

By John Hernandez, Susanne F. Machacz, and James C. Robinson

US Hospital Payment Adjustments For Innovative Technology Lag Behind Those In Germany, France, And Japan

DOI: 10.1377/hlthaff.2014.1017
HEALTH AFFAIRS 34,
NO. 2 (2015): 261–270
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ABSTRACT Medicare pioneered add-on payments to facilitate the adoption of innovative technologies under its hospital prospective payment system. US policy makers are now experimenting with broader value-based payment initiatives, but these have not been adjusted for innovation. This article examines the structure, processes, and experience with Medicare's hospital new technology add-on payment program since its inception in 2001 and compares it with analogous payment systems in Germany, France, and Japan. Between 2001 and 2015 CMS approved nineteen of fifty-three applications for the new technology add-on payment program. We found that the program resulted in \$201.7 million in Medicare payments in fiscal years 2002–13—less than half the level anticipated by Congress and only 34 percent of the amount projected by CMS. The US program approved considerably fewer innovative technologies, compared to analogous technology payment mechanisms in Germany, France and Japan. We conclude that it is important to adjust payments for new medical innovations within prospective and value-based payment systems explicitly as well as implicitly. The most straightforward method to use in adjusting value-based payments is for the insurer to retrospectively adjust spending targets to account for the cost of new technologies. If CMS made such retrospective adjustments, it would not financially penalize hospitals for adopting beneficial innovations.

John Hernandez (john.hernandez@av.abbott.com) is divisional vice president of Health Economics and Outcomes Research at Abbott Vascular, in Santa Clara, California.

Susanne F. Machacz is senior manager of Health Economics and Outcomes Research at Abbott Vascular.

James C. Robinson is the Leonard D. Schaeffer Professor of Health Economics and director of the Berkeley Center for Health Technology, School of Public Health, at the University of California, Berkeley.

Medicare pioneered new technology add-on payments to facilitate the adoption of innovative technologies under its hospital prospective payment system (PPS). Most developed nations have adopted their own supplementary payment mechanisms for new technology, which represent modifications of the version used by the Centers for Medicare and Medicaid Services (CMS). As required by provisions of the Affordable Care Act (ACA), US policy makers are experimenting with bundled and prospective value-based payment methods to improve the

efficiency, quality, and outcomes of health care. These payment methods base future rates on past costs, trended forward using changes in easily measured input prices such as wages.

The life sciences industry invests in the development of devices, drugs, diagnostic tests, and other inputs to improve quality and outcomes. Some new technologies reduce the cost of care, such as when less invasive treatments shorten hospital stays, enable patients to be treated in less intensive settings of care, and reduce patient recovery times. Hospitals are given financial incentives by the PPS to adopt these cost-reducing innovations. Indeed, this adoption is an explicit

policy goal. However, other clinically beneficial innovations involve higher costs but produce clinical benefits that accrue over months or years.

Many policy analysts have highlighted the need for adjustments to the PPS to remove financial disincentives to adopting innovations that increase costs.^{1,2} For example, inadequate diagnosis-related group (DRG) payments for cochlear implants under the PPS before the availability of new technology payments delayed access to this beneficial technology in the first decade after its introduction.^{3,4}

Congress and CMS have recognized the PPS's potential to impede the adoption and, indirectly, the development of innovative technology. In 2001 CMS created the new technology add-on payment program for new technologies that represent a "substantial clinical improvement" and are inadequately paid under the DRG system.⁵ New technology add-on payments supplement hospital DRG reimbursement with temporary payments for high-cost technologies.

Many other countries, including Germany, France, and Japan, have adopted new technology payment adjustments for their hospital payment systems. For example, 80 percent of the fifteen European countries in a recent study had adopted new technology payment mechanisms to remove short- and long-term disincentives for hospital adoption of beneficial innovations with higher initial costs when compared to existing treatments.⁶

Congress and CMS struggled to balance the goals of innovation and efficiency when they pioneered Medicare's technology payment mechanisms.^{7,8} They adopted criteria to limit the number of eligible technologies, the payment level at which they are reimbursed, and the duration of the supplemental payments. Minor modifications were made to the program in 2004 and 2012,^{9,10} but the basic original structure has been retained.

In contrast, economic incentives facing US hospitals have changed considerably. The new technology add-on payment program was designed before passage of the ACA, which has further shifted financial risk from the Medicare program to hospitals and has decreased the historically prominent role of physician adoption of new technologies based on clinical preference. The ACA has also reframed the system of checks and balances that governed the adoption of new medical innovations in the United States.

These changes challenge hospitals' adoption of cost-increasing medical innovations in the United States and other countries in the future. A review of new technology add-on payments and other technology payment mechanisms is

merited in today's context.

This article examines the structure, processes, and experience with Medicare's new technology add-on payment program since its inception in 2001 and in comparison to analogous payment systems in other nations. We compared the program to new technology payment mechanisms adopted within hospital inpatient prospective payment systems in Germany, France, and Japan. The countries in our study have the four largest hospital prospective payment systems in the world. We focused on inpatient technology payment because most new technologies are first introduced in the inpatient setting and because inpatient technology accounts for a majority of hospital costs.

Study Data And Methods

We reviewed the existing literature on each country's hospital prospective payment system and technology payment mechanisms. We benefited from excellent existing reviews of the US, German, and French new technology payment mechanisms.^{9,11-13} Several cross-country reviews were also available.^{6,14}

We worked with local experts in Germany, France, and Japan. These colleagues obtained data from each national payer on technology payment mechanisms and approvals and had them translated into English for our review.¹⁵⁻¹⁸

We used claims data from the Medicare Provider Analysis and Review (MedPAR) files to quantify new technology add-on payments for each approved technology since the program's inception, and we compared the results to CMS and congressional projections of those payments.¹⁹ Our review of Medicare's new technology add-on payments process was informed by an earlier analysis by Alexandra Clyde and colleagues through 2006.⁹

LIMITATIONS There were several limitations to this study. First, we did not have access to claims data or new technology payment amounts outside the United States. Second, given the complexity of each payment system, it was not feasible to include the outpatient setting within the scope of this review.

Study Results

UNITED STATES In US Medicare, each hospital admission is assigned to one of 751 Medicare severity DRGs (MS-DRGs) based on the patient's primary and secondary diagnoses, procedures performed, complicating conditions, and discharge status. Payment rates are based on national average costs for "bundles" of the services assigned to the same payment category. CMS

A review of technology payment mechanisms is merited in today's context.

recalibrates the MS-DRG payment rates annually based on changes in national average hospital costs (not the costs incurred by each hospital individually), derived from historical claims data. This introduces a time lag of two to three years.

In designing the new technology add-on payment program, Congress and CMS took action to reduce short-term financial risks for hospitals by “bridging” the time lag until MS-DRG payment rates could be updated to incorporate new technology costs. However, CMS was more concerned about overadoption than underadoption of expensive new technology, as evidenced in the three central design elements of the program reviewed below. When Congress enacted the program, the Congressional Budget Office projected that ten-year costs would be \$500 million.⁹

►**CRITERIA FOR ELIGIBILITY:** To have a new technology approved for the program, manufacturers must submit an application demonstrating that the technology is truly novel, that it represents a “substantial clinical improvement” for Medicare beneficiaries, and that it exceeds cost criteria established by CMS. CMS solicits public comments through its annual rule-making cycle.

The Medicare program is unique among global hospital payment systems in that specific cost thresholds must be exceeded. Manufacturers must show that the incremental cost of a new technology exceeds the lesser of 75 percent of the standard MS-DRG payment amount and 75 percent of one standard deviation above the charge for the MS-DRG or DRGs to which the technology is assigned. This cost threshold establishes a high bar for eligibility. New drugs and biologics are subject to the same requirements as devices.

►**PAYMENT LEVEL:** Payments for new technologies that qualify for the add-on payments are determined case by case using CMS formulas that are driven by a hospital's charges for each patient admission, deflated to reflect estimated costs and hospital-specific operating cost-to-charge ratios. These are determined by CMS

based on the hospital's most recent Medicare cost report. They are not adjusted to account for charge compression, in which high-cost procedures typically involve lower markups than other services in hospital chargemaster accounting systems.²⁰

Payments are set at the lesser of 50 percent of the estimated difference between the hospital's estimated costs and the DRG payment amount and 50 percent of the new technology cost. This means that hospitals incur financial losses when adopting cost-increasing new technologies, even with the new technology add-on payment program.

►**PAYMENT DURATION:** New technology payments are limited to three years after FDA approval and commercialization of the technology. At that time, Medicare claims reflect the commercial use of the technology, so CMS can incorporate the incremental costs into an MS-DRG category.

►**GERMANY** After the introduction of the German DRG system in 2004, lawmakers created a new technology reimbursement mechanism to support the adoption of innovative technologies. Beginning in 2005, the Institute for the Hospital Remuneration System or InEK (Institut für das Entgeltsystem im Krankenhaus) began providing hospitals with opportunities to apply for and obtain short-term supplementary funding for new medical products (referred to as NUB, which stands for *Neue Untersuchungs- und Behandlungsmethoden*, or new diagnostic and treatment methods) used in inpatient procedures until the products were assigned permanent reimbursement levels.¹²

The program for these new medical products has two key objectives. First, it bridges the financing gap by providing supplementary funding beyond the DRG payment for new technologies used in inpatient procedures. Second, it uses the data generated during this interim period to identify the appropriate payment for the technologies in the regular system. For a new technology to qualify, individual hospitals must submit an application to the Institute for the Hospital Remuneration System (Exhibit 1) that may also be supported by other clinical organizations such as specialty societies and clinical organizations. In contrast to the application process for Medicare's new technology add-on payment program, manufacturers cannot submit the German application.

Applications must demonstrate that the medical technology in question is truly new, which implicitly takes into account the clinical improvements associated with the technology, and involves costs that are inadequately paid under the existing German DRG system. By design, the

EXHIBIT 1

Cross-National Comparison Of Payment Mechanisms For Inpatients' Use Of New Technology In Four Countries

	United States	Germany	France	Japan
Decision maker	Centers for Medicare and Medicaid Services	Institute for the Hospital Remuneration System	Ministry of Health	Ministry of Health, Labor, and Welfare
PAYMENT MECHANISM				
New technology payment mechanism	New technology add-on payment program	New diagnostic and treatment methods	List of Reimbursable Products and Services	C1 and C2
Application process	Manufacturer applies annually	Individual hospital applies annually	Manufacturer applies on a rolling basis	Manufacturer applies on a rolling basis
Payment determination	Statutory formula based on hospital charges, limited to 50% of incremental costs or 50% of device costs	Each hospital negotiates payments with local sickness funds	Manufacturer and ministry negotiate national fee schedule payment	Manufacturer and ministry negotiate national fee schedule payment
Duration of payment	Payments limited to 3 years after FDA approval and commercialization	Option to renew annually for 2-5 years or longer	Option to renew annually for up to 5 years (longer in actual practice)	Permanent with payment adjusted biannually
Different levels of innovation?	No	No	Yes (5 levels)	Yes (3 levels)
REQUIREMENTS FOR APPROVAL				
Newness	Yes	Yes	Yes	Yes
Substantial clinical improvement	Yes	No (only implicit)	Yes	Yes
Specific cost thresholds	Yes (75% of DRG payment or 75% of one standard deviation above DRG charge)	No	No	No
Cost-effectiveness	No	No	Yes (for ASA levels 1-3)	No
DATE				
Year implemented	2001	2005	2005	2002
Approval data timeframe	2001-15	2005-13	2005-13	2008-13
Payment approvals				
Total	19	234	745	265
Mean approvals per year	1.4	26.0	82.8	44.2

SOURCE Authors' analysis of data from the following sources: (1) Centers for Medicare and Medicaid Services. Prospective payment system final rules, fiscal years 2002-14. (2) InEK-Institut für das Entgeltsystem im Krankenhaus. Neue Untersuchungs- und Behandlungsmethoden (NUB) (see Note 18 in text). (3) Haute Autorité de Santé. Rapport d'activité annuel (see Note 15 in text). (4) Ministry of Health, Labor, and Welfare. Chuikyo Proceedings: Chuikyo Document Reference Material (see Notes 16 and 17 in text). **NOTES** C1 and C2 are reimbursement classifications for new device technologies in Japan. FDA is Food and Drug Administration. DRG is diagnosis-related group. ASA is Amélioration du Service Attendu.

Institute for the Hospital Remuneration System retains broad discretion in determining whether or not a technology meets these requirements.¹²

Once the institute has approved the new technology, individual hospitals negotiate payment amounts directly with regional insurance authorities (which are referred to as local sickness funds). These negotiations may involve the payers' anticipated volume of use, budgetary impact (the volume times the price per unit), and the new technology's perceived clinical and economic value. Unlike Medicare's new technology add-on payment level, the German payment amount is not a standard or statutorily defined amount.

The Institute for the Hospital Remuneration System's status decision is valid for only one year, so a new application needs to be submitted and approved annually. The period of eligibility for the payment supplement is not specified, but

eligibility typically lasts for two to five years. During this time, the institute collects data on the new technology to determine the permanent reimbursement level. Initial use of the technology is reflected in the claims data within three years. However, new medical product status can be maintained until use of the new technology has stabilized and it can be integrated into the German DRG system. As noted by Cornelia Henschke and coauthors, 25 percent of new technologies retained that status after five years.¹²

Upon expiration of the status, the Institute for the Hospital Remuneration System may create a new payment category or restructure the existing German DRG classification. It also may provide for permanent supplementary device payments outside of the German DRG payment through *Zusatzentgelte* (supplementary payments), which are recalibrated annually based on claims

Three of four countries in our study require new technologies to demonstrate a substantial clinical improvement.

data. These can be national fee schedule rates based on the average technology costs or supplemental payment amounts that are negotiated between individual hospitals and regional payers in the same manner as new medical product payments.

FRANCE In France the Ministry of Health (Haute Autorité de Santé) has adopted numerous policies designed to encourage innovative technologies' entry into the market through separate payments from the national budget. These include payments for new devices, drugs, and procedures plus "coverage with evidence development" programs.¹⁴ Manufacturers can apply for technology-specific reimbursement beyond normal hospital payments (Exhibit 1).

Additional payments for inpatient hospital services are available only for implantable devices included on the national List of Reimbursable Products and Services (Liste des Produits et Prestations Remboursables). Hospitals can obtain reimbursement for new technologies on the list, in addition to the base payments for homogeneous groups of stay, the French version of the MS-DRG hospital payment.

Applications for incremental technology reimbursement require manufacturers to prepare dossiers with evidence of clinical improvement and budget impact and submit them to the French health care system. The Committee for the Evaluation of Medical Devices and Health Technologies determines whether the technology has sufficient value for inclusion on the List of Reimbursable Products and Services.²¹ It assesses the technology's value relative to comparable products or services and determines whether it offers a significant improvement. It classifies the innovation on a five-point Added Clinical Value (Amélioration du Service Attendu, or ASA) rating scale in which 1 is major; 2, substantial; 3, moderate; 4, minor; and 5, none.

In France, manufacturers seeking innovation levels 1-3 for a technology are required to demonstrate its cost-effectiveness to the Ministry of Health. In contrast, the US Congress has limited the use of economic considerations in Medicare's coverage and reimbursement policies. The actual reimbursement amount for a technology in France is determined by the Economic Committee of Health Products, an agency within the Ministry of Health, and involves direct negotiations with the manufacturer that may define payment levels and utilization. Payment amounts are national and updated annually. Unlike Medicare's new technology add-on payment program, the French hospital payment system does not have a defined cost threshold.

Based on the recommendations of the Committee for the Evaluation of Medical Devices and Health Technologies, the Ministry of Health determines which products will be on the national "add-on list." Placement on the list is designed to be temporary, lasting up to five years, but in practice it often exceeds this time frame. Each year, products are reevaluated for either renewal or explicit integration into the permanent reimbursement system.

JAPAN In Japan, reimbursement for medical devices is determined by the Central Social Insurance Medical Council (Chuikyo), a body appointed by the Ministry of Health, Labor, and Welfare. The council is a consultative group consisting of representatives of the government, the public, the medical profession, and other entities. It evaluates technology reimbursement applications submitted by manufacturers on a rolling basis and designates a specific payment category based on innovation level (Exhibit 1).

The current framework for device reimbursement was introduced in 2000 and revised in 2002.¹⁶ Through this process, manufacturers can request assignment of the product to existing categories to qualify for supplemental payment. Payments can apply to technologies used in both the hospital inpatient and outpatient settings. However, the majority of devices are associated with inpatient procedures.

The manufacturer can apply for one of two categories, C1 or C2, in Japan's device reimbursement scheme. If a new device technology can be used as part of an existing procedure but is shown to be a significant improvement, a new C1 category is assigned to it (this was the case, for example, with drug-eluting stents and new artificial joints). If a new device technology results in a completely new procedure or therapy, it is classified in a C2 category. For these technologies, payment is evaluated for the new procedure as well as the new technology (for example, for transcatheter heart valve implants such as trans-

catheter aortic valve replacement and Mitra-Clip). In these cases, the Central Social Insurance Medical Council may create separate payments for the technology and the procedure or just one payment for the procedure.

Japan’s Ministry of Health, Labor, and Welfare relies on manufacturers to submit reimbursement applications that seek a specific rating and reimbursement, with supporting evidence of value including clinical benefits. Using the information in the application, a determination is made about the degree of innovation and the amount of reimbursement. Similar to France and Germany, the overall reimbursement for a new technology is determined by confidential negotiations between the manufacturer and the reimbursement agency. The Ministry of Health, Labor, and Welfare is developing criteria for which cost-effectiveness data manufacturers will be required to include.

The payment category assignment (C1 or C2) is permanent. However, the payment amount is adjusted biannually based on market pricing data collected by the ministry.

Experience With New Technology Payments

UNITED STATES Between 2001 and 2015, CMS approved nineteen of fifty-three applications

for the new technology add-on payment program (fifteen devices and four drugs or biologics were approved). The mean number of approvals per year was 1.4 (Exhibit 1).

The program has resulted in \$201.7 million in Medicare payments in fiscal years 2002–13 (Exhibit 2). This is less than half of the amount anticipated by Congress and only 34 percent of the amount projected by CMS. Actual payments exceeded CMS projections for only two of thirteen new technologies. A single technology (cardiac resynchronization therapy with defibrillation) generated 64 percent of the total payments (\$128.1 million; Exhibit 2). The annual number of technologies approved for the new technology add-on payment program is low, and the corresponding payments are well below the amounts estimated by CMS and manufacturers.¹⁹

Most hospitalizations involving approved technologies qualified for supplemental payments, but mean payments per case were half of the payment maximum (see online Appendix Exhibit A1).²² For six of the ten technologies no longer eligible for the program, payments lasted two years; two of the technologies received payments for one year, and two received payments for three years. For three of the ten technologies that became ineligible, CMS changed DRG assignments (Exhibit 2). Incremental costs for the remaining seven technologies were incorpo-

EXHIBIT 2

Technologies Eligible For Medicare’s New Technology Add-On Payment Program, Fiscal Years 2002–13

Technology	Fiscal years eligible	Number of cases	Payments (millions of US dollars)			DRG reclassification
			Projected by CMS	Actual	Actual as percent of projected	
Drotrecogin alpha, activated (Xigris) ^a	2003–04	9,803	74.8	12.1	16	No
Bone morphogenetic proteins for spinal fusion ^a	2004–05	7,724	12.2	18.7	153	No
Cardiac resynchronization therapy with defibrillation (InSync) ^a	2005	33,700	341	128.1	38	No
Implantable neurostimulator for deep brain stimulation (Kinetra)	2005–06	483	24.7	2.3	9	Yes
Endovascular graft repair of the thoracic aorta (GORE TAG)	2006–07	3,348	32.2	18.3	43	Yes
Rechargeable implantable neurostimulator (Restore)	2006–07	336	12.0	2.1	16	No
Interspinous process decompression system (X-STOP)	2007	3,747	9.4	9.0	96	Yes
Temporary total artificial heart system (CardioWest)	2009–11	— ^b	28.5	0.5	1	No
Intra-Bronchial Valve (IBV) Valve System (Spiration)	2010–11	— ^b	15.6	0.0	0	No
Auto Laser Interstitial Therapy (Autolitt) System	2011–13	— ^b	2.7	0.1	4	No
Glucarpidase injection or infusion (Voraxaze)	2013–	12	6.3	0.2	2	— ^c
Fenestrated AAA endovascular graft (Zenith)	2013–	2,410	4.1	10.1	200	— ^c
Fidaxomicin tablets (DIFICID)	2013–	224	34.8	0.2	0	— ^c
Total since inception	2002–13	— ^b	598.3	201.7	35	— ^d

SOURCE Authors’ analysis of data from the following sources: (1) Centers for Medicare and Medicaid Services (CMS). Prospective payment system, final rules, fiscal years 2006–13. (2) Medicare Provider Analysis and Review limited data set, fiscal years 2005–13. **NOTE** DRG is diagnosis-related group. ^aData from Clyde AT et al. Experience with Medicare’s new technology add-on payment program (see Note 9 in text). ^bNot available. ^cNot applicable. ^dDRG assignments were changed for three out of ten technologies for which the new technology add-on program has expired.

rated implicitly through the standard MS-DRG recalibration process.

Hospitals experienced losses for ten of ten technologies during the period of eligibility for new technology add-on payments, and losses were substantial for four of these technologies. In these cases, mean “stop loss” hospital outlier payments—which are designed to protect hospitals from large financial losses because of unusually expensive Medicare cases—actually exceeded new technology add-on payments (see online Appendix Exhibit A1).²² In fiscal years 2006–13, mean new technology add-on payments were \$4.5 million per product.¹⁹

GERMANY In 2005–13 the German Institute for the Hospital Remuneration System approved 234 technologies for new medical product supplementary payment status (Exhibit 1).¹⁸ The mean number of approvals was twenty-six per year. For approved technologies, 60 percent of hospitals were successful in negotiating payments with regional payers. Of the twenty-six technologies that the institute approved in 2005, twenty had been incorporated into the permanent German DRG system by 2009, either through the creation of a unique German DRG or through approval of supplementary payments.¹²

Drugs and biologicals were incorporated more quickly and frequently into the German DRG system than were devices. At three years after initial approval, the Institute for the Hospital Remuneration System maintained supplementary payment status for 87 percent of devices; at five years, the share was 25 percent.¹² Of the new medical products that were incorporated in 2008–14, forty-six were approved for long-term

supplementary payments, and seven received a new German DRG classification upon losing new medical product status.¹⁸

FRANCE From 2005 to 2013 the French Committee for the Evaluation of Medical Devices and Health Technologies approved supplementary reimbursement for 745 new technologies. The mean annual number of approvals was 82.8 (Exhibit 1). The distribution of innovative ratings was as follows: There were 15 approvals (2 percent) for ASA level 1, 40 (5 percent) for level 2, 42 (6 percent) for level 3, 104 (14 percent) for level 4, and 544 (73 percent) for level 5—as noted above, the level assigned to products offering no innovation (data not shown). Thus, most of the technologies reviewed by the Ministry of Health were not rated as improvements over the existing standard of care.

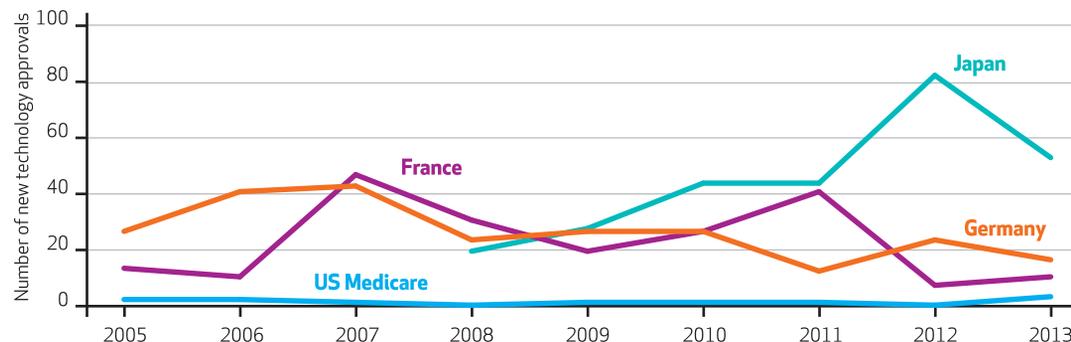
JAPAN In 2008–13 the Ministry of Health, Labor, and Welfare approved 265 new technologies for incremental reimbursement (Exhibit 1). Of these, 168 were C1 new device/existing procedure category approvals, and 97 were C2 new device/new procedure category approvals (data not shown). The mean number of approvals was 44.2 per year (Exhibit 1). The annual number of approvals has increased over time (Exhibit 3).

Technology Payment Comparisons

As shown in Exhibit 1, there are similarities and differences between Medicare’s new technology add-on payment program and technology payment mechanisms in other nations. Compared to its peers, Medicare’s program has adopted a narrow approach to paying for new technolo-

EXHIBIT 3

Annual Number Of New Technology Payment Approvals In Four Countries, 2005–13



SOURCE Authors’ analysis of data from the following sources: (1) Centers for Medicare and Medicaid Services. Prospective payment system final rules, fiscal years 2002–14. (2) InEK–Institut für das Entgeltsystem im Krankenhaus. Neue Untersuchungs und Behandlungsmethoden (NUB) (see Note 18 in text). (3) Haute Autorité de Santé. Rapport d’activité annuel (see Note 15 in text). (4) Ministry of Health, Labor, and Welfare. Chuikyo Proceedings: Chuikyo Document Reference Material (see Note 17 in text). **NOTE** Approvals are as follows: in the United States, for Medicare’s new technology add-on payment program; in Germany, for new diagnostic and treatment methods; in France, for the List of Reimbursable Products and Services, ASA levels 1–4; for Japan, categories C1 and C2 (see text for details).

gies, with a high cost bar for eligibility, a payment rate lower than the full cost of the technology, and short defined payment duration. Other nations have adopted broader approaches, albeit with lower base payment rates to hospitals and increased payer flexibility to use discretion for specific technologies.

Three of four countries in our study require new technologies to demonstrate a substantial clinical improvement, whereas in Germany the newness requirement implicitly considers whether the technology provides a clinical improvement (Exhibit 1). Whereas Germany, France, and Japan employ a general cost criterion for eligibility, the United States uses specific cost thresholds. By limiting supplemental payments to 50 percent of incremental costs, Medicare's new technology add-on payment program alone requires hospitals to share in the financial burden of adopting new technologies.

France and Japan classify the level of innovation associated with a new technology and set payments that reflect the full incremental costs to the hospital. In Germany the Institute for the Hospital Remuneration System approves new technology applications, and payments are negotiated between hospitals and regional payers. For most technologies approved in Germany for *Zusatzentgelte* supplementary payments after eligibility for new medical product status has ended, payments are determined using a national fee schedule similar to the processes used in France and Japan.

Medicare specifies that eligibility for the new technology add-on payment program cannot extend beyond three years after FDA approval. However, the other three countries allow longer time periods, at the discretion of the national payer. As documented by Henschke and co-authors¹² and Corinna Sorenson and colleagues,⁶ the time needed to fully integrate new technologies into practice and collect sufficient real-world data to reflect costs is three to five years.

In Japan the government has created separate payment pathways for new device technologies used in existing procedures and new device technologies involving new procedures.¹⁶ In contrast, Medicare has not created a formal "new technology DRG" pathway for new technologies involving new procedures. However, it used regulatory discretion to create new DRGs for drug-eluting stents upon the introduction of this new technology.

Examples Of New Technology Payments

Exhibit 4 provides examples of how specific new technologies were reimbursed across the four

countries studied. There are some broad similarities between the United States, Germany, and France, in that all have short-term payment mechanisms for new technologies. In France and Japan new technology payment mechanisms also share multiple features including rolling manufacturer applications that are classified according to levels of innovation for listing on a national fee schedule.

Germany, France, and Japan provide flexibility for the payer to maintain supplemental device payments beyond three years after approval (Exhibit 1). All four countries have mechanisms for adjusting the permanent DRG payment level (that is, reclassifications), but there are differences across countries in how these adjustments are applied.

Implications For Emerging Value-Based Payment Mechanisms

Medicare pioneered prospective payment for inpatient hospital admissions and other nations adopted similar prospective payment systems as a first step toward value-based mechanisms that cover broader sets of services. Shared savings payments, as represented by Medicare accountable care organization (ACO) contracts, combine physician, hospital, and ancillary services into an annual spending target for a patient population. CMS will share any savings below this spending target with the providers. Capitation payments—for example, in Medicare Advantage health maintenance organization contracts—bundle a similarly wide range of services together but pay providers on a prospective basis. This allows providers to keep all of the savings and requires them to absorb all of the losses if actual spending diverges from spending targets.

These emerging payment methods are called *value-based* since they reward providers for efficiency and quality, whereas fee-for-service rewards providers for the volume and complexity of the care they provide. In both cases, payments are adjusted for differences among patients in the severity of their illness and comorbidities, because these influence the costs and outcomes of the care provided. However, these new payment methods have not been adjusted for innovations in medical technology.

Implicit adjustment for innovation, through periodic recalibration or renegotiation, can account for the cost of some new technology. Nevertheless, the direct financial incentive created by emerging value-based payments is for providers to avoid or delay the adoption of cost-increasing devices, diagnostics, and drugs, regardless of long-term savings or improved clin-

EXHIBIT 4

Examples Of New Technologies That Qualified For New Technology Payments In Four Countries, 2003–15

Technology	United States	Germany	France	Japan
Drug-eluting stents (DES)	New DRGs created upon FDA approval	Short-term device supplement ^a followed by permanent device supplement ^b	Device supplement ^c	Device supplement ^d
Rechargeable implantable neurostimulator (Restore)	Short-term supplement ^e	Short-term device supplement ^a followed by permanent device supplement ^b	Device supplement ^c	Device supplement ^d
Endovascular graft repair of the thoracic aorta (GORE TAG)	Short-term supplement ^e	Short-term device supplement ^a	Device supplement ^c	Device supplement ^d
Interspinous process decompression system (X-STOP)	Short-term supplement ^e followed by DRG reassignment	Short-term device supplement ^a followed by new DRG	Reimbursement under review	Device and procedural supplement ^f
Transcatheter heart valve implants (TAVR and MitraClip)	Short-term supplement ^e for MitraClip and new DRGs for TAVR	Short-term device supplement ^a followed by new DRGs for MitraClip and TAVR	Device supplement ^c for TAVR, MitraClip in process	Device and procedural supplement ^f for TAVR, MitraClip not yet approved
Intracranial stenting	Rejected for short-term supplement, ^g coverage limited to clinical trials	No short-term supplement, reimbursement under review	No supplement, reimbursement under review	Coverage limited to clinical trials

SOURCE Authors' analysis of data from the following sources: (1) Centers for Medicare and Medicaid Services. Prospective payment system final rules, fiscal years 2002–14. (2) InEK-Institut für das Entgeltsystem im Krankenhaus. Neue Untersuchungs- und Behandlungsmethoden (NUB) (see Note 18 in text). (3) Haute Autorité de Santé. Rapport d'activité annuel (see Note 15 in text). (4) Ministry of Health, Labor, and Welfare. Chuikyo Proceedings: Chuikyo Document Reference Material (see Note 17 in text). **NOTES** DRG is diagnosis-related group. FDA is Food and Drug Administration. ^aNew diagnostic and treatment methods. ^bZusatzentgelte. ^cList of Reimbursable Products and Services. ^dC1 new device, existing procedure. ^eMedicare's new technology add-on payment program. ^fC2 new device, new procedure.

ical outcomes. Given that available quality metrics used in value-based payment are not designed to detect changes associated with new technologies, there is an even greater need for explicit value-based payment adjustments for innovation.

Conclusion

It is important to adjust payments for new medical technologies explicitly as well as implicitly within prospective and value-based payment systems. A high-value health care system adopts new clinical technologies in cases where societal benefits exceed costs, and the system thereby finances new investments in research and development. As our analysis shows, the German, French, and Japanese inpatient payment sys-

tems have adapted the US Medicare new technology add-on payment program to provide more explicit adjustments for new technology innovations. As the United States moves toward value-based payment methods, it is important that appropriate incentives be created for the adoption of beneficial innovations while maintaining incentives for efficiency. The most straightforward method to use in adjusting value-based payments is for the insurer to retrospectively adjust spending targets (for example, in ACO programs) to account for the cost of new technologies that have been approved for new technology add-on payments. If CMS made such retrospective adjustments, it would not financially penalize hospitals for adopting beneficial innovations. ■

The authors acknowledge the support from reimbursement experts in Germany (Hank Schiffers), France (Karine Levesque, Sophie Cros) and Japan (Makoto Tamura, Katsumi Shinkawa) in collecting and evaluating information on

new technology payment mechanisms in each country as well as statistical support with empirical analysis of Medicare Provider, Analysis, and Review claims (Eric Hammelman at Avalere Health LLC). They also extend their

appreciation to Tanya Schikorr, who assisted them in manually reviewing and tabulating data on new technology payment approvals.

NOTES

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