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Patients May Lose Out on New Cancer Therapy Options

For the past several years the oncology community has responded to numerous initiatives launched by the Clinton Administration or the Health Care Financing Administration that threatened the financial stability of the cancer care delivery system. The ambulatory payment classification (APC) proposal, various budgetary proposals dealing with average wholesale price (AWP) and Medicare drug payments, and most recently the Administration's effort to redefine AWP have all threatened access to or choice of care and ultimately the quality of care.

In May HCFA published a notice of intent to publish a proposed rule on criteria for making Medicare coverage decisions. This "notice of intent to publish a proposed rule" has not received as much attention as the Administration's economic proposals, although it represents a potentially major reduction in Medicare benefits compared to current policy by restricting the availability of newer cancer therapies.

Traditionally, Medicare generally covers only those items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." HCFA may issue policies ruling that certain items and services are not considered reasonable and necessary, or are considered so only under some specific circumstances; however, the agency has never issued regulations defining "reasonable and necessary." The new notice proposes two factors that would be considered in deciding a "reasonable and necessary" covered benefit.

First, Medicare would cover an item or service only if it was "medically beneficial for a defined population." HCFA cites reduction of mortality and extension-of-life expectancy as possible measured health outcomes to meet the requirement for rigorous proof that the new standard is met. Too much risk of toxicity or adverse side effects could negatively impact determination of medical benefit. Typically, the risk-benefit discussions and decisions to treat occur between the physician and patient and not with a federal agency. This approach is potentially very restrictive and in cancer care could block coverage for new chemotherapy or supportive care until such objective evidence is produced. Most new anticancer drugs initially gain approval from the Food and Drug Administration by demonstrating objective tumor response or reduced symptoms related to cancer. Under this proposal, HCFA could narrowly define medical benefit, undermining the ability of the medical oncologist to make new therapy options available to Medicare beneficiaries.

Second, once 'medically beneficial' is proven, Medicare would provide coverage if it were further established that the new item or service has "added value." Clearly, a breakthrough therapy or new clinical modality would have "added value." The only other way to meet this requirement is if the item or service results in the same or lower cost of the current Medicare-covered alternative. The proposal makes cost-effectiveness the major factor in coverage for most items and services, while in current coverage, criteria cost-effectiveness is not a consideration. This requirement almost certainly will delay development and increase the cost of producing new therapies in order to produce data on cost-effectiveness. Thus, Medicare beneficiaries could be denied access to new technologies. In fact, such a policy would discourage the research that has led to incremental improvements we have seen over the last 30 years.

No one would argue with the requirement that a medical service ought to have medical benefit and should add value to patient care. However, it is likely to take years of study and experience to generate outcome evidence to meet the standards suggested by HCFA. Also, the potential restrictions on coverage of newer therapies under this proposal would be detrimental to Medicare beneficiaries. HCFA should not proceed further with this proposal.

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