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Local Coverage Determinations Cannot Be Used to Limit Reimbursement for Medicare Covered Drugs

Kristin Cilento Carter
410-347-7309
kccarter@ober.com

In an opinion issued on December 22, 2009, the United States Court of Appeals for the District of Columbia Circuit held that regional Medicare contractors are prohibited under the Medicare statute from utilizing local coverage determinations (LCDs) as a vehicle for limiting reimbursement for covered drugs.

In ***Hays v. Sebelius***, No. 1:08-cv-01032-HHK (D.C. Cir. Dec. 22, 2009) [PDF], a Medicare Part B beneficiary challenged a policy published in the Medicare Program Integrity Manual that permitted contractors to apply the "least costly alternative" approach when determining whether a treatment is "reasonable and necessary" in an LCD. *See* Medicare Program Integrity Manual § 13.4.A. Under the least costly alternative approach, Medicare reimburses for treatments only up to the price of the "reasonably feasible and medically appropriate" least costly alternative. This case arose when a LCD was issued to apply the least costly alternative policy to a nebulizer drug that provides a combination of two drugs in a single dose, which can be slightly more expensive than separate doses of the component drugs. The LCD provided that payment for the combined drug "[would] be based on the allowance for the least costly medically appropriate alternative," the two component drugs as administered separately. This LCD resulted in a price that is lower than the statutory Medicare reimbursement for covered drugs, which is 106% of the drug's average sales price. 42 U.S.C. § 1395w-3a(b)(1).

Under the Medicare Act, the Secretary of Health and Human Services ("Secretary") is permitted to delegate certain functions to regional Medicare contractors, including the drafting of LCDs, which are determinations as to "whether or not a particular item or service is covered" in the contractor's geographic area in accordance with the following provision:

> (a) Items or services specifically excluded. Notwithstanding any other provision of this subchapter, no payment may be made . . . for any expenses incurred for items or services--
> (1)(A) which, except for items and services described in a

Paul W. Kim

Robert E. Mazer

Christine M. Morse

Laurence B. Russell

Donna J. Senft

Susan A. Turner

Associates

Kristin Cilento Carter

Joshua J. Freemire

Mark A. Stanley

Lisa D. Stevenson

> succeeding subparagraph or additional preventive services . . . , are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning body member[.]

42 U.S.C. § 1395y(a)(1)(A). The Secretary argued that the term "reasonable and necessary" modifies the word "expenses" and, therefore, Medicare may decline to compensate providers for the marginal difference in price between a prescribed item or service and its least costly alternative. Finding the Secretary's interpretation to be improper, the Court held that the clause "reasonable and necessary" modifies the term "items and services" and, therefore, permits the Secretary to make only a binary coverage decision, namely to reimburse at the full statutory rate or not. The Court was further persuaded that the title of the statute, "[i]tems or services specifically excluded," along with the surrounding subsections, indicate that items and services, not expenses, must be reasonable and necessary to qualify for Medicare coverage. Moreover, the Court held that application of the "least costly alternative" policy is inconsistent with the Medicare Act's mandatory reimbursement formula that requires the Secretary to reimburse a covered drug at 106% of the average sales price for drugs within its billing and payment code. The Court noted that, if Congress had wanted to permit the Secretary to limit payment to the least costly alternative, it could have drafted the statute to include reimbursement formulas that were discretionary or based on the cost of an item or service's least costly therapeutic equivalents.

Ober|Kaler's Comments: While it is still unclear whether the Secretary will ask the D.C. Circuit Court of Appeals to reconsider its opinion, this opinion is expected to confine CMS' ability to limit reimbursement for covered items and services, including prescription drugs and durable medical equipment, where the reimbursement formula is established by statute. Moreover, this opinion clearly provides that LCDs should only set forth binary coverage decisions, *i.e.*, determining whether an item or service is reimbursable under Medicare, rather than being used as a vehicle for limiting reimbursement for covered items and services.