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Paying for New

Medical Technologies:

Lessons for the Medicare

Program from Other Large

Health Care Purchasers

*A study conducted by the Project HOPE
Center for Health Affairs for the
Medicare Payment Advisory Commission*

PAYING FOR NEW MEDICAL TECHNOLOGY: LESSONS FOR THE MEDICARE PROGRAM FROM OTHER LARGE HEALTH CARE PURCHASERS

Final Report

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TABLE OF CONTENTS

Executive Summary	ii
I. Background and Objectives	1
II. Methods	2
III. Findings.....	4
A. General Observations	4
1. Classification of Technologies.	4
2. Use of Non-price Policy Levers.	6
3. Involvement of End Users in Product Selection.....	7
4. Ties Between Technology Assessment, Coverage and Purchasing Decisions.	7
5. Aggressive Monitoring of Technological Advances.	8
6. Influence of Medicare on Pricing Policies.	8
B. Observations by Organization Type	9
1. Insurers.....	9
2. Group Purchasing Organizations.....	13
3. Integrated Delivery Systems.....	14
4. Large Hospital System	19
5. Pharmaceutical Benefit Management Organizations	21
6. Medicaid Program	22
7. Veterans' and Military Health Care Systems	24
8. Other Countries	29
IV. Lessons for Medicare	32
V. References	35
Appendix 1. Case Study Technologies	
1. Drug Eluting Stents:.....	1
2. Implantable Cardiac Defibrillators:.....	1
3. Monoclonal Antibody for Treating Breast Cancer	2
4. Biologically-manufactured Skin Substitutes	2
APPENDIX REFERENCES	4

EXECUTIVE SUMMARY

This paper presents the results from a series of structured interviews with large purchasers of health care conducted by the Project HOPE Center for Health Affairs for the Medicare Payment Advisory Commission. The goals of these interviews were to identify methods developed by payers other than Medicare to establish prices for new medical technology and to critically examine their relevance to Medicare for paying for new medical technology. This project supports the Commission's continuing interest in evaluating better methods to pay for new medical technologies within the constraints of a prospective payment system.

Qualitative interviews were conducted with key informants from large public and private purchasers of health care, including health care insurers, group purchasing organizations, pharmaceutical benefit management organizations, the military health system, and other countries. The overall intent was to understand the array of mechanisms these payers use to set prices for new technology and their relative advantages and disadvantages. Informants were asked how they specifically set prices for four case study technologies in order to illustrate common themes and highlight differences in pricing approaches.

Pricing strategies differed depending on the relative clinical advance offered by a technology over existing treatments and its competitive environment. Purchasers generally pay manufacturer's price for breakthrough products that offered a substantial clinical improvement over existing treatments and had no competitors. For therapeutically-equivalent technologies, many purchasers, such as integrated delivery systems, group purchasing organizations, pharmaceutical benefit management organizations, and the military health system, commonly use a competitive bidding process. Successful bids are selected based on a product's relative quality and price. Product use is then restricted to successful bidders. Pricing strategies were more diverse among respondents for "physician's-preference" items, which may offer some clinical benefit, but sometimes for a substantial increase in price over existing treatments. Some respondents paid close to manufacturer's price, or billed charges, for these items, while others sometimes used competitive bidding to negotiate discounts.

Purchasers commonly use an array of other mechanisms to control new technology use and channel it to the most appropriate persons including, step therapy, tiered co-payments, the development of clinical guidelines and the education of physicians and consumers. All respondents had formal methods for involving end users (usually physicians) in coverage, product selection, and product purchasing decisions. Because of the importance of clinical evidence for developing pricing strategies, nearly all respondents had close, formal linkages between technology assessment, coverage determination, pricing and procurement decisions. Cost-effectiveness analyses are also used by some respondents to discriminate among physician's preference or therapeutically-interchangeable products, and their use during coverage determinations in the United Kingdom and Australia has an indirect effect on a manufacturer's price established at launch.

Insurers, which are structured more similarly to Medicare – establishing prices for physicians and hospital services rather than individual technologies—moderate the use of high-cost technology through their coverage determination process. Once a positive coverage determination is made, however, the insurer is usually at risk for the increased cost of that technology – paying on the basis of invoice cost plus a mark-up or billed charges –which it passes on to employers or individuals through its premiums. Insurers rarely negotiate directly with manufacturers for price.

Notably, many respondents look to Medicare as the leader in setting prices for new technologies. Once fees have been established by Medicare, private and public purchasers alike use them in the course of negotiations with manufacturers, or incorporate them into their fee schedules.

The influence Medicare exerts on the market through its pricing system is illustrated by the recent emphasis a large hospital system has placed on restructuring its procurement process for medical equipment and pharmaceuticals three years ago. Because of declining margins, this hospital system moved away from the use of a group purchasing organization to conduct its own direct purchasing for high-volume products. Procurement decisions and information systems were centralized throughout its 50 hospitals and 400 clinics, and the hospital invested heavily in conducting market research and contract negotiations.

Many respondents felt the techniques they used to set prices were of limited relevance to the Medicare program for setting prices for new technologies paid through the pass-through mechanism for outpatient prospective payment system. First, technologies that have only been on the market two to three years often do not have competitors and rarely are subject to competitive bidding. Second, respondents questioned whether Medicare would have adequate resources to conduct the required market research and enter into aggressive negotiations with manufacturers in cases where competitive bidding might be applicable. Finally, many respondents felt, because of political constraints, Medicare would be unable to restrict access to a few suppliers.

However, respondents also noted Medicare does not obtain the best price available by paying on the basis of billed charges, cost-to-charge ratios, or the average wholesale price, and that these methods might encourage providers to game the system. Better prices might be obtained by requesting invoices for payment and paying a certain percentage above invoice price. More thorough evaluative research of patterns of use, prices paid by other purchasers, and assessment of the financial impact of pricing decisions could also help Medicare set better prices.

Respondents also noted that a closer interface between Medicare's reimbursement and coverage divisions could help the government make more prudent payment decisions. For example, prices could be set equivalent for therapeutically-interchangeable products. Or, when the medical evidence is "suggestive" but not strong that a product offers a relative therapeutic advance, beneficiaries might be charged a higher co-payment so that determinations of value are shifted back to the consumer. Cost-effectiveness analyses also could assist in establishing prices when formal coverage determinations are made. If a product does not meet a certain threshold of cost per quality-adjusted life year, Medicare might wish to not cover the product or go back to the manufacturer and assess whether they would adjust the price of their product. Finally,

many respondents commented that Medicare might better moderate the use of high-cost new technology by improving upon the evidence-based processes used by its contractors in making coverage determinations.

I. BACKGROUND AND OBJECTIVES

The Medicare program is the single largest purchaser of health care in the United States, covering 40 million Americans and accounting for 20 percent of overall health spending. Over the years, the program has evolved into an administered pricing system – setting prices prospectively for bundles of health care services and individual technologies for all of its beneficiaries. One of the challenges facing the Medicare program is to administer a pricing system that is flexible enough to pay for new, quality-enhancing technologies, without encouraging the inefficient use of resources.

In recent years, Congress has taken a renewed interest in the way in which Medicare pays for new technology. The Balanced Budget Refinement Act (BBRA) of 1999 required that the Centers for Medicare and Medicaid Services (CMS) include a pass-through transitional payment for new technology covered in the hospital outpatient setting. A similar mechanism was recently extended to the inpatient setting. Implementation of this payment mechanism in the outpatient setting has raised a host of serious concerns, causing the Medicare Payment Advisory Commission (MedPAC) and other policymakers to evaluate other options. One of the recommendations made by MedPAC was that Medicare replace rates based on reported costs for pass-through technologies with a national rate. This recommendation was made because of concerns that cost or charge-based criteria provided incentives to inflate these measures (MedPAC, 2001). The Commission, however, did not have specific ideas about how Medicare might establish national rates for new technologies.

In light of this concern, MedPAC contracted with Project HOPE's Center for Health Affairs to conduct a two-stage investigation. The first stage of this investigation is a series of structured interviews with large purchasers of health care services. The goals of these interviews were to identify methods developed by payers other than Medicare to establish prices for new medical technology

and to critically examine their relevance for paying for new medical technology under Medicare. For the second stage of the investigation, Project HOPE convened a panel of individuals expert in Medicare policy, technology assessment, and device and pharmaceuticals reimbursement who considered the available options for paying for new medical technology and weighed their relative merits for the Medicare program. This briefing paper summarizes the finding from interviews with large purchasers. A summary of the expert panel meeting is provided in a separate document.

II. METHODS

Qualitative interviews were conducted with about 35 key informants from large public and private purchasers of health care services with large purchasing power, including:

- large health care insurers;
- multi-hospital group purchasing organizations;
- integrated delivery systems;
- pharmacy benefit management groups;
- a large hospital chain;
- the Veterans' Health Affairs;
- the Department of Defense;
- the New York State Medicaid program; and
- the United Kingdom and Australia –two countries with national health care systems that use cost-effectiveness analyses for coverage determinations.

Key informants held diverse responsibilities within these various organizations, and included medical directors, pharmacy directors, directors of product evaluation committees, reimbursement policy, technology assessment, and provider contracting. In some instances, Chief Executive Officers or Vice Presidents of Finance were interviewed.

Because of the wide variety of types of organizations we interviewed, questions were tailored for each informant. Our overall intent was to understand the array of mechanisms that might be used to set prices (including negotiated pricing, micro-costing, and competitive bidding) and their relative advantages or disadvantages. We also obtained information about:

- the structure of their organization;
- which individuals or groups were involved in establishing prices for new technologies;
- the interface between pricing decisions, technology assessment and coverage determinations;
- the types of information used in the price negotiation process;
- the nature of contracts with manufacturers and health care providers;
- how setting of care or the type of a product affected their ability to obtain a good pricing outcome; and
- how cost-effectiveness information is used to establish prices.

To illustrate common themes and highlight differences in pricing approaches, we also asked informants about how they set prices for four case study technologies. Our case study technologies were selected from a list of those that have been eligible for transitional pass-through payments in recent years and are used in both the inpatient and outpatient setting. We also chose an array of different types of technologies – two devices, a biological product, and a cancer drug:

- drug-eluting coronary artery stents;
- implantable dual chamber cardioverter defibrillators;
- live dermal replacement grafts; and
- a monoclonal antibody approved for the treatment of breast cancer.

A brief description of these case study technologies has been provided in Appendix 1.

We also asked informants to reflect on lessons they have learned that may be relevant to Medicare.

III. FINDINGS

A. General Observations

Despite wide differences in mission and structure among the large health care purchasers we interviewed, there were a few common observations, which are discussed in this section.

1. Classification of Technologies.

First, respondents commonly classified new technologies into three distinct groups based on their clinical impact relative to existing therapies, which influenced a purchaser's ability to obtain a good price.

- Breakthrough technologies have no competitors and offer a significant clinical advance over existing treatments. Most respondents pay manufacturer's price for breakthrough technologies, as is the case with the monoclonal antibody used for treating breast cancer.
- Therapeutically-equivalent technologies, commonly called "me-too" therapies, offer similar clinical outcomes to existing or other new therapies for the treatment of a specific disease or condition. Once a declaration of therapeutic-equivalence is made, discounts from manufacturer's price (from 10 to more than 24 percent) are obtained by initiating an iterative competitive bidding process, or prices may be set at the same level paid for the competing technology. An example of this kind of technology would be similar models of leads for implantable cardiac defibrillators.
- Physician's preference technologies comprise the large grey area between "me-too" and "breakthrough" products. These products offer clinical improvements, which are commonly greater among select patient subgroups, but often these benefits are obtained for substantial increases in cost. An example of this type of product is the new dual-chamber implantable cardiac defibrillator. One respondent reported that the majority of new technologies fit into

this category. While some respondents used cost-effectiveness analyses to make discriminating purchasing or coverage decisions for these types of products, others purchase these products at close to the manufacturer's price.

Respondents underscored that very early in a product's cycle it is often difficult to classify a technology into one of these categories because of uncertainty about a technology's relative benefits. Information for pharmaceuticals and the small fraction of devices that are subject to pre-market reviews is generally better than that available for surgical procedures and other devices because the Food and Drug Administration (FDA) requires data be gathered to demonstrate the safety and efficacy of these products¹. However, even when clinical trials are available, respondents expressed concerns about whether trial findings will generalize to other settings and other patient populations. Also, because the FDA's focus is on safety and efficacy, products are often compared to placebo and efficacy relative to alternative therapies is not available. A further problem arises with devices as, unlike drugs, there is a lack of a standard nomenclature for devices, which impairs price comparisons and determinations of therapeutic equivalence².

Implantable cardiac defibrillators (ICDs) can serve to illustrate the difficulties faced in establishing prices. The implantation of any ICD can significantly improve health-related quality of life and outcomes for appropriately-selected candidates, but little direct comparison has been done between dual chamber ICDs and traditional ICDs. Despite the lack of comparative data, 66 percent of

¹ Devices that are "substantially equivalent" to products previously on the market are subject to expedited review and are not required to submit a pre-market approval application. Only devices that have not established a performance standard and are used to support life, prevent health impairment, or present an unreasonable risk of injury or illness or subject to the similar clinical scrutiny as pharmaceuticals. An estimated 8 percent of new devices fall into this latter category (Foote, 1992). New surgical procedures are outside the purview of the FDA.

² New chemical entities are assigned unique National Drug Codes that indicate the product's strength, dosage form, and formulation. These are organized by major drug class, which facilitates their placement into therapeutically-exchangeable groups. Devices, by contrast, are given alphanumeric codes by CMS, which are quite broad. For example, biliary stents are assigned one code, which includes expandable stents, stents with balloon delivery systems, and other types of stents.

ICDs implanted in the USA during the 12 months ending April 30 2001 were dual chamber devices (Wilkoff, 2001). CMS and other insurers currently make no distinctions between models of ICDs, which they pay for on the basis of billed charges under the same code within their existing system. According to one respondent, the acquisition cost of traditional ICDs was \$6000, and the new dual-chamber ICDs now cost \$20,000.

2. Use of Non-price Policy Levers.

While early in a product's life cycle, there may be little room for price negotiation with manufacturers, respondents use an array of other policy levers to control new technology use and channel it to the most appropriate persons. These include step therapy, tiered co-payments, the development of clinical guidelines, and the education of consumers and physicians. For example, most purchasers surveyed paid manufacturer's price for the monoclonal antibody for treating breast cancer. However, its use was restricted based on FDA-labeled indications. The drug is also reserved for second-tier therapy, and candidates for its use must have failed prior chemotherapy. It should be noted that Medicare uses these same criteria for covering this monoclonal antibody.

For those respondents who do not have closed formularies for pharmaceuticals, tiered co-payments are a common policy lever used to channel patients to cheaper, but therapeutically-interchangeable drugs. Drug formularies are commonly arrayed into three preference classes: generic, preferred brand name, and other products. Graduated co-payments provide incentives to use the generic or preferred brand name products. The use of tiered co-payments also directly influences the price a manufacturer may charge for their product, and negotiations between the buyer and the manufacturer to be placed on a preferred brand list often results in substantial savings from the average wholesale price (AWP). Notably, a system of tiered co-payments was not used by any of our respondents for devices.

3. Involvement of End Users in Product Selection.

Insurers, integrated delivery systems, hospitals, pharmaceutical benefit management organizations, the military health systems, and the other countries we included in this survey had formal methods of involving end users of technologies (usually physicians) in coverage, product selection, and product purchasing decisions. As part of this process, a physician committee may be charged with developing quality specifications for a product to meet or guidelines for a product's use. (When should a dual-chamber ICD be used rather than a single-chamber device? When should drug-eluting stents be used in place of bare stents?) These guidelines might be disseminated via the internet to affiliate physicians, or more formal training seminars might be used. Notably, group purchasing organizations are sometimes called upon by their member hospitals to lead educational seminars and disseminate guidelines that support procurement decisions.

4. Ties Between Technology Assessment, Coverage and Purchasing Decisions.

Because of the importance of clinical evidence for developing pricing strategies, nearly all respondents have close linkages between technology assessment, coverage determinations, pricing, and procurement decisions. Evidence-based medicine is used both in technology assessment and in direct negotiations with manufacturers for prices. An illustration of a comprehensive system from assessment to final procurement used by one of our respondents in one of their regions is described in more detail under the integrated delivery system section of this report.

5. Aggressive Monitoring of Technological Advances.

Apart from having highly-integrated payment and coverage determination processes, respondents also aggressively monitor technologies that are in the pipeline so that they can be well prepared to make coverage decisions and enter into contract negotiations for pricing early in a product's life cycle. They monitor the clinical trials docket of the FDA, technology hotlines developed by commercial technology assessment organizations, and may have their own internal capabilities of tracking the medical literature. Price information may be obtained from industry analysts, commercial databases, European experience, or monitoring of purchase contracts of member hospitals or claims data for affiliate health plans.

6. Influence of Medicare on Pricing Policies.

As a final general observation, Medicare is often looked to as the leader in setting prices. Medicare has a large impact on the pricing of new technologies because of its large buying power and the nature of its administrative pricing system. Once Medicare establishes a price, other buyers use that price as a benchmark for negotiations, or set a similar price. This was true for commercial purchasers and the military health care system alike, although commercial purchasers may pay a certain percentage above Medicare's price, while public purchasers might pay a certain percentage below Medicare's price. For example, in an unusual step, Medicare has created a new diagnosis-related group (DRG) for drug-eluting stents, although approval by the FDA is not expected before next year. Medicare set their price by examining prices paid in Europe, where drug-eluting stents have been in common use. Initial prices cited by the manufacturer were reportedly more than twice as high as the final price Medicare developed. None of the US respondents currently has payment policies for drug-eluting stents, as they have not yet been approved by the FDA.

Most respondents said they would use this price in their future negotiations with hospitals and manufacturers.

B. Observations by Organization Type

In addition to the general observations made above, specific observations by organization type deserve mention. In this section we discuss in more detail the processes used for establishing prices for new medical technologies by each different type of organization.

1. Insurers

Insurers might be considered one of the more passive actors in the health care system with respect to obtaining the best prices for new technology. Similar to Medicare, these purchasers are one step removed from the manufacturer when making reimbursement decisions. Under an indemnity system, physicians, manufacturers, and other providers have wide latitude in establishing the rate they are paid for a new procedure, as the fees they charge become the usual customary and reasonable (UCR) rate.

In general, insurers negotiate prices for physician, clinic, and hospital services and not with manufacturers of new technology, per se. Insurers often offer a mix of risk-based or indemnity products and arrangements for payment vary by product. Within their managed care products, physicians may be capitated or fees may be set prospectively for each of the physician services codified by the American Medical Association's Current Procedural Terminology (CPT) system. Within their indemnity products, insurers pay physicians based on UCR rates for these same services. Hospitals may be paid a per diem rate, case rates, or fees may be established for DRGs.

For pharmaceutical products, insurers commonly operate their own pharmaceutical benefit management organization, or contract with an outside firm for these services. All three insurers we interviewed had their own pharmaceutical benefit management groups and these negotiated discount pricing directly with the pharmaceutical manufacturer. For therapeutically-interchangeable products, payments are negotiated down from the AWP, which is considered the retail price.

Early in the life cycle of a technology, an insurer's decisions about payment are usually made on a case-by-case basis, often in conjunction with the plan medical director. In day-to-day claims review, payment rates are established in several ways:

- If there is a code, insurers look to Medicare's fee schedules or commercial relative value databases, to see if there is a relative value established.
- If there is no code, but there is a comparable procedure, they may price it the same as that comparable procedure.
- If there is enough claims history (this usually takes a year), they will pay UCR rates.
- If there is not enough claims history and there is no comparable procedure, they will pay billed charges.
- Device- or drug-related expenses for unlisted procedures may be paid at invoice plus a percentage, and invoices must accompany the payment request.
- Upon rare occasion, insurers may develop their own resource-based payment, examining the impact of the technology on physician time, cost of capital equipment, throughput and payments for similar technologies (e.g., lithotripsy for plantar fasciitis³).

³ Lithotripsy is now being used to break up the calcium deposits in a person's foot who is suffering from plantar fasciitis. A technology assessment found this procedure is highly effective. However, the company that developed this technology decided not to sell the machine, but instead to lease it on an as-needed basis to the ambulatory surgical center where this procedure is performed. The company charged \$5000 per foot for this service. The insurer examined the

If claims for a specific type of technology appear frequently enough, and plan decisions regarding its payment are inconsistent, the claims review unit may forward the technology to the technology assessment department for a formal assessment. All three of the insurers we interviewed had strong evidence-based technology assessment programs in house. These departments aggressively keep abreast of new technologies that are in the pipeline, conduct their own reviews of the medical literature, and subscribe to commercially-available technology assessment resources to stay informed. Recommendations about coverage are based on how well the new technology performs relative to existing therapies (relative efficacy). Some insurers will consider costs in coverage determinations if two procedures are considered equally effective. Cost considerations nearly always come into play in formulary decisions about drugs. Relative costs determine which tier of preference a drug is placed on within a therapeutic class and a sliding co-payment rate provides an incentive to use the most preferred drugs.

Insurers are usually at risk to pay for their coverage decisions about new technologies. Both hospital and physician contracts have provisions for the payment of new technology. In cases where physicians are capitated or hospitals are paid a fixed per diem, carve-out arrangements may be made for selected new technologies that become covered in the life of the contract. Also, nearly all contracts with hospitals have a wrap-around clause for “all other” services, which includes the majority of new technologies. Technologies in this wrap-around agreement are usually paid for at invoice plus a specified percentage. Biologically-manufactured skin is an example of a technology for

physician time required for this procedure and the capital cost for a similar lithotripsy machine (devised for other uses) and priced the procedure at \$1400 per foot. Affiliate facilities were told they could buy their own machines, or would have to take a loss with vendor pricing, which puts the pressure back on the vendor to change their marketing plan. Taking such aggressive action in setting prices, however, is relatively rare and is reserved only for those technologies that may have large cost consequences for the insurer.

which insurers are paying hospital invoice price plus a percentage. When contracts are re-negotiated with hospitals or physicians, these new technologies are folded back into per diem or capitation rates.

If charges for a hospital stay exceed a specified stop-loss amount, insurers pay for new technology used within a hospital or ambulatory surgical center based on billed charges, which can sometimes be four times as high as the invoice price. For example, insurers may have a contractual agreement to pay billed charges if the costs for a patient stay exceed \$100,000 per day. The new dual chamber ICDs are an example of where a decision to use a new technology results in exceeding the stop-loss agreement. Hospitals may pay \$20,000 for the dual-chamber ICDs, but bill the insurer \$80,000 for that device. Because the total charges for the hospital stay exceed the \$100,000 stop loss agreement, the insurer pays \$80,000 for the ICD, rather than invoice plus a percentage. When asked why insurers had such provisions in their contracts with hospitals, we were told hospitals make much of their revenue from billed charges and are reluctant to enter into a contract that does not allow them to bill for occasions when the stop-loss was exceeded.

On rare occasions, insurers may negotiate directly with manufacturers of a device, laboratory test, or medical service. This might occur when there is only one supplier of the service. For example, one insurer negotiated a rate with the only laboratory that performs genetic breast cancer testing in the United States. Another insurer negotiated a rate for thin-layer cytology Pap smears with the laboratory service that analyzes these tests. Notably, this rate was below the UCR rate established for this technology, placing pressure on the laboratory to obtain a good price from the manufacturer.

2. Group Purchasing Organizations

Group purchasing organizations (GPOs) negotiate volume discounts from manufacturers on behalf of their members, providing members with favorable pricing, contract terms, and other benefits, such as technology assessment, market research, administrative support for member procurement decisions, and the education of physicians and other staff about the effective use of products. The array of products they offer includes medical devices, pharmaceuticals, durable medical equipment, housekeeping services, food, and office supplies. At least for their larger clients, GPOs may not make their own decisions about which products to offer, but pursue products that their clients (e.g., hospitals, clinics, ambulatory surgery centers, integrated delivery systems) wish to purchase.

One of the biggest challenges these types of organizations face with new medical technologies is getting manufacturers to enter into a contract agreement. Some contracts contain language that if the manufacturer brings a new product to market within a contracted product line, the new product must also be offered to the GPO. Small companies with new products may contract with a GPO to gain market expertise and customer base. One of the manufacturers for biologically-manufactured skin, for example, had listed their product with a GPO, even though the product is considered a “breakthrough” and it has only been on the market a short while. This manufacturer was willing to negotiate a discounted rate for its product in exchange for market share and access to donor skin from member hospitals, which is used in the manufacture of its product.

Like the new product committee structure described earlier used by the integrated delivery system, all three of the GPOs are organized along product lines (e.g., pharmaceuticals, medical, surgical, laboratory) comprised of clinical specialists, managers and financial people. These product teams synthesize information about a product’s clinical- and cost-effectiveness, examine a

manufacturer's production and supply capability, and analyze the fiscal impact of moving from one vendor to another. This information is distributed to members through white papers and regular newsletters. All have internal technology assessment capabilities. They all aggressively monitor technologies in the pipeline, but also continuously re-assess older technologies against modern standards.

For therapeutically-interchangeable products with no differences in quality, GPOs solicit bids from manufacturers to be listed on their inventory. Physician-preference items may be restricted to items available from a few select manufacturers, which nevertheless meet the specifications of physicians affiliated with member hospitals. In this manner, GPOs can negotiate sometimes deep discounts in exchange for market share.

Contract terms with manufacturers range from 1-8 years, but the contract usually contains language that nullifies the agreement if a breakthrough technology appears on the market and renders the product obsolete. The contract length is longest for therapeutically-interchangeable products and shortest for breakthrough products.

3. Integrated Delivery Systems

Integrated delivery systems provide insurance to their beneficiaries, but also own or contract for most components of the health care delivery system. As a result, they are in the business of both making coverage decisions about new technologies for their beneficiaries and procuring these technologies for their physicians, hospitals, and clinics. The two integrated delivery systems in our survey are structured somewhat differently from each other. One owns most of its hospitals and has exclusive capitated contracts with its physician groups. The other system has salaried physicians, but contracts with hospitals for inpatient and outpatient services more along the lines of a commercial insurer. However,

there are many similarities in their structure regarding the procurement of new medical technologies.

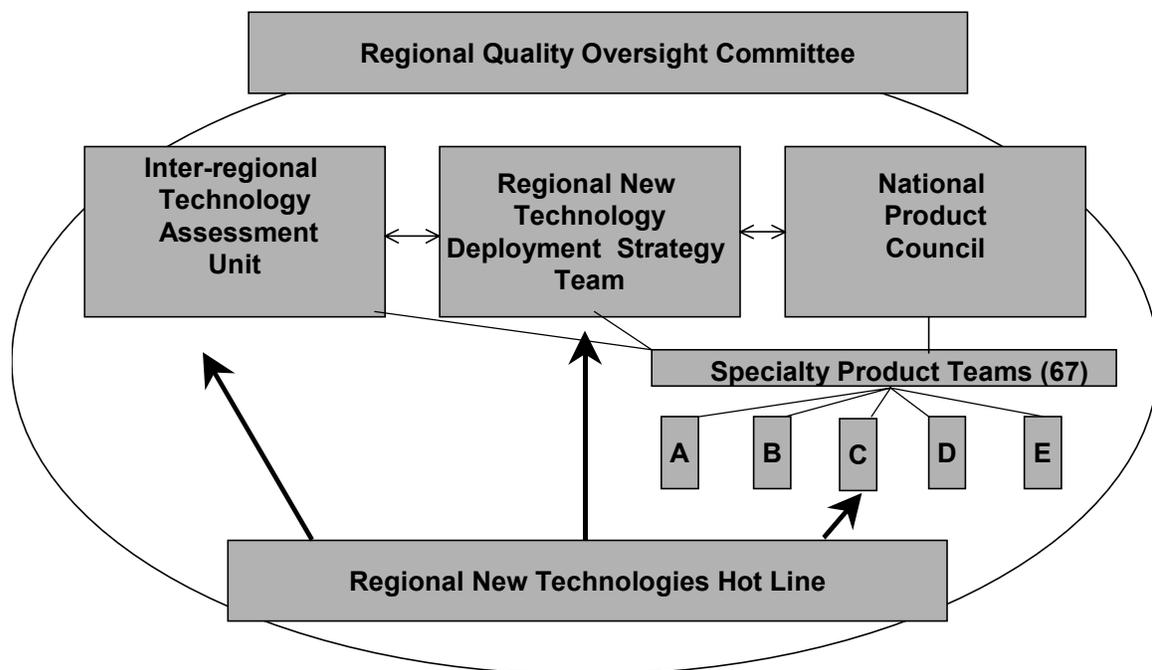
Both systems used GPOs to procure medical supplies and equipment for their physician's offices or facilities, but also had their own internal processes for determining which products to buy, which mirrored the GPO's processes. These processes are evidence-based, directly involve affiliate physicians in the purchasing decisions, and have close links with technology assessment and coverage decisions. The intent is to standardize an agreement between physicians and procurement personnel about which products are used within the system, and to achieve cost savings.

Because of the relatively closed nature of these systems, both organizations reported that they sometimes conducted clinical trials to evaluate the efficacy and cost of products in support of procurement decisions. They both also collect primary data within their organization relating to patterns of use and cost, which are used to project the financial implications of buy or lease decisions. Cost-effectiveness analyses are done internally by both systems, but cost is not formally considered by one of the systems during their technology assessment or coverage determinations. Instead, total cost analyses – from the perspective of the integrated delivery system – are used to forecast the implications of coverage decisions on beneficiary premiums. Implications on quality of life are also considered.

Very early in a product's cycle, both systems usually contract directly with manufacturers for a product. At one of the systems, this may be done by the regional plans. Notably, regional contracting arrangements may precede a formal technology assessment. In these arrangements, it is often difficult to obtain a favorable price from a manufacturer, especially when no competitors exist.

Below we describe a cohesive system of technology assessment, procurement and pricing used by one of the integrated delivery system respondents. The committee network, illustrated in Figure 1, portrays the close ties that have been developed between technology assessment, coverage, and pricing decisions among many large private and public health care purchasers.

FIGURE 1. A COMPREHENSIVE SYSTEM OF TECHNOLOGY ASSESSMENT, PRICING AND PROCUREMENT



This respondent has a centralized, formal **technology assessment committee**, charged with making recommendations to its semi-autonomous regions about whether a new technology is safe and effective, and comparatively useful to existing therapies. The committee is staffed by executive medical directors and other experts. The committee considers evidence on safety, efficacy, cost, cost-effectiveness, quality of life, system impact and legal and social implications. Evidence is derived from information synthesis, expert opinion, epidemiological or other observational methods, and clinical trials. Once a decision has been

made that a product is safe and effective, it is usually covered by all regions, although variation may occur if there are benefits implications. For example, some states may mandate certain transplants be covered, and this would be explicit in the benefit language for plans in that state.

Within one of this system's regions, a **new technology deployment strategy team** then determines the potential volume of use within the system, the most appropriate procurement method (e.g., buy, lease, regionalize, sub-regionalize, contract), and its total cost impact. Analyses may begin before the technology assessment is complete, if it seems likely that a product will be granted coverage. This team may use techniques, such as decision analytic modeling, to examine the implications of restricting the use of a technology to particular sub-groups of patients who might benefit most. They critically examine the available price information, and turn the broad clinical specifications for a product's procurement into a business case.

Nationally, a **products council** mirrors these two activities and develops the final clinical specifications for procurement. The products council is a governing body that ensures standard processes are used by the nearly 70 specialty product teams charged with reviewing every product that is purchased for use by the integrated delivery system. These teams establish clinical and quality specifications for a technology's procurement. After a review of the medical evidence, they may declare therapeutic-equivalence for competing technologies. These teams make recommendations about which products to buy based on relative quality, relative total costs, and manufacturer's service. Specialty product teams are comprised of end users (e.g., physicians, nurses, technicians) organized by clinical area. For example, orthopedics and anesthesiology are separate specialty product teams. Recommendations about procurement are then turned over to this organization's group purchasing organization, which works to obtain the best price from manufacturers through a process of negotiation.

The national product council and their specialty product teams usually evaluate relatively established technologies that are used in large volume. Of our case study technologies, only drug-eluting stents had been evaluated for contracting by these teams, although the others had recently been reviewed by the technology assessment unit. Early in a product's life cycle, case-by-case decisions are usually made about payment, similar to the process used by insurers that was described earlier.

In the same region where the technology deployment teams operates, a **new technologies inquiry line** has been created. Its purpose is to provide on-the-spot information about new technologies to member physicians, beneficiaries, and plan medical directors. This group is responsible for rapidly assembling information available from commercial technology assessment groups, and conducting their own rapid syntheses of medical information. These rapid assessments, which may take from a couple hours to a few weeks, depending on the complexity of the question, serve as the initial groundwork for more formal assessments that might be conducted later. The inquiry line is currently supporting other regions and helping their medical directors make more informed decisions about paying for technology early in a product's life cycle.

There are both formal and informal links to ensure these various groups share information. Committees share common members and reports, and a **quality oversight committee** ensures that evidence-based standards are used for decision making. This committee also has budgetary authority and reviews each service area's budget submission to ensure monies are made available for new technologies and that procurement implementation occurs consistent with the new technology deployment team's recommendations and the new product council's specifications.

Although, arguably, the system we have described is one of the most comprehensive we found, similar structures were also used by group purchasing organizations, the military health systems, and our hospital informant.

4. Large Hospital System

Most hospital systems have a decentralized procurement process with purchasing left in the hands of individual department heads. Physicians, in large part, determine the demand for new medical technologies and exert a strong influence on which products the hospital buys. To obtain discounts for the medical devices and drugs they use, hospitals typically rely upon their arrangements with GPOs. However, for very new technologies that do not yet have competitors, hospitals may be left to negotiate directly with manufacturers.

The one large hospital system that we included in this study had reorganized its purchasing functions substantially three years ago. Executives felt that they could leverage the hospital system's size (encompassing nearly 50 hospitals and 400 outpatient clinics) and guarantee a higher degree of compliance with a given product than their GPO, in exchange for a better price from manufacturers. The reorganization has been very successful. During the first three years, the hospital system saved more than \$30 million and its expenditures for medical-surgical and pharmaceutical products have increased by only 3 percent per year, a rate far below general inflation for these types of products.

Currently, the hospital system is focusing its direct purchasing efforts on high-volume items that account for the top ten percent of medical products it uses. Its purchasing functions were centralized across all delivery sites, and the hospital system is modeling their procurement process on those used by other industries, such as the aerospace or automotive industries. These other industries have achieved economies in their product procurement process by having a high degree of centralization in purchasing, relying on uniform information technology

throughout the organization to understand patterns of use, conducting thorough market research in advance of the contract negotiation phase, and using competitive bidding.

Once they have decided to purchase an item, a group of stakeholders from their hospitals is charged with developing the specifications for the products. These stakeholders, who are usually physicians, define the minimum clinical standards for a product. If there are at least two competitors, the hospital system will then issue an RFP and initiate a competitive bidding process. This is an iterative process and bidders have a chance to make a subsequent offer. The length of contract varies by product, but is usually for 2-3 years. With the rapidly evolving medical marketplace, there is a trend toward entering into contracts of shorter duration. If there is only one supplier of a product, the hospital system has little room for negotiation.

To support the product procurement process, the hospital system has also established a committee to devise a plan for purchasing technologies that are newly on the horizon. This committee is comprised of representatives from purchasing, field sites, physicians, legal affairs, and strategic planning. Topics on their list included all of the items we selected for case study: drug-eluting stents, new cancer drugs, dual chamber ICDs, and biologically-manufactured skin.

One of the biggest challenges they face is countering the demand from consumers and physicians. Most manufacturers work around hospitals and try to get physicians and consumers to influence the choice of technology. This hospital system is investing in substantial education of physicians. There is a lot of sharing of best practices across the system. For selected technologies, the hospital system will conduct a clinical trial, in which they will collect cost data and look at longer-term effects (e.g., rehospitalizations).

5. Pharmaceutical Benefit Management Organizations

Pharmaceutical Benefit Management organizations (PBMs) specialize in the procurement of pharmaceuticals and the management of drug benefits. More than 200 million people in the United States receive their drug coverage through PBMs (Cook et al., 2000). PBMs are successful at managing drug costs in three ways. First, they obtain discounts through bulk purchasing of pharmaceuticals, which are then distributed by mail order. Second, they negotiate rebates with manufacturers, which determines drug placement on a tiered formulary. Third, they negotiate with the retail network (pharmacies). If health plans are willing to channel their beneficiaries to select pharmacies, additional discounts may be obtained. PBMs are able to negotiate a good price for products, because of their ability to influence market share and volume of use.

As we noted for most of our respondents to this survey, PBMs aggressively monitor new drug development. Sometimes more than a year before a new drug is approved, internal clinical departments at PBMs begin examining the medical evidence about safety and efficacy, competing therapies, and the potential budgetary impact. Price negotiation with manufacturers precedes FDA approval. One respondent noted the cost of monitoring, evaluating and negotiating exceeds \$20 million per year.

In general, the manufacturer sets the price – i.e., the AWP -- without external input from the PBM and then the contracting departments within the PBM negotiate. As noted for other respondents and other products, a PBM's ability to negotiate depends largely on the degree of innovation offered by the drug. A company with a me-too drug entering a crowded field has much less negotiating room and the PBM has more flexibility to get discounts. On the other hand, if the new drug represents a true breakthrough product, such as the monoclonal antibody for treating breast cancer, the manufacturer has little or no incentive to

give discounts. Cost-effectiveness information is used during the course of negotiations.

PBMs also use various other levers of control, such as utilization management, prior authorization, tiered co-payments, and educating physicians – that may not affect the price of the drug per se, but affects volume of the drug used and the cost of managing the disease.

6. Medicaid Program

The New York State Medicaid program is the largest in the nation in terms of total expenditures. This program is often relatively generous in the benefits that it provides to Medicaid recipients and has been innovative in the way in which it pays for health care services. For example, New York State was an early adopter of prospective payment for outpatient surgeries, and uses a modified-Medicaid-specific DRG system to pay for inpatient care. However, fiscal constraints in New York have left this program inflexible for accommodating new technology.

For example, like Medicare, New York Medicaid pays prospectively-determined fees for inpatient and outpatient services. However, unlike Medicare, there is no systematic method to incorporate the costs of new technology in their pricing structure. Both inpatient and outpatient fees are constrained to increase no faster than the rate of general inflation. New codes for new technologies or services have not been added to their outpatient service classification scheme since 1995, and payment for medical visits are subject to a flat fee, which has been capped since 1995 at \$67 per visit irrespective of the type of service delivered. Payment groups for outpatient surgery consist of relatively large bundles of care, such as vascular surgery, which encompass services with widely varying treatment costs. There are only 42 Products of Ambulatory

Surgery categories (Shalala, 1995), which can be contrasted to the more than 500 APCs used by Medicare.

For inpatient services, fees were established in 1981 by examining hospital cost reports, and although hospitals are required to file cost reports with the Medicaid program, the last time fees were re-examined was in 1988. Because of the lags in their system, respondents said they did not expect to have a new DRG for drug-eluting stents until 2004 – the next time they plan to re-examine the cost basis for all DRGs.

The New York State Medicaid program also has a closed formulary for pharmaceuticals and prices are established by statute as AWP less ten percent. Prices are equivalent for therapeutically-interchangeable products. Unlike the pricing system for hospital and clinic services, carve-out payments may be made for some breakthrough new laboratory technologies, such as new human immunodeficiency virus tests. Prices paid for laboratory test carve-outs are usually developed through recommendations made by clinical experts, or a review of their claims system. Decisions about carve-out payments for laboratory services are currently made on an ad-hoc basis, and consideration is given to the effects of the technology on health outcomes, quality of life, and costs to the program.

Partly because of the inflexibility of their pricing system, New York has faced considerable pressure to be more accommodating for new technologies. A proposal to formalize the assessment of coverage and payment for new technologies is being developed, although this is in the early planning phase. Under the new system, one department would be responsible for reviewing all requests for carve-out payments for laboratory services and coverage determinations. This department would work closely with the Medical Director, rate setters, and the legal department.

7. Veterans' and Military Health Care Systems

a) Veterans' Health Care

The Veterans Health Administration (VHA) provides health care to 6 million military veterans in the United States, treating about 4.8 million individuals per year. It owns 1300 sites of care, including 163 hospitals, 850 ambulatory care and community-based outpatient clinics, and 206 counseling centers (Department of Veterans Affairs, 2002 (a)). The VHA's goal is to provide high quality, safe, and effective care to its beneficiaries. The medical benefits package encompasses a comprehensive array of inpatient and outpatient services, including prescription drugs. Generally, the same services are available to all enrolled veterans (Department of Veterans Affairs, 2002(b)).

Although policies are centralized, the delivery system is decentralized. Currently, the Veterans Health system is organized into 21 separate integrated delivery systems. A major difference between the VHA and private integrated delivery systems is that they cannot charge a higher premium to their beneficiaries if they decide to acquire expensive medical technology. As a result, they are more conscientious about being a prudent purchaser.

The VHA has a national closed formulary for drugs and is beginning to establish a national procurement program for durable medical equipment, which includes prosthetics, devices, and capital equipment. The formulary restricts provider's choice of drugs to the least-cost alternative for therapeutically-interchangeable products. For pharmaceuticals, the VHA has leveraged its buying power to obtain prices better than the Federal Supply Schedule, which pays AWP less 24 percent (GAO, 2002). Cost-effectiveness analyses that consider patient quality of life and the effects of therapy choice on use of other health services are examined when making formulary decisions.

The VHA's procurement process is strongly rooted in evidence-based medicine and is data driven. The unique nature of the VHA allows it to conduct its own clinical evaluations, which can be done to support decisions about which products to put on its national prosthetics or pharmaceuticals formulary. Vital to the success of the drug procurement process was the establishment of a national drug database, which allowed the VHA to examine national purchasing patterns. The VHA has begun to develop a similar database, based on the HCFA Common Procedural Codes System (HCPCS) as a standard nomenclature for devices, to allow them to monitor device utilization within their system.

Under the new procurement system for durable medical equipment, decisions about which products to buy will be made by clinical work groups, which are organized around clinically-similar products (e.g., orthopedics for hips and knees), and are staffed by physicians from within the VHA system. This system is very similar to the one adopted by an integrated delivery system described earlier in this paper. Each group of 10-15 physicians is responsible for developing guidelines for a product's use. According to VHA staff, physician buy-in regarding their procurement decisions is essential for the success of the program.

A competitive bidding process is initiated if there are two or more suppliers. If there are many suppliers, the VHA typically will enter into contracts with the three lowest bidders that meet clinical standards. The decision to select three manufacturers, rather than one, is to be able to obtain better buy-in from their physicians by not narrowing the choices too much. Through this competitive bidding process, the VHA is usually successful at negotiating discounts over manufacturer's price because of their large size. A typical discount for durable medical equipment may be 10 percent off manufacturer's price. However, manufacturers are often not willing to provide their "best" price to the VHA system, because this information is publicly available. During negotiations, information on prices for new technologies are often obtained informally from

their affiliate academic medical centers or from within the VHA system based on earlier regional contracts.

The VHA has withstood legal challenges to its decisions about the formulary and product acquisition, because they have demonstrated they rely on scientific evidence and have a physician-driven process in place.

b) Military Health Care

Health care for active duty and retired members of the uniformed services, their families, and survivors is provided by the Federal program known as TRICARE. TRICARE delivers health care to 8.2 million people through two types of plans: Prime — where Military Treatment Facilities are the principal source of health care; and Extra – where TRICARE purchases care from private entities that use either preferred provider organization or fee-for-service arrangements. About 80 percent of TRICARE expenditures are spent for their purchased care arrangements. As legislated by the 2001 National Defense Authorization Act, uniformed service beneficiaries 65 or older that are Medicare-eligible and have purchased Medicare Part B are eligible for “TRICARE for Life.” This is a permanent health care benefit that pays secondary to Medicare for additional health care costs that TRICARE covers (TRICARE Management Authority, 2001).

Outside of military treatment facilities, TRICARE contracts with four different companies to manage the purchased care system in different regions. The contracts with these companies are fixed price for health care costs with some pass-through allowances. These companies in turn purchase health care by contracting with different health care providers and facilities. Because budgets are fixed annually, the contractors are at partial risk for the care that they provide.

The Office of the Chief Medical Officer and the Medical Reimbursement Division work closely together to determine coverage policy and reimbursement,

respectively, for new medical technologies. Because of fixed budget constraints, TRICARE is a prudent purchaser of new technologies, which it achieves largely through its coverage determination process. New technology is covered only if the medical evidence clearly shows that a technology is comparable or relatively more effective than conventional treatment. Notably, TRICARE might not cover technologies considered to be “standard of care” by other purchasers because the evidence about their relative efficacy is lacking. For example, TRICARE does not cover ultrasound for routine obstetric care, nor does it cover universal newborn hearing screening, despite the fact that some states have mandated its use. Off-label use for pharmaceuticals is covered only when there is reliable evidence that demonstrates such usage is safe and effective.

TRICARE conducts its own technology assessments, and it works closely with the Cochrane Collaboration, the US Preventive Services Task Force, and uses assessments prepared by commercial technology assessment firms. Coverage is based on medical effectiveness and cost. Once a technology is considered effective, TRICARE employs a consulting firm to do independent cost estimates of coverage decisions. These cost estimates include information on cost effectiveness, outcomes, and cost avoidance. TRICARE then prioritizes its coverage decisions. Coverage determinations are uniform throughout the TRICARE system.

During the period after a positive coverage decision has been made, but before contracts have been re-negotiated in the purchased care system, TRICARE will pay for new technologies through a “special emergent” carve-out. Within this carve out, TRICARE will pay billed charges until eight claims have been processed. Biologically-manufactured skin is currently being paid through this carve out. All subsequent claims are paid at a percentage of the prevailing rate (Champus maximum allowable charge – or CMACs) for a regional contractor. When 50 or more observations occur annually, a national prevailing rate is established. Once Medicare has established a payment rate, TRICARE sets

payments that are closely aligned with Medicare's rates, as is the case for dual-chamber implantable cardiac defibrillators. Discounts from CMACs may be obtained by network providers. Vendor acquisition cost plus a dispensing fee is paid for pharmaceuticals obtained through retail pharmacies, although network pharmacies provide discounts from the AWP.

TRICARE works with the VHA to negotiate prices with manufacturers for its military treatment facilities for high-volume medical devices and supplies. However, most new technologies are not used at high-enough volume to be included in this competitive bidding process.

TRICARE and the VHA share a closed formulary for pharmaceutical products. TRICARE often obtains prices that are 25- 35 percent below manufacturer's price through an aggressive competitive-bidding process for therapeutically-interchangeable drugs. According to informants, the Department of Defense offers potential bidders more volume than any other health care purchaser in the United States.

TRICARE is currently re-structuring its purchased care contracts. They will reduce the number of regions from seven (previously) to three. The new contracts will provide incentives to beneficiaries to use the military treatment facilities and include performance measures on quality of care, health care access, and customer satisfaction. Reimbursement arrangements will also shift some of the risk from contractors back to the Department of Defense. Pharmaceutical benefits and a dual-eligibility plan for Medicare-eligible retirees will be carved out from these services.

8. Other Countries

a) *Australia*

Australia provides universal coverage to many areas of health care through a complex mix of public and private financing and delivery. The Australian health insurance scheme, called Medicare, provides access to doctors of choice, free public hospital care, and a subsidized pharmaceuticals benefit (Population Health Division, 1999). Health care is funded through a system of subsidies and grants to health care providers, States, and Territories, supplemented by local taxes and private payments. In 1998, about 31 percent of Australians had private insurance, and this proportion has been declining steadily since Medicare was introduced in 1984. Hospitals within the public sector are paid based on case-mix adjusted budgets, using Australian-refined DRGs to define case mix. Physicians are paid on a fee-for-service basis under **Medicare Schedule** fees.

Because Australia has a centrally-managed universal pharmaceuticals benefit with a closed formulary, it is in a strong position to negotiate prices with manufacturers. New drugs are listed on the national schedule only after a pharmaceutical company has made a submission to the Pharmaceutical Benefits Advisory Committee (PBAC), an independent, statutory body, which considers the medical evidence about the drug's safety, efficacy, relative efficacy, and cost-effectiveness. Cost-effectiveness information is required in the application.

Typically, a company proposes a price in its submission for a new drug listing. The PBAC determines whether the drug offers a substantial innovation. If it does not, the new drug may receive the price of others in its class. If it does offer a substantial improvement over existing therapy, Medicare may agree to pay a premium. If the PBAC decides that the drug is not cost-effective at the price submitted in the application, it may either restrict the use of the drug to a

population subgroup where it is cost-effective or negotiate with the manufacturer to reduce the price.

Cost-effectiveness analysis is also being applied to other health care interventions, such as devices, procedures, diagnostics, vaccines, and blood products. Device manufacturers make an application to a separate committee on new technology. If the committee decides that the technology is cost-effective, the application goes to a separate committee where its price is negotiated – before the device becomes listed on a fee schedule. How price is ultimately determined is complex. There is no good link between cost-effectiveness information and price, in part because like the United States, the technology is part of a larger bundle of services (involving physician time and other resources), and hospitals and physicians may obtain different prices than the list price from manufacturers.

Similar to the United States, new technologies may be used by providers in advance of the process discussed above and incorporated into an existing bundled payment for a service. This has been the case for drug-eluting stents, dual chamber ICDs, and biologically-manufactured skin. The ease of incorporating new technology into the existing system depends on how close the new technology approximates other services.

b) United Kingdom

The United Kingdom (UK) offers health care coverage to its residents through a tax-financed public insurance system (Mohr et al., 1993). The basic package of covered services is regulated through the National Health Service (NHS) at the central level and is quite comprehensive including most medically-necessary services. Consonant with broad service coverage, patient cost sharing is limited to modest fees. Most of the health care delivery system in the UK is publicly owned and services are delivered through the District Health Authorities, operated under the aegis of the federal government. In the mid-1990s, the UK

introduced a system of primary care trusts, where primary care physicians are granted global budgets through which hospital care is purchased. Funding for primary trusts comes from the NHS according to a risk adjustment formula.

In 1999, The National Institute for Clinical Excellence (NICE) was set up as a Special Health Authority for England and Wales to provide guidance to the NHS about the use of individual health technologies, and the clinical management of specific conditions. A special horizon-scanning group in the Secretary of State refers topics to NICE. Topics can also be referred by members of the public. NICE is largely involved in the assessment of new technologies and in the issuance of guidance for its use. Based on a review of the clinical and cost-effectiveness evidence, NICE may recommend that the use of a particular technology be restricted to various subgroups. Drug-eluting stents are currently being reviewed by the agency.

Although NICE is not directly involved in establishing prices for new technologies, it does influence manufacturers' pricing decisions indirectly by examining cost-effectiveness analyses when making their recommendations. The agency has loosely adhered to a 30,000 pound per quality-adjusted life year threshold for their recommendations. That is, if a cost-effectiveness ratio exceeds this amount, NICE is less likely to recommend the product.

Price determination occurs at several different levels within the NHS. First, pharmaceutical prices are subject to a cap based on "reasonable" return on equity. Manufacturers that exceed specified sales volume thresholds are required to submit audited financial returns detailing their investment in the UK. A reasonable rate of return on equity is limited to 21 percent for annual reviews and 17 percent for price increase applications (Department of Health, 1999). According to internal formulas, if the rate of return exceeds these targeted rates, the manufacturer must grant the NHS a rebate or reduce the price of the drug

Second, physicians and hospitals can negotiate directly with manufacturers for both drugs and devices. Primary care practices and hospitals are constrained by the generally tight budgets and have a strong incentive to negotiate. Discounts manufacturers are willing to give vary by both the financial condition of the provider and its size, among other local factors. For drugs used on an inpatient basis, a hospital drug and therapeutics committee has additional negotiating power, because – unlike on the outpatient side – they have the power to limit the number of drugs on a formulary.

Although, a purchasing and supply agency exists with the NHS to use government bargaining power to help hospitals get better prices on certain services, medical items are usually restricted to such things as bandages, surgical gloves, and needles. According to a UK health policy expert, the agency tends not to buy devices or biologics, such as stents or biologically-engineered skin products, as decisions about their use are driven more by physician preference rather than price, and they are not well-suited to bulk purchasing.

IV. LESSONS FOR MEDICARE

Informants offered a few insights that are of relevance to Medicare. First, respondents noted that Medicare exerts its buying power on the delivery system through establishing prices for hospital, clinic, and physician services. The prospective payment systems adopted by Medicare provide incentives for health care providers to contain the cost of new technologies. In particular, the DRG system by its nature encourages providers to be more efficient and takes the onus off the Medicare program to enter into direct negotiations with manufacturers for their best price. The major restructuring undertaken by our large hospital informant of its procurement system illustrates this point.

Many respondents felt the techniques they use to establish prices were of limited relevance to Medicare. First, pass-through items are inherently “new” and many of them might be considered “breakthrough” technologies, leaving little room for negotiation with manufacturers about prices. Second, for products that might be considered to be therapeutically-interchangeable, respondents noted the administrative costs of tracking, evaluating, and negotiating with manufacturers is high, and Medicare may not have adequate resources to conduct negotiations. Moreover, it may not have the political ability to limit access to a selected few products.

However, several informants commented that Medicare does not obtain the best price when it pays based on billed charges, cost-to-charge ratios, or AWP, and that these methods may encourage providers and manufacturers to game the system. For technologies that have been on the market only a few years, Medicare might establish payments based on a percentage increase above invoice price and request invoices for payment. In addition, respondents felt that a greater investment by CMS into understanding existing patterns of technology use from within the Medicare claims system, ascertaining potential prices from a variety of sources, and examining the financial impact of pricing decisions could help Medicare establish better prices.

Some informants also stated that more prudent payment decisions might be made if there was a closer interface between Medicare’s reimbursement and coverage policy divisions. Notably, a 1997 reorganization of the Health Care Financing Administration (CMS’ predecessor agency) separated its coverage from its pricing policy divisions. As a result, reimbursement decisions are generally made separately from coverage decisions, although informal communication channels between the two divisions have strengthened in recent years. Nevertheless, many respondents underscored the importance of medical evidence for making good pricing decisions. In their opinion, prices should be equal for therapeutically-equivalent technologies.

Also, both the UK and Australia have demonstrated that evaluating cost-effectiveness information during coverage decisions can influence a manufacturer's price and assist in the pricing decision. Respondents noted that Medicare has been politically constrained from using this information for coverage determinations, and may face political difficulties if it tries to use cost-effectiveness analyses for its pricing decisions. Also, when clinical evidence suggests a technology may be equally effective as a less expensive alternative, sliding co-payments have been a very effective policy tool among PBMs to steer consumers to preferred products. Respondents suggested that sliding co-payments might be effectively used for Medicare-covered drugs and other technologies.

Finally, while coverage determination was not the focus of this structured interview, several respondents noted that in order for Medicare to be a prudent purchaser, it might strengthen the evidence-based processes for making coverage decisions, particularly those used by its contractors. Respondents noted that Medicare has made considerable strides in recent years to improve the evidentiary basis for national coverage decisions. However, only a small percentage of new technologies are considered by Medicare at a national level. Medicare's contractors, who make most of the coverage decisions, have varying capabilities for conducting technology assessments and evaluating medical evidence. Respondents from insurers and integrated delivery systems pointed out that Medicare's decisions greatly affect aggregate health care spending. Once Medicare contractors have made a positive coverage determination, it is difficult for private insurers to adhere to standards that are more stringent.

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APPENDIX 1. CASE STUDY TECHNOLOGIES

1. Drug Eluting Stents:

Stents are tiny cylinders that open arteries, flatten plaque against the vessel wall, and are primarily used to prevent recurrence of the arterial narrowing after balloon angioplasty. A drug-eluting stent provides a controlled release of anti-proliferative drug into surrounding tissue to slow down the growth of unwanted cells (restenosis) that occurs in 20 to 30 percent of cases. Drug eluting stents have been tested with the anti-proliferative antibiotic Rapamycin (sirolimus) and are currently in clinical trials with statins, Actinomycin (an anti-proliferative antibiotic), and Paclitaxel (an anti-tumoral). Clinical trials with sirolimus-eluting stents have reported a reduction of restenosis from 26% to 0% (Curfman, 2002).

2. Implantable Cardiac Defibrillators:

Implantable cardioverter defibrillators (ICDs) are surgically implanted devices that monitor the heart's rhythm through electrodes connected to the heart. Traditional ICDs have been used in the management of ventricular arrhythmias, specifically ventricular tachycardia (VT) and ventricular fibrillations (VF). Recent technology has led to the development of dual chamber ICDs that use algorithms to detect and treat episodes of a VT, VF as well as atrial fibrillation (AF).

The scientific evidence about the relative effectiveness of this technology over traditional ICDs is mixed. Among appropriately-selected candidates, the implantation of any ICD significantly improves health-related quality of life and outcomes but little direct comparison has been done between dual chamber ICDs and traditional ICDs. One trial found that dual chamber ICDs provide little benefit over traditional ICDs for the prevention of stroke or death due to cardiovascular causes (Connolley et al., 2002). However, patients with sick-sinus syndrome have been shown in other studies to benefit from dual chamber (Lamas et al., 1998). A head-to-head trial (The Dual Chamber And Vvi

Implantable Defibrillator Study or DAVID) is currently being conducted to evaluate the relative efficacy of these devices over traditional ICDs.

3. Monoclonal Antibody for Treating Breast Cancer

Herceptin (trastuzumab) is a monoclonal antibody designed to slow or stop the growth of cancer cells overproduce human epidermal growth factor receptor 2 protein (HER-2), which is found on the surface of cancer cells. Herceptin was approved in 1998 for the treatment of metastatic breast cancer that overexpress HER2 and for patients who have already received at least one chemotherapy regimen or, in the absence of a prior chemotherapy regimen, in conjunction with paclitaxel (FDA, 1998). The addition of Herceptin to chemotherapy slowed disease progression, improved and sustained objective response, and lowered mortality (Slamon et al., 2001). There is no evidence of benefit in patients whose tumors do not overexpress HER-2 (Genentech 2002). Because there are many types of tumors that can overexpress HER2 there is much research being done on which cancers Herceptin can successfully treat. It is currently in clinical trials with non-metastatic breast cancer and cancers of the lung, pancreas, salivary gland, colon, prostate, and ovaries (National Cancer Institute, 2002). This medication is a sole source drug.

4. Biologically-manufactured Skin Substitutes

Biological skin products generally are either temporary dressings that protect skin wounds and in some cases promote the patient's own skin growth and healing. The manufacturing processes and FDA-approved indications for use vary by product. Indications include the treatment of skin graft wounds in burn patients, treatment for non-healing diabetic foot ulcers, treatment of venous insufficiency ulcers (Falabella et al., 2000; Falanga et al, 1998). To date, Apligraf is the only living bilayered skin construct approved by the FDA for marketing in the United

States. In 2001, Medicare made a national coverage determination for biologically manufactured skin (j7340) with an accompanying payment rate of \$1270.62. These products are narrowly indicated for the treatment of burns and leg/foot ulcers. Clinical trials are beginning to explore other uses for these products.

APPENDIX REFERENCES

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