



**Medicare Authorities to Reduce Payment for Covered Items or Services**  
July 9, 2010

	<b>Least Costly Alternative</b>	<b>Inherent Reasonableness</b>	<b>Functional Equivalence</b>	<b>Comparison of ASP, Widely Available Market Price, and AMP</b>
<b>Description</b>	<p>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.</p>	<p>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.</p>	<p>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.</p>	<p>The OIG is mandated to compare average sales price (ASP) of drugs to the widely available market price and the average manufacturer price (AMP).</p> <p>If the OIG finds that the ASP for a drug exceeds the widely available market price or AMP by a certain percentage (currently 5%), HHS has the authority to disregard the ASP for the drug when setting its reimbursement amounts.</p> <p>In these cases where the difference is 5% or greater, the payment limit in the quarter following the transmittal of this information to the Secretary is the lesser of the widely available market price or 103 percent of AMP.</p>
<b>Examples of Use</b>	<p>Prostate cancer drugs such as Lupron® which are paid by reference to price of Zoladex®.</p> <p>COPD treatment DuoNeb®.</p>	<p>CMS used the authority in the 1970s to reduce payment for certain items of durable medical equipment (DME) but has not used it recently.</p>	<p>CMS invoked the authority to deny pass-through status to Aranesp®.</p>	<p>CMS has not yet invoked its authority to adjust ASP payment limits based on OIG's pricing comparison findings.</p>

<p><b>Statutory and Regulatory Basis</b></p>	<p>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.)</p> <p>2000 Advance Notice of Proposed Rulemaking (later withdrawn) proposing to permit CMS contractors to use LCA.</p> <p>Medicare Program Integrity Manual § 13.4.</p>	<p>Social Security Act § 1842(b)(8) and (9).</p> <p>42 C.F.R. § 405.502(a)(7), (g), and (h).</p>	<p>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).</p> <p>67 Fed. Reg. 66758 – 59 (Nov. 1, 2002).</p>	<p>Social Security Act § 1847A(d)(2)(B).</p> <p>42 C.F.R. § 414.904(d)(3).</p>
<p><b>Legal Risk</b></p>	<p>Significant legal risk for CMS. HHS earlier won a court case challenging the policy (solely on the basis that pharmaceutical manufacturers lacked standing to challenge the policy), (see TAP Pharmaceuticals v. Shalala, 163 F.3d 199 (4th Cir. 1998)). In 2008, HHS lost a District Court case challenging the policy. See Hays v. Leavitt, 583 F. Supp. 2d 62 (D.D.C. 2008). The government appealed Hays v. Leavitt to the D.C. Circuit.</p> <p>On December 22, 2009, the D.C. Circuit upheld the D.C. District Court's ruling that the statute "unambiguously forecloses" a Medicare</p>	<p>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.</p>	<p>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).</p> <p>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 §</p>	<p>No legal risk because CMS has clear statutory authority to make price adjustments to ASP based on the OIG's findings.</p>

	contractor's determination to use LCA policy. Hays v. Sebelius, 589 F.3d 1279 (D.C. Cir. 2009).		1833(t)(6)(F).	
<b>Current Status</b>	CMS contractors have been instructed to suspend and remove all LCA provisions in current LCDs and to adjudicate claims without using LCA for all Part B drugs.	CMS does not utilize inherent reasonableness. They view it as a cumbersome process.	CMS does not currently utilize a functional equivalence standard.	OIG issues a quarterly report to CMS comparing ASP and AMP, as well as analyzing the impact on Medicare reimbursement.
<b>Potential Future Use</b>	Given the recent D.C. Circuit ruling in the Hays case, Congress could decide 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, as the D.C. Circuit has ruled against CMS' use of LCA, CMS may view inherent reasonableness as an available fallback, despite how cumbersome it is to use.	In theory, Congress could apply a functional equivalence standard outside of the OPPTS 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.	CMS may at some point decide to use its authority to change ASP for a drug based on the OIG's comparison findings and on the impact such a modification could have on Medicare reimbursement.