

Tracking Reimbursement and Payment Trends

By Charles E. Schneider

Device firms with well-planned reimbursement strategies position themselves to secure market share and sales they might otherwise have lost.

Most major functions of medical technology companies are inextricably linked to reimbursement. It directly affects capital funding, company valuations, and the commercialization of products. Because of reimbursement's central role, the device company executive must carefully consider the impact that coding, coverage, payment, and policies have on target markets and corporate reimbursement functions. These activities support the future use of codes, sales projections, insurance coverage, regulatory filings, product labeling, and other key company business. Device firms that thoughtfully plan their reimbursement strategies are positioned to secure market share and sales they might otherwise have lost.

This article examines U.S. reimbursement trends, future coverage, coding, and payment mechanisms likely to affect medical technology companies, innovators, care providers, and patients. After a brief review of the recently passed healthcare bill, the article considers trends affecting coverage and coding, then looks at payment trends. Issues such as comparative effectiveness research, financial risk, and evidence development for product commercialization are also addressed. Finally, the article considers whether medical devices and biologics technologies will fall prey to formulary limitations or selective contracting by payors in the future.

Healthcare Policy

In 2009, five major reform bills were proposed between the U.S. House of Representatives and the Senate. On February 22, 2010, President Obama announced his healthcare reform proposal, and held a political forum with members of the Executive branch, House, and Senate in order to discuss policy differences. Partisan efforts continued, and the Patient Protection and Affordable Care Act (PPACA) passed into law on March 23, 2010 (Pub.L 111-148). These regulations were further amended through passage of the Health Care and Education Reconciliation Act of 2010 that was signed into law by the president on March 30, 2010 (Pub.L 111-152).

Despite passage of the PPACA, there appears to be little consensus among Democrats and Republicans, as issues presented during the healthcare reform debate continue to linger. Judicial, political, and financial challenges are expected to continue, and medical technology companies are encouraged to pay close attention to regulatory activities in Washington and in states that also intend to pursue their own reform initiatives.

Policy and politics aside, stakeholders within the healthcare reform debate seem to agree that fundamental changes are required. Healthcare spending now exceeds 16% of the U.S. gross domestic product. At its current pace, projected spending on healthcare is expected to exceed \$4.3 trillion, or 19.3% of GDP, by 2019. Medicare beneficiaries are expected to increase from 46 to 60 million during this same period, while hospitals, physicians, allied, and ancillary care providers continue to see declining payment levels, without relief from increased business-related expenses.

Notwithstanding passage of the PPACA, as amended, healthcare reform has been occurring for many years. Led principally by the Centers for Medicare & Medicaid (CMS), commercial insurance companies, professional societies, and other stakeholders have been successfully modifying U.S. reimbursement systems for many years. Reforms already in motion are attempting to transform U.S. healthcare from a volume-based system to one that rewards quality outcomes and evidence-based medicine. These include coverage policy changes that require published evidence supporting access to medical technologies, the evolution of severity adjusted diagnosis related group (MS-DRG) payment systems, and CPT-4 code development and society guideline development now based more upon outcomes presented within the literature. The emergence of hospital value analysis assessments prior to facility adoption as well as demonstration projects promoting risk-sharing relationships between facility and physician are among the changes as well. In addition, there has been a shift in financial risk relating to hospital-acquired conditions.

Coverage Analysis

Insurance coverage is directly related to published clinical evidence that clearly communicates outcomes and makes comparisons to alternative treatments and technologies. Payors consider whether there are biases that may influence outcomes, consider statistical methods used, and study designs. Major insurers have initiated more formal review processes of technologies, and make public some of their coverage decisions. Absent a randomized, controlled trial, many carriers reject case series data that help to explain outcomes, define patient populations, or provide meaningful insight into the technology's use or limitations. Payors frequently dismiss regulatory approval of technologies that have undergone the rigorous review process required by FDA. Some may delay or deny coverage requiring long term outcomes of more than two years, despite published data to the contrary. However, comparisons between different policies suggests consistent review methods are not used by these organizations, and the full body of published literature is frequently not considered when making benefit decisions that affect patient access to care. This is true as well for technology assessment organizations that claim to evaluate technologies using a rigorous review process, which has not proven to be true in many instances.

Regardless of payor bias, technology companies must be mindful of the need to support development of high-quality, published outcomes that continue to

demonstrate quality, safety, and direct impact on economic outcomes as compared with competing technologies and alternative treatment options. Thorough review of these issues, literature and payor education strategies are required to overcome these barriers.

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Payment Trends

Depending upon the procedure, facility payments continue to show some favorable trends, while physician payments from Medicare remain suppressed. According to the data management company PearlDiver Technologies (Ft. Wayne, IN), from

January 1, 2005, to December 31, 2007 the average facility charges for total knee replacements (see Figures 1 and 2) increased from \$35,262 to \$41,998 (19.1%). For total hip replacement (see Figures 3 and 4) the average facility charges increased from \$38,521 to \$45,621 (18.4%). Actual Medicare payments for these same services increased from \$10,411 to \$11,108 (6.7%)

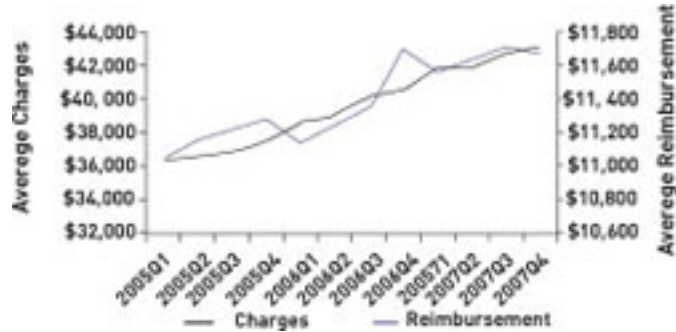
and \$10,216 to \$10,850 (6.2%), respectively. For Medicare fiscal year 2010, the national average payment for total hip and total knee replacement is \$10,766 (MS-DRG 470) when the procedure has no complications or associated comorbidities. Given that Medicare payments are based upon historical claims data and cost reporting, one would expect near-term payment trends for these procedures to continue. On average, the Centers for Medicare & Medicaid (CMS) announced an overall increase for in-patient facility payments of 1.9% for FY2010.

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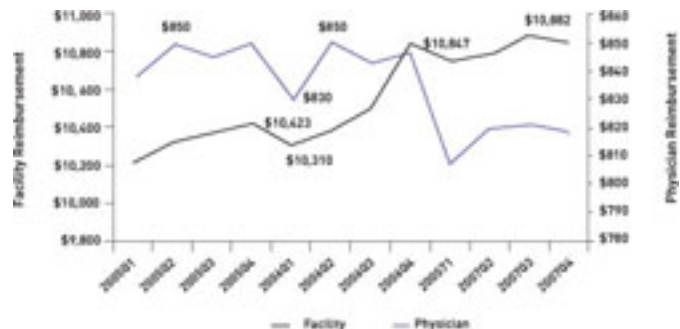
Figure 1. Payment trends (average charges and reimbursement

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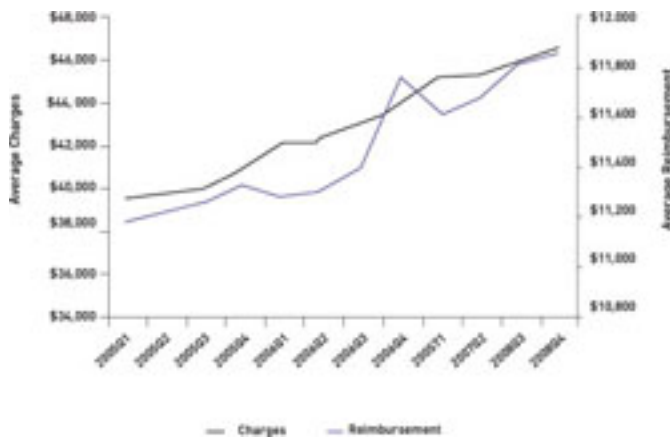
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Conversely, physician payments have remained stagnant for the past several years. In part, physician payment rates have been suppressed because of congressional mandates based upon a flawed calculus that requires payment reductions to meet budget expectations.

Using total hip and total knee procedures for illustration, average billed charges for total hip procedures (see Figure 3) decreased from \$972 to \$942 (-3.1%), while actual payments decreased from \$771 to \$753 (-2.3%) from January 1, 2005, to December 31, 2007. Total knee replacement procedures (Figure 4) showed similar decreases in billed charges from \$1,053 to \$1,023 (-2.9%), while payments decreased from \$837 to \$818 (-2.3%) during this same period.

The national average of allowed payment amounts for total hip (CPT-4 Code: 27130) and total knee replacement (CPT-4 Code: 27446) is reported to be \$1,375 and \$1,055, respectively.



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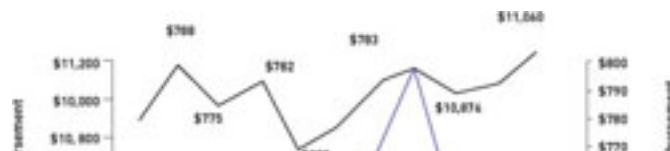
Figure 3. Hip replacement average charges and reimbursement

Congress must once again act and provide supplemental appropriations in support of physician payments, or the Medicare sustainable growth rate will decrease payments to physicians. On February 26, 2010, the House of Representatives passed a supplemental bill that would avoid a 21% automatic payment reduction to physicians until the end of March 2010. On March 15, the President signed legislation

to extend current Medicare payment rates through May 31, 2010. However, Senators must once again act to avoid significant payment reductions on June 1, as this issue was not addressed through passage of the PPACA. Given recurring payment concerns and pricing/reimbursement pressures, technology innovators must develop products that directly reduce the overall cost of care, increase efficiency, and demonstrate actual value to the healthcare community.

Ongoing Payment Reforms

Payment reforms have been continuing for some time. A few examples include quality-based purchasing (also called pay-for-performance), shifting financial risk through policies that exclude payment for hospital-acquired infections, and composite payments for episodes of care.



The Medicare Prescription Drug, Improvement, and Modernization Act of 2003

(MMA, Pub.L. 108-173) included provisions that would attempt to transition from payments based on service volume to one based on quality outcomes. This set the stage for quality based purchasing initiatives, including pay-for-performance demonstration projects encouraging sustainable patient outcomes through various methods of clinical delivery and management.

Figure 4. Hip replacements trends regarding facility and physician

Beginning October 1, 2008, the 2005 Deficit Reduction Act (DRA) requires CMS to identify hospital-acquired conditions and preclude assignment of a hospital stay to a higher paying diagnosis-related group unless it can be demonstrated by the hospital that the condition was not present upon admission. The list of hospital-acquired conditions grows each year, as allowed under Section 5001(c) of the DRA. Medicare, as well as many commercial insurance carriers, has also published noncoverage policies for “never events” in which certain activities (for example, amputation of the wrong appendage) should never occur.

Using its authority under Section 1866C of the Social Security Act, Medicare in fiscal year 2009 initiated several demonstration projects that included global payments for an episode of care, in which the physician and hospital would have financial incentives to lower the overall costs of care. For example, the Medicare Acute Care Episode (ACE) Demonstration focused upon select cardiovascular and orthopedic services.

Financial Burden Shifting

While none of these initiatives represents new payment methodologies, they do represent a continuing trend towards delegated risk relationships that shift the financial burden to care providers. Physicians and hospitals will pay even closer attention to clinical outcomes associated with technologies, impact on cost, and price. Quality training, monitoring patient outcomes, post-approval studies, and support of long-term registries are some of the areas where technology companies may support outcomes associated with alternative products, procedures, and techniques. It is now clear that innovators have a stake in quality clinical outcomes to ensure future viability of the product offered to medical prescribers.

Foreseeable trends in U.S. healthcare finance include the continuing consolidation of the insurance community, making it more difficult for providers to negotiate favorable payment rates. Demand for quality published outcomes will continue, resulting in a substantial increase in comparative effectiveness studies between different procedures, technologies, diagnostic tools, and techniques. Selective contracting may become more prominent among healthcare providers and payors, including delegated authority granted to the Secretary of Health and Human Services. While at some point in the future, implantable medical devices, biologics,

and other supplies may find competition for placement on formularies similar to experiences found within pharmaceuticals.

To remain competitive or introduce new technology into the U.S. marketplace, innovators must first consider each of these trends. Then they need to understand the mechanics associated with coverage, coding, and payment, and execute thoughtful strategies that support not only market entry but also sustainable success within this marketplace.

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