use	Prostate cancer drugs such as Lupron® which are paid by reference to price of Zoladex®. COPD treatment DouNeb®.	CMS used the authority in the 1970s to reduce payment for certain items of durable medical equipment (DME) but has not used it recently.	CMS invoked the authority to deny pass-through status to Aranesp®.
Statutory and Regulatory Basis	Social Security Act § 1862(a)(1)(A) (Medicare prohibited from paying for expenses for any covered item or service that is not "reasonable or necessary" for the diagnosis or treatment of illness or injury.) 2000 Advance Notice of Proposed Rulemaking (later withdrawn) proposing to permit CMS contractors to use LCA. Medicare Program Integrity Manual § 13.4	Social Security Act § 1842(b)(8) and (9) 42 C.F.R. 405.502(a)(7), (g), and (h).	Social Security Act §§ 1833(t)(2)(E) (giving the agency authority to administer the pass-through statute in a manner "determined to be necessary to ensure equitable payments" under OPPS) and 1833(t)(12)(A) (precluding judicial review of use of the equitable adjustment authority). 67 Fed. Reg. 66758 – 59 (Nov. 1, 2002)
Legal Risk	Significant legal risk for CMS. Although the Department had earlier won a court case challenging the policy on the basis that pharmaceutical manufacturers lacked standing to challenge the policy (see *TAP Pharmaceuticals v. Shalala*, 163 F.3d 199 (4th Cir. 1998)), more recently, HHS lost a District Court Case challenging the policy. See *Hays v. Leavitt*, 583 F. Supp. 2d 62 (D.D.C. 2008). The government has appealed *Hays v. Leavitt* to the DC Circuit.	Little legal risk for agency. Congress has specifically sanctioned use of inherent reasonableness authority and CMS has gone through notice and comment rulemaking to specify how it will utilize the authority.	The manufacturer of Aranesp® challenged use of CMS' functional equivalence authority. The U.S. Court of Appeals for the D.C. Circuit concluded that the preclusion of judicial review in section 1833(t)(12)(A) divested it of jurisdiction over the complaint and granted the government's motion to dismiss. See *Amgen v. Smith*, 357 F.3d 103 (D.C. Cir. 2004). Shortly before *Amgen v. Smith* was decided, Congress prohibited CMS from using functional equivalence in applying the transitional new drug or device pass-through. Social Security Act § 1833(t)(6)(F).

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Current Status	CMS contractors continue to use LCA for prostate cancer drugs such as Lupron®. CMS contractors are enjoined, by the *Hays* case, from implementing LCA for DuoNeb®.	CMS does not utilize inherent reasonableness. They view it as a cumbersome process.	CMS does not currently utilize a functional equivalence standard.
Potential Future Use	If CMS prevails in the DC Circuit in the *Hays* case, it is likely to significantly expand its use of LCA, especially in the context of a comparative effectiveness regime. If CMS loses the *Hays* case, Congress is likely to expressly codify CMS' ability to use LCA authority. Even in the absence of Congressional action, CMS could, in theory, adopt LCA through notice and comment rulemaking and, by doing so, potentially insulate itself from legal challenge. CBO budget options white paper has proposed greater use of LCA.	Unlikely that CMS will expand its use of inherent reasonableness authority. However, if CMS is blocked (by a court or legislatively) from using LCA, it may view inherent reasonableness as the only available fallback, despite how cumbersome it is.	In theory, Congress could apply a functional equivalence standard outside of the OPPS transitional new drug or device pass-through. The statute quite clearly limits the prohibition on use of the standard for drugs or biologicals paid under the pass-through and not any other covered item. However, CMS would need a statutory basis to adopt the policy and would have to go through notice and comment rulemaking to implement it.

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