

Commentary on the reimbursement paradox

Nancy L. Reaven; Judy Rosenbloom

Reimbursement policies are a critical step in the incorporation of new technologies and therapies into the clinical armamentarium. Reimbursement is an umbrella concept describing the process to manage and pay for healthcare services, including benefit coverage, coding, and payment processes. The technologies and services used in therapeutic temperature management are not directly reimbursed, leading to challenges by hospitals and physicians that the services are too expensive to use. The reimbursement models used in the United States make it increasingly difficult for new technologies and therapies to gain direct reimbursement, part of a strategy by insurers, including Medicare and

private insurance companies, to manage access to health care services. Insurers, physicians, hospitals, and other providers face conflicting financial incentives in current reimbursement systems. Aligning the financial incentives underlying reimbursement systems is necessary to adequately support new technologies of merit. (Crit Care Med 2009; 37[Suppl.]:S285–S289)

KEY WORDS: add-on payments; coverage; coding; diagnosis-related groups; Medicare; Medicare severity-related groups; payment; normothermia; reimbursement; therapeutic temperature management

In an issue of the supplement devoted to all things clinical about temperature management and its relationship to the physiology of cardiac arrest, stroke, traumatic brain injury, and a host of other clinical conditions, why include a contribution on reimbursement? What does reimbursement have to do with the important clinical effects of managing, maintaining, or lowering body temperature?

This is a reasonable question, because we typically separate the clinical impact of therapies and technologies and the practical realities of how they are paid for (and how much they are worth) into separate conceptual buckets. Bucket 1 is the realm of clinicians, scientists, and engineers investigating, testing, writing, and reading about how a technology and the therapy that uses it change the cascade of clinical events in illness or injury and how, when the technology or therapy is good and useful, it actually improves the outcome of that clinical cascade. Bucket 2 is the realm of insurance plans, hospital

administrators, manufacturers, and physician administrators trying to negotiate the slippery slope of sales prices and payments, billing codes, and coverage policies. Reimbursement is the set of practical decisions, processes, and activities that take a new technology or therapy from being merely an interesting innovation or improvement to its ultimate place in the clinical armamentarium.

How Did Reimbursement Get to Be So Important?

Reimbursement is an umbrella concept describing the process to manage and pay for healthcare services. At its core, the process involves three broad elements: the establishment of benefit coverage, the assignment of codes, and the determination of payment. Medicare and private insurers (e.g., Blue Cross, Blue Shield, Aetna) use coverage policies to determine which therapies and technologies health insurance will pay for. Codes are used to report the therapy and the clinical circumstance necessitating its use. Payment is established through specific reimbursement methods and budgetary processes that are specific to the insurer. Medicare, for example, uses distinctive payment approaches that are often mimicked by private insurers, but private insurers use their own methods as well. These three elements of our reimbursement system—coverage, coding, and payment—operate somewhat independently of each other; but their integration is an essential part of obtaining payment.

Without any one of these elements, a provider will not be paid for services rendered.

Over the past several decades, reimbursement policies have increasingly been used to manage access to new technologies and therapies in addition to directing how to pay for them. Nowhere is this more evident than in the evolving coverage criteria under the Medicare program. Until just a few years ago, the Centers for Medicare and Medicaid Services (CMS), the U.S. federal regulatory body governing Medicare and Medicaid, had two responses to new therapies it reviewed for coverage: “coverage” or “noncoverage.” Starting in 2006, under guidance issued by the agency, CMS instituted additional categories of decisions under an umbrella policy called Coverage with Evidence Development (1). Along with the new coverage decision categories came new evidentiary requirements with a focus on determining how the new therapy or technology improved the clinical outcomes of patients compared with existing approaches. Although this guidance was not heralded as a fundamental change, in fact the CMS has turned traditional reimbursement policy making on its head. In only a few years, we have gone from CMS coverage approval based on Food and Drug Administration–determined clinical efficacy and safety combined with CMS determination that the technology or therapy met the minimum criteria for benefit coverage, to a policy that also requires proof that the new technology is superior to existing

From Strategic Health Resources, La Cañada, CA; and JR Associates, Reseda, CA.

No financial support was provided to either author for the work involved in this manuscript. Nancy L. Reaven has been paid as a consultant to Medivance, Inc, and Alsus Corporation. Judy Rosenbloom has been paid as a consultant to Medivance, Inc, and Alsus Corporation.

For information regarding this article, E-mail: nancy.reaven@strathealth.com

Copyright © 2009 by the Society of Critical Care Medicine and Lippincott Williams & Wilkins

DOI: 10.1097/CCM.0b013e3181aa6288

approaches with respect to measurable clinical outcomes.

This fundamental shift in policy begs the question: if new therapies are better than existing approaches, do we have an obligation to pay more for them? Furthermore, where does (or should) cost containment fit into the reimbursement equation? Given that patients hospitalized for cardiac arrest, stroke, or traumatic brain injury often have long and costly hospital stays, should payment take into account new therapies that may reduce the cost burden?

Indeed, this change in the basic requirements of coverage policy has deepened an existing chasm between how we pay for new technologies and therapies and what we decide should be covered under benefit policies. To explore the basis of this chasm, we need to review the prevailing methods of payment for new technologies generally and for therapeutic temperature management specifically.

Payment Models for Therapeutic Temperature Management

Physician Payments. CMS establishes payments for physicians based on a fee schedule called the Resource Based Relative Value System. Virtually all private insurers mimic this system. Current Procedural Terminology (CPT) codes, reported by physicians, are linked to payment through the assignment of a relative weighting algorithm. Each CPT code receives a resource-based relative value weight based on three criteria: (1) the amount and complexity of physician work; (2) the cost to “produce” the procedure, a concept called *practice expense*; and (3) allocated estimated malpractice costs. These weights are assigned by the Relative Value Scale Update Committee, which includes representatives from many of the medical specialty societies and is operated by the American Medical Association. Together, they act as an expert panel in developing relative value recommendations for CMS to consider. The relative weight is multiplied by an annually adjusted conversion factor to calculate the actual physician payment for a given CPT code.

Physicians do not receive additional payments for performing new procedures unless there is a new CPT code created to describe the procedure or the weighting algorithm of an existing code is changed to reflect changes in one of the three underlying criteria. In all events this is a

Table 1. Current Procedural Terminology (CPT) codes and national average Medicare payments to physicians for critical care services

CPT Code	Description	2008 Medicare National Payment
99291	Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 mins	\$204
99292	Critical care, each additional 30 mins (list separately in addition to code for primary service)	\$102

lengthy process, taking a minimum of 2 years subsequent to the widespread introduction of the new technology. Currently, the physician work associated with hypothermia induction and temperature management is not separately reportable by a specific CPT code. Rather, the additional time and effort associated with temperature management may be captured by reporting CPT critical care codes, which are reported according to the amount of time a physician spends providing critical care to a patient. These codes include specific services that are integral to critical care, such as the review and analysis of physiologic data, ventilator management, and certain vascular access procedures. Critical care codes are described in Table 1. Given the spectrum of possible clinical applications for therapeutic temperature management and the complexity of physician work associated with this treatment, it is debatable whether the general critical care codes are adequate to describe this service. However, in the absence of a specific CPT code covering therapeutic temperature management, the work performed by physicians is reimbursable only under the existing critical care codes.

Hospital payments. Payment methods for healthcare facilities are specific to the setting of care; thus, payments for hospital inpatient services are calculated differently than hospital outpatient services, services provided in physicians’ offices, or services provided in patients’ homes. Because virtually all of the current applications for therapeutic temperature management take place in the inpatient setting, the payment systems for inpatient services are most relevant for this discussion. The Medicare program uses the Inpatient Prospective Payment System to reimburse hospitals for inpatient services based on diagnosis related groups (DRGs). Within DRGs, diagnoses and procedures are classified into clinically cohesive groups that, on average, exhibit similar use of hospital resources and length of stay. Under DRGs, hospitals receive a fixed payment

designed to pay for the entire hospital admission, irrespective of actual costs or length of stay. (There are some financial protections for hospitals for individual cases where extraordinarily high costs reach a statistically determined “outlier” threshold.) The payment amount assigned to each DRG is based on average resource use and specific hospital characteristics. The DRG payment rates are intended to cover the costs that “efficient” hospitals would incur in delivering high-quality care, thereby rewarding hospitals whose costs fall below the payment rates and penalizing those with costs above the payment rates.

To address changes in the cost of inpatient care, including the use of new technologies like therapeutic temperature management, CMS annually reviews hospital claims and charge data and the collection of diagnoses and procedures reported within the DRG category. However, the information used by CMS is based on inpatient claims provided 2 yrs prior, which is nearly 3 yrs old by the time CMS issues DRG payment adjustments. By definition, revisions to DRG payments do not reflect the cost of new technologies or those adopted by hospitals in the previous 2 yrs. Furthermore, the integration of new therapies and associated costs into DRG adjustments can only be captured in the claims data if there is an available *International Classification of Disease, Ninth Revision (ICD-9)* procedure code for the hospital to report. The induction of hypothermia can be reported with ICD-9 procedure code 99.81. Importantly, specific medical record documentation by physicians about their clinical management of patients requiring controlled hypothermia will help coders capture ICD-9 code 99.81 in the claims data. The increased documentation of this code can potentially help in future rate setting. However, an ICD-9 code is not available to report the therapeutic management of fever (normothermia).

In an effort to specifically accommodate the financial stresses of new technol-

ogies on hospitals, CMS developed a mechanism of add-on payments to supplement DRG-based payments for new technologies (2). CMS considers a technology to be new if $\leq 2-3$ yrs have passed from the date when the technology was first released into the market and the request for add-on payment. The idea behind add-on payments involves paying an incremental amount for the cost of the new technology for a prescribed period of time, until such point when the new technology can be included in the DRG itself. CMS identified this time period to be 2-3 yrs. In addition to being new, to qualify for an add-on payment, a technology must also represent a "substantial clinical improvement" over existing technologies. Finally, the technology must be considered to be high cost, by meeting a specific cost-threshold. The effectiveness of the program remains to be seen. According to the U.S. Government Accountability Office, as of fiscal year 2007 CMS had received 25 applications for add-on payments, an average of about five per year since fiscal year 2002 (3). The majority of new technology add-on payment applications have been rejected because the technology failed to meet the newness criterion. Of the 25 applications received, CMS evaluated 14 under the cost criterion. Of these 14 technologies, CMS approved seven for new technology add-on payments. The technologies used in therapeutic temperature management do not meet the cost threshold and therefore do not qualify for the add-on payment under Medicare.

In fiscal year 2008, CMS transitioned from DRGs to Medicare Severity DRGs to recognize patients' severity of illness in payment calculations. Severity is measured by the presence or absence of a complication or comorbidity (CC) or a major CC. Under Medicare Severity DRGs, hospitals receive higher payments for treating more severely ill patients who require more resources and lower payments for less severe conditions. These acute conditions are designated by ICD-9 diagnosis codes that must be documented in the medical record by treating physicians. Many of the conditions associated with therapeutic temperature management are designated for the CC or major CC list, such as cardiac arrest, acute myocardial infarction, stroke, and brain trauma. This transition has ameliorated, to some extent, the cost impact of unreimbursed technologies.

Private Insurance Payment Systems for Inpatient Care. Some private insurers

reimburse hospital inpatient services using Medicare's former DRG system. Others use a per diem system, where payment is paid based on a negotiated price for each day of a patient's treatment for a particular condition. Still others use a "case rate" method, a variant of the DRG system in which payment is based on a specific procedure and may include physician services as well. The primary difference between Medicare and private insurers' approaches to payment has to do with Medicare's market strength and size. As a federal program, Medicare establishes a standard policy across the full Medicare spectrum of patients and services, whereas private insurers negotiate reimbursement specifics with each hospital or hospital system. Thus, there is wide variation in private insurer policies. The Medicare Severity DRG system is so new that private insurers have not yet adopted the system. However, it is reasonable to expect that those private insurers that currently use the former DRG systems may shift to Medicare Severity DRGs.

In sum, our payment systems have limited mechanisms for financially recognizing and rewarding effective new technologies and therapies in a timely way, even for those technologies that are judged by Medicare and private insurers to be worthy of benefit coverage. For hospitals, the limitations of current reimbursement systems are most pronounced in any of three following circumstances: new technologies used predominantly in inpatient care and covered under fixed reimbursement (as described at length previously); new technologies that create positive externalities (i.e., the hospital pays the cost, but the economic benefits accrue to another party, such as the insurer or the patient); and new technologies that improve the effectiveness of nursing care (the hospital is expected to bear nursing costs). Therapeutic temperature management technologies fit all three. Consequently, despite wide consensus about the clinical utility of therapeutic hypothermia in certain clinical conditions (4, 5) and emerging consensus about the utility of managed normothermia in others (6-11), there is no pathway for separate payment for the technologies that are used to achieve this clinical utility.

The Paradox of Reimbursement

In a system where physician practices and hospitals must function as businesses, why should a hospital opt for a

high-cost technology that improves clinical results, when much of the financial benefit may go somewhere else? Given the rapid development of new technology and the fixed nature of reimbursement, to do so persistently would be financial suicide for a hospital. When extra reimbursement is *not* available for a new technology, each hospital has to carefully balance the clinical impact of a new technology or therapy against potential cost reductions or the market appeal potential if the hospital can advertise that it is currently offering the "best new thing." In the case of exciting new technologies, like robotic surgical systems or state-of-the-art diagnostics, this calculation sometimes works in the technology's favor. However, many new therapies are hard to brand this way. Therapeutic temperature management to protect cognitive function after a stroke or traumatic brain injury is one of these. Is it useful? Yes. Is it sexy? No.

Physicians are affected by the same paradoxical payment environment. If a new procedure is less time-consuming to perform, requires fewer clinical personnel, or uses less expensive equipment or supplies, the reimbursement received by the physician is less, even if the clinical outcomes for patients are better and the procedure reduces downstream care and is more efficient for the system as a whole. Again, in a system where all of the financial incentives are aligned, this makes perfect sense. It's exactly how it should work. However, in the current U.S. system, where physicians make money by seeing more patients and doing more procedures, the financial incentives are not well aligned.

Economics of Temperature Management

Examining the financial impact of therapeutic temperature management for cardiac arrest, stroke, and traumatic brain injury helps to illuminate this paradox. In a recent study in Germany, Storm et al (12) found that therapeutic hypothermia was associated with reductions in total hospital length of stay, intensive care unit length of stay, and time on ventilator in patients with out-of-hospital cardiac arrest. Therapeutic hypothermia was also associated with better cerebral performance category scores, a measure of cognitive disability (12). In the multivariate analysis conducted by Storm et al, only hypothermia and low Acute Physiology and Chronic Health Evaluation score at admission were inde-

pendent predictors of the shorter intensive care unit length of stay. Graf et al (13) found that cardiac arrest patients discharged without significant neurologic difficulties had Health-Related Quality of Life scores just slightly lower than their apparently healthy age and gender-matched cohort at 5 yrs postdischarge, and total costs per life year gained €9,817 during the same time period. The authors calculated a quality-adjusted life year gain associated with the absence of significant neurologic difficulties to be €14,487, well within guiding parameters of cost-effective interventions. In an independent analysis, Polderman (14) estimated the quality-adjusted life year gained with therapeutic hypothermia to be <€900.

In our own research (15, 16), we have documented that fever associated with stroke and traumatic brain injury is associated with worse clinical outcomes and longer intensive care unit and total hospital lengths of stay. There is some evidence, particularly in stroke patients, that managing body temperature may improve cognitive and functional outcomes after discharge (17), and simulation models have been developed to estimate the reduction in long-term costs attributable to improved functional outcomes (18). The documented benefits of therapeutic hypothermia and managed normothermia—reduction in disabilities and improved quality of life—accrue, paradoxically, to the various stakeholders who do not pay for the extra costs incurred in therapeutic temperature management.

It's not a great surprise, then, that some U.S. hospitals balk at the cost of sophisticated temperature management systems. In effect, hospitals and physicians have to be persuaded to use new technologies even if they are not going to be paid for these technologies and even in situations where they will lose money by using them. Hospitals and physicians are supposed to be willing to do this in the interests of better clinical care. However, why are these entities expected to carry the financial burden for technologies that are measurable improvements in clinical care?

The answer goes to the core of the contradiction in the U.S. healthcare financing and delivery systems: the misalignment in financial incentives among the entities that provide insurance benefits and the entities that provide healthcare services. Insurers, both public (like Medicare) and private (like Aetna), are

trying to provide benefit coverage in the face of ever-growing costs. Some costs are largely unavoidable, like the naturally occurring costs of an aging population; some costs are technology-related, like new expensive devices and drugs; and some costs are attributable to providers, hospitals, physicians, and others providing many services, some of them possibly unnecessary and many of them provided inefficiently. To try to manage the financial risk that insurers call "underwriting," they have developed reimbursement systems that shift their risk to the providers of care and to patients. Simultaneously, providers of healthcare services—hospitals, physicians and others—are trying to survive in an environment of constrained reimbursement and increasing requirements for data reporting, expensive quality improvement measures, and other attempts to get them to standardize their business and clinical practices. In the midst of this great divide sit the manufacturers of technologies, both devices and drugs, trying to get their technologies approved by the insurers on one side of this divide and then sold to and used by the providers on the other side of the divide. This leads to a strange reality in which manufacturers take on the role of reimbursement advocate; manufacturers lead the push for new codes and higher payments to make their technologies more attractive to doctors and hospitals.

So what is to be done? How do we support interesting therapies that have little or no chance of reimbursement? How do we convince hospitals to buy things that they will not get paid for, maybe for years or ever? How do we persuade doctors to use complex new technologies requiring über skills when no extra payment is attached? These queries go to the heart of the debate between health care as a privilege, as in a free market where it has become a profitable business and patients have become customers, or as a right, as in Canada. As the public debate continues about how to fix our ailing healthcare system, we have to give careful thought to creating reimbursement systems that are closely aligned with the goals of the system itself and not in conflict with them. We have to create reimbursement systems that pay fairly for the value that therapies and technologies bring to the public while sustaining new innovation, that consciously take into account the complexity of decision making and skill required by physicians to use these therapies and

technologies, and that deliberately provide for the institutions that buy them. This is not so hard to do if we keep patient care the mission and the financial, business, and reimbursement specifics truly aligned to that mission.

REFERENCES

1. Guidance for the public, industry, and CMS staff. National coverage determinations with data collection as a condition of coverage: coverage with evidence development. Document issued on July 12, 2006. www.cms.hhs.gov/mcd/npcv_view_document.asp?id=8. Accessed February 6, 2009
2. Swygert T, Treitel M: Overview of the Medicare inpatient prospective payment system new technology add-on payment provision. Paper presented at: New Technology Informational Workshop, Baltimore, MD, February 22, 2007
3. GAO report: Medicare inpatient hospital payments: CMS has used external data for new technologies in certain instances and Medicare remains primary data source. Washington, DC: US Government Accountability Office, 2007
4. Nolan JP, Morley TL, Vanden Hoek TL, et al: Therapeutic hypothermia after cardiac arrest: An advisory statement by the Advanced Life Support Task Force of the International Liaison Committee on Resuscitation. *Circulation* 2003; 108:118–121
5. The Hypothermia after Cardiac Arrest Study Group: Mild therapeutic hypothermia to improve the neurologic outcome after cardiac arrest. *N Eng J Med* 2002; 346:549–556
6. Hajat C, Hajat S, Sharma P: Effects of post-stroke pyrexia on stroke outcome: A meta-analysis of studies in patients. *Stroke* 2000; 31:410–414
7. Azzimondi G, Bassein L, Nonino F, et al: Fever in acute stroke worsens prognosis: A prospective study. *Stroke* 1995; 26:2040–2043
8. Reith J, Jorgensen HS, Pedersen PM, et al: Body temperature in acute stroke: Relation to stroke severity, infarct size, mortality, and outcome. *Lancet* 1996; 347:422–425
9. Boyson G, Christenson H: Stroke severity determines body temperature in acute stroke. *Stroke* 2001; 32:413–417
10. Morimoto T, Ginsberg MD, Dietrich WD, et al: Hyperthermia enhances spectrin breakdown in transient focal cerebral ischemia. *Brain Res* 1997; 746:43–51
11. Stocchetti N, Protti A, Lattuada M, et al: Impact of pyrexia on neurochemistry and cerebral oxygenation after acute brain injury. *J Neurol Neurosurg Psychiatr* 2005; 76:1135–1139
12. Storm C, Steffen I, Schefold JC, et al: Mild therapeutic hypothermia shortens intensive care unit stay of survivors after out-of-hospital cardiac arrest compared to historical controls. *Crit Care* 2008; 12:R78
13. Graf J, Mühlhoff C, Doig G, et al: Health care

- costs, long-term survival, and quality of life following intensive care unit admission after cardiac arrest. *Crit Care* 2008; 12:R92
14. Polderman K: Induced hypothermia and fever control in neurological injury. *ICU Management* 2007; 3:14–16
 15. Greer DM, Funk SE, Reaven NL, et al: Impact of fever on outcome in patients with stroke and neurologic injury: A comprehensive meta-analysis. *Stroke* 2008; 39:3029–3035
 16. Diring M, Reaven N, Funk S, et al: Elevated body temperature independently contributes to increased length of stay in neurologic intensive care patients. *Crit Care Med* 2004; 32:1489–1495
 17. Aiyagari V, Diring MN: Fever control and its impact on outcomes: What is the evidence? *J Neurol Sci* 2007; 261:39–46
 18. Samsa GP, Reutter RA, Parmigiani G, et al: Performing cost-effectiveness analysis by integrating randomized trial data with a comprehensive decision model: Application to treatment of acute ischemic stroke. *J Clin Epidemiol* 1999; 52:259–271