**Editorial**

**Medicare Drug Coverage: LMRP, CAC, and NCD**

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Are you confused by these unfamiliar acronyms? I was, until I began to sort through the process of how Medicare decides to pay for new drugs. I think that you might benefit from my recent review of this fascinating and arcane process.

First, a true or false question: Medicare does not pay for outpatient drugs.

If you’ve answered false, as most people probably have, you are wrong. In 2001 dollars, Medicare spent more than $7.5 billion for outpatient medications. I can explain how this process works, based largely on my review of a document from the Centers for Medicare and Medicaid Services (CMS), entitled “Health Care Industry Market Update.”

Although Medicare pays for drugs administered to hospitals and nursing homes under bundled payment rates, it does not usually pay for most outpatient prescription drugs. Medicare does, however, cover a limited number of drugs that are typically provided in hospital outpatient settings, dialysis centers, or doctors’ offices and that physicians or other providers purchase directly. This particular subset of drugs covered by Medicare in outpatient settings includes such products as:

- certain drugs for oral cancer and nausea.
- immunosuppressive drugs, especially those needed for organ-transplant patients.
- epoetin alfa, which is used primarily to treat anemia in patients with end-stage renal disease and cancer (this one product constituted Medicare’s largest outpatient drug expenditure and currently costs nearly $2 billion annually).
- osteoporosis drugs for which injection is required.
- certain vaccines for influenza, pneumonia, and hepatitis B.

Altogether, Medicare covers more than 450 outpatient prospective payment system drugs, but only 35 account for more than 90% of all spending on prescription drugs (by Medicare).

How, then, does Medicare decide which of these 450 covered drugs are accepted onto its outpatient formulary? Here is where our story gets interesting. According to the CMS document, “While the FDA approves a drug for marketing if it is safe and effective, CMS, on the other hand, acts as an insurer and determines whether it is appropriate for Medicare to pay for a drug.”

Medicare accomplishes this evaluation through what it calls a coverage-determination process. A new drug is examined to determine whether it improves net health outcomes in Medicare beneficiaries as well as, or better than, other available therapies and whether it therefore warrants expenditure of taxpayer dollars. These coverage decisions are actually made at the local level by Medicare contractors, fiscal intermediaries who process claims. Medicare allows these contractors some flexibility in making coverage decisions. Most new drugs are paid for without a specific review by the contractors. Coverage for certain drugs may be determined on a case-by-case basis if a new drug is brought to the contractor’s attention or if the contractor “becomes aware of the new drug when reviewing trends in previously paid claims.” In other words, if a new product gets on the Medicare radar, it might trigger a local medical review policy (LMRP).

During the policy determination, a contractor gathers and examines the clinical evidence and determines whether the drug has a benefit category, is excluded by statute, and is reasonable and necessary. During the LMRP, the carrier may be required to consult with the Carrier Advisory Committee (CAC), a panel of local physicians. The local physicians advise the local fiscal intermediary throughout the LMRP determination.

This process may also include a period of public comment, an open meeting, and other forms of communication between providers, patients, and the federal government. In October 2002, Medicare required each contractor to develop a special procedure to allow Medicare beneficiaries and providers to submit suggested revisions to the LMRP process.

At times, a national policy might be necessary to cover a particularly important new product. Medicare may then call for a national coverage determination (NCD), which supersedes all local policies. As it turns out, most NCDs are actually triggered by manufacturers, but occasionally Medicare initiates a coverage determination when the item or service raises significant scientific issues, when it might have a substantial effect on the Medicare population, or when there are major variations in local policies.

CMS may conduct a complete evidence-based review to determine whether the drug is clinically effective and thus reasonable and necessary. At the beginning of each NCD, Medicare posts a tracking sheet and allows for 30 days of comments to be reviewed during the decision-making process. According to these official documents, each NCD includes a complete technology assessment, including the collection and careful evaluation of all relevant data.

For more complex NCD assessments, Medicare can request external assistance in the form of an independent review from the Medicare Advisory Committee (MCAC). The MCAC can issue a decision memorandum summarizing the analysis and informing the public of the intent to implement the policy decision. There may be as many as 270 days between the issuance by the NCD from the MCAC and the deadline by which individual Medicare contractors must reflect the coverage decision in their processing systems. Simply put, especially important new products may trigger a top-down, evidence-based review at the

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national level from an independent review board that must answer to Medicare.

What about Medicare payment for drugs administered by physicians, especially in offices? Medicare pays for some covered drugs administered as part of a physician office visit. These payments are made to physicians through local carriers and contractors to Medicare. Typically, drug payments by carriers to physicians are based on the lower of the billed charges, or 95% of the average wholesale price (AWP). For the calendar year 2001, the top 25 drugs paid for by Medicare carriers accounted for approximately 80% of all Medicare carrier drug spending. Typical drugs paid for by Medicare carriers in outpatient settings, in addition to epoetin alfa, include leuprolide acetate (Lupron®, TAP), ipratropium (Atrovent®, Boehringer Ingelheim), goserelin acetate (Zoladex®, AstraZeneca), albuterol sulfate (e.g., Proventil®, Schering), and rituximab (Rituxan®, IDEC/Genentech). Taken together, these six products account for most Medicare outpatient drug expenditures.

So there you have it—LMRP, CAC, and NCD. Here is the bottom line, however:

“New drugs that represent incremental or marginal changes to existing technology and whose cost is similar to existing technology are almost always automatically covered by Medicare contractors.”

New technologies that are significantly more expensive than existing technology may take more time for additional costs to be recognized under Medicare’s payment system. Medicare, however, almost always begins making some type of payment after a product has been approved by the FDA.

So the next time someone at a P&T committee meeting asks you whether Medicare covers outpatient drugs, you will have a correct and comprehensive answer.

As usual, I am interested in your views. My email address is david.nash@jefferson.edu.

REFERENCE


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