Medicare Advantage: Reforms Needed to Ensure Access to Clinical Trials

Clinical trials are the foundation of progress in the treatment of cancer. Consideration of participation in clinical trial therapy is often the first, best option for a cancer patient. For diseases without effective treatments, a clinical trial may be the only opportunity for treatment. The rigor of clinical trial care serves the patients who participate in them, and the knowledge from trials allows advancement in therapeutic options for future cancer patients.

The 2000 Executive Memorandum that authorized Medicare payment for routine costs of clinical trials provided landmark recognition of the critical role of clinical trials in patient care. However, a loophole in the regulations governing Medicare Advantage (MA) plans has created a disparity in the way that clinical trial services are covered for MA enrollees. MA plans are the private health plans in which Medicare participants can enroll to receive their Medicare coverage.

Medicare Advantage

The Medicare Advantage (MA) program enables Medicare beneficiaries to choose health care coverage through private health plans rather than the traditional fee-for-service model. In 2008, 10.1 million people were enrolled in MA plans, which represents approximately 23% of Medicare beneficiaries overall. MA penetration varies in different parts of the country, ranging from a low of 1% in Alaska and 3% in Vermont to as much as 37% in Arizona and Pennsylvania, and 40% in Oregon.⁴

Before 2000, some Medicare contractors customarily denied coverage for routine patient care costs associated with clinical trials, citing the experimental nature of such treatment. In 2000, the cancer community worked with the Clinton administration to assure these routine costs would be recognized as a covered program benefit. The result was an Executive Memorandum issued in June of that year that authorized Medicare payment for routine patient care costs associated with clinical trial participation, as well as for related medical complications. The Centers for Medicare and Medicaid Services (CMS) defines routine costs as: 1) items or services that are typically provided absent a clinical trial (eg, conventional care); 2) items or services required solely for the provision of the investigational item or service (eg, administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and 3) items or services needed for reasonable and necessary care arising from

the provision of an investigational item or service—in particular, for the diagnosis or treatment of complications.¹ Costs for the agent under investigation are not covered and would be considered the obligation of the trial sponsor.

While this policy was immediately implemented on the fee-for-service (FFS) side of Medicare, CMS was required to follow legal mandates that prohibit imposition of any significant new cost on MA plans in the middle of the contract year. CMS indicated it would address necessary changes in MA capitation rates in subsequent years through regulation. CMS required MA enrollees to revert to FFS Medicare coverage until this change was made. CMS has never adjusted the MA capitation rates to account for any costs related to the clinical trials coverage requirement. As a result, MA enrollees continue to receive FFS coverage for clinical trial–related costs. This often has significant financial implications, given that FFS coverage involves a 20% coinsurance and deductible, while MA plans typically do not.

To appreciate the significant and positive impact of the 2000 Executive Memorandum, we can look at findings by researchers at the Southwest Oncology Group (SWOG), one of several National Cancer Institute–funded cancer clinical trial cooperatives. Before 2000, although seniors accounted for 63% of cancer patients in the United States, the proportion of seniors in SWOG trials was only 25%. In 2001 to 2003, that proportion had increased to 38%. After considering other possible influencing factors, researchers concluded that the Medicare reimbursement policy had a positive impact for patients who had other coverage to assist with coinsurance costs.² The study concludes that “patients on Medicare-managed care plans, who generally do not have supplemental insurance, often cannot afford the coinsurance costs for clinical trial participation.”

What Does This Mean for Patients?

As coverage of clinical trials under Medicare continues on an FFS basis, providers receive FFS-based payments for the routine costs of clinical trials. However, this also means that enrollees are subject to FFS coinsurance requirements, which are typically much higher than their Medicare Advantage coinsurance obligations. Under Medicare FFS, beneficiaries must pay 20% of the Medicare-approved amount. Whereas original Medicare beneficiaries often carry a Medigap policy that will cover the coinsurance, MA plan beneficiaries do not have access to Medigap plans. Indeed, avoiding the cost of secondary insurance is an important reason why many seniors choose MA plans in the first place.

Cost is one reason why some older patients who meet the criteria for Medicare-qualifying clinical trials eschew

participation. In addition to the SWOG study, a University of Pittsburgh Cancer Institute study announced in September 2008 found that at one regional cancer center in 2007 alone, 103 Medicare-enrolled patients screened for qualifying clinical trials and, when informed of their anticipated costs, declined participation because of the financial burden.³

The University of Pittsburgh Cancer Institute study concluded that because of the significant personal expense necessitated by the CMS requirement to return to FFS Medicare, the disparity between eligibility of Medicare beneficiaries for clinical trials and clinical trial representation is likely related.³ “Under-representation affects our ability to provide older patients with innovative, cutting-edge care,” says Peter G. Ellis, MD, director, Medical Oncology Network, University of Pittsburgh Medical Center Cancer Centers. “In the Pittsburgh area, which has one of the highest rates of Medicare patients (60%) in the country, and with half of them on MA plans, approximately one third of our patients have no access to trials on which we spend huge amounts of time and effort to further the pace of research.”

While the National Cancer Institute clearly emphasizes the importance of federally sponsored clinical research, the CMS payment policy has inadvertently constructed a barrier between MA enrollees and cutting-edge treatment. Between 2003 and 2008, the number of individuals in MA plans rose

from 5.3 million to 10.1 million.⁴ If this sharp trend continues, a greater percentage of Medicare enrollees will be affected by the CMS clinical trial payment policy as it relates to private health plans.

ASCO and other members of the cancer community have formally requested resolution at CMS. In 2007, as CMS considered revisions to the clinical trials coverage policy, ASCO urged the agency to address this issue to ensure that financial barriers do not continue to translate into access barriers for patients who may benefit from enrollment in clinical trials. To date, however, CMS has not heeded these requests.

“The CMS coverage group has done their part to require MA organizations to follow the CMS national coverage determination,” says Sam Turner, a Washington, DC–based attorney. “However, CMS payment policy hasn’t moved to adjust payment levels to capitated plans.”

Resources

Detailed information on the Medicare clinical trial policy is available at <http://www.cms.hhs.gov/ClinicalTrialPolicies/>

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