

Attachment

Additional AdvaMed Comments on the May 16, 2000, Notice of Intent to Publish Proposed Rule on Medicare Coverage Criteria

June 30, 2000

I. Practice of Medicine

The Notice would have the unfortunate effect of centrally controlling the practice of medicine. It would do so by limiting the items and services eligible for Medicare reimbursement in specific treatment modalities and by increasing the evidentiary burdens required for coverage. In particular, the Notice requires that new products demonstrate "added value" for defined populations when there is a Medicare-covered alternative. To do so would limit beneficiary access to appropriate medical care.

AdvaMed's concerns:

1. In the four-step process that is set forth in the Notice, HCFA is proposing to pick—from an array of possible treatments and diagnostics—particular technologies that it believes should be used by physicians and other health care professionals in treating Medicare beneficiaries. Technologies that are judged to be less beneficial (or more costly) by HCFA coverage officials will be dropped from coverage.

Currently, HCFA does not drop from coverage the various treatments among which physicians may choose to treat their patients. To restrict coverage to one treatment selected by HCFA—and to deny coverage to other treatments which medical practitioners may prefer for an individual patient—would inappropriately deny patients and physicians access to the medical "tools" that they need and that are currently available to them.

HCFA's current approach—to cover a number of medically beneficial items and services, and to make use of utilization controls and payment incentives—ensures greater patient access to appropriate care and more responsiveness to real-time information on the effectiveness (and relative effectiveness) of covered services.

2. The Notice is too prescriptive with respect to the types and levels of evidence that will be required for coverage. There will often be insufficient information to make conclusive judgments of this sort early in a new technology's life cycle. Yet the Notice indicates that HCFA would deny coverage in the absence of conclusive evidence. Here again, this approach threatens highly promising technologies and, by prohibiting them, the Notice halts the process of information-generation that emerges from routine, everyday use.

3. The law does not require that new medical technologies surpass existing ones in order to be covered.

II. Cost as a Coverage Criterion

The Notice includes cost as a coverage criterion and requires new products to be equivalent or lower in cost when there is a Medicare-covered alternative of "equivalent benefit." To do this would restrict beneficiary access to appropriate care.

AdvaMed's concerns:

1. In the 35 years of Medicare's history, cost has not been used to deny beneficiaries access to "reasonable and necessary" medical care. This is not to say that Medicare has not made use of utilization controls or the many payment levers at its disposal to ensure that covered services are appropriately used. The Medicare statute sets out categories of covered benefits, and it prohibits payment for items and services that are not "reasonable and necessary." There is nothing in the law authorizing federal officials to deny beneficiaries access to appropriate medical care because of its cost.
2. It is not practical to factor in costs during the coverage process, since new technologies will probably be associated with higher costs—due to the illness of patients who typically first use the new technology, as well as the higher costs usually associated with the first iterations of new technology. It is further impractical to include cost as a Medicare coverage criterion because it would require resources and expertise that are beyond the capability of the agency. Reserving cost considerations for the payment context—rather than coverage—works to maximize patient access to care, it rewards technologies that can demonstrate their value in the marketplace (both in medical and in economic terms), and it promotes continuing research on the effectiveness of alternative treatments.
3. HCFA's four-step process would produce a situation where incremental improvements are not covered if they produce incremental increases in cost.
4. HCFA has sufficient tools available in the payment area to factor in cost considerations. It will soon implement a prospective payment system for hospital outpatient services; it also has cost control systems in place for inpatient, nursing home, and physician services, among others. In addition, Congress limits total Medicare spending annually.
5. HCFA should, instead, develop coverage criteria that empower beneficiaries and physicians to choose from a variety of beneficial treatments, matching the appropriate treatment with the needs of the individual patient. To restrict the number of treatments that are made available, or to prescribe which particular treatment should be used for an individual patient, is not good policy. HCFA's coverage decisions should reflect the marketplace value of the various treatment options that exist.

III. Increased Burden of Evidence

The Notice requires sufficient evidence that demonstrates that the item or service is medically beneficial for the defined population. Unfortunately, the Agency—as well as the Medicare Coverage Advisory Committee—has often made clear that "sufficient evidence" means randomized controlled clinical trials. Such data are rare, and obtaining them can be extraordinarily expensive and time-consuming. The net effect is two-fold: patients must endure delays, and the requirement itself becomes a barrier to entry for new technologies, especially from highly-innovative smaller companies.

AdvaMed's concerns:

1. The Notice is very clear about what happens to technologies that do not offer "sufficient evidence"—they do not proceed beyond the first-step of the proposed four-step Medicare coverage process. In effect, they are not covered, and they cannot be made available to Medicare beneficiaries.
2. To date, "sufficient evidence" appears to be defined both by HCFA and by MCAC as meaning randomized controlled clinical trials. Though other types of evidence are technically not eliminated, the clear preference of both entities is the RCT—in fact, often multiple and extremely rigorous RCTs. We believe this represents more than simply movement upward through the traditional "hierarchy" of evidence; it represents a clear and growing demand for absolute scientific proof of medical benefit.
3. Two other aspects of HCFA's extraordinarily high demand for evidence are worth noting. One involves the agency's reference in the Notice to providing evidence that proves the technology adds benefit to the "defined population." This is the question of external validity. The other involves its requirement that evidence be provided that shows the product superior to other products. In both cases, these demands would further heighten the evidentiary burden on device manufacturers and would result in diminished beneficiary access to promising medical technologies.
4. Many evidence types are appropriate for coverage determinations, in AdvaMed's view. As noted in the cover letter, this can include randomized controlled clinical trials. But it can also include other evidence types. Given the wide diversity of medical technologies, conditions, and illnesses, we believe that no one type of evidence should be required for coverage decisions.
5. Standards of evidence that are put in place to guide coverage decisions should be sufficient to demonstrate the effectiveness of the medical technology or procedure under review. Clinical evidence should be reasonable, clinically relevant, and cooperatively developed with those practitioners and product innovators who know the technology best. Further, evidentiary standards should take into account practical impediments (e.g. time, cost, patient impact) to the development of this information.