

Key Medicare Issues for Coverage and Reimbursement of Specialty Pharmaceuticals

Advances in biotechnology have brought many effective new treatments for serious and debilitating diseases, but concern has emerged regarding the costs of these therapies, which can reach over \$100,000 per year for a single patient. In the United States, spending on biotechnology products is increasing at over double the rate of traditional pharmaceuticals.¹ It now represents ten percent of spending on outpatient drugs, and over fifty percent of revenue for some specialized medical practices.² These trends will likely persist: spending on biologics is expected to increase at 21 percent annually through 2012, due largely to increases in utilization as well as price.³ These trends are bearing on insurers, health plans, providers and patients alike: insured patients are now required to pay out-of-pocket up to one third of the cost of these drugs.

Biotechnology drugs, or “specialty drugs,” include injectable medications, oral chemotherapeutic agents, and chemotherapy infusions, and may be administered in health care settings or self-administered by patients. Specialty drugs are usually biologically derived rather than chemical (requiring additional development and production costs). They generally require special storage, handling and administration, and close patient monitoring. Until recently, these medications were limited to treating cancer and rare diseases. More recently, the conditions treated with specialty drugs are increasingly common, and include chronic cancer treatment, rheumatoid arthritis, multiple sclerosis, immune disorders, hepatitis, and anemia.

As utilization and spending increase, challenges arise in the management of specialty drugs, driven by the critical nature of the illnesses being treated, uncertain evidence regarding benefits, high cost in the absence of generic equivalents, and growing use for indications beyond those approved by the Food and Drug Administration (FDA). Government programs have begun to manage the cost of specialty drugs through new reimbursement strategies, and private payers are addressing it through reimbursement, distribution, and benefit design. Specialty pharmacy providers (SPPs), pharmacies that distribute biologics and the clinical, patient education, and cost management services to support specialty drugs, are a growing presence in the market.

A particularly vexing challenge for both public and private payers is the fact that these drugs can be covered under either a medical or outpatient drug benefit, depending on site of service, contracting, and other factors. This leads to difficulties in management of patients and drug regimens across different reimbursement systems and providers. **Figure 1** illustrates the parallel distribution channels and reimbursement prices for specialty drugs that exist in both the public and private sectors. It demonstrates just how different coverage and payment is for drugs covered under the medical compared to the outpatient drug benefit.

MEDICARE AND SPECIALTY PHARMACEUTICALS

For Medicare, the management of specialty pharmaceuticals is of critical importance. While fewer than five percent of covered individuals in the private sector receive specialty medications,⁴ the percentage is considerably higher in the Medicare population, as many of the diseases for which specialty medications are indicated are age-related. Medicare has historically covered a limited number of physician-administered specialty drugs under Part B (the medical benefit). As more biologics emerged on the market, spending on these drugs grew from \$2.8 billion in 1997 to \$11

billion by 2004,⁵ leveling off in 2005 after Medicare changed its payment method (Figure 2). Since 2006, many specialty medications that are not covered under Part B are now covered under Part D, the outpatient drug benefit.

In spite of the significance of specialty drugs to Medicare and specialty physician practices, the program has limited flexibility to make changes in response to the above trends, due to legal and regulatory requirements regarding coverage and reimbursement (e.g., mandated program structure and reimbursement rates, and policies against limiting drug distribution networks). As a result, Medicare until now has not adopted some of the more promising approaches used in the private sector.

This paper discusses key issues for Medicare as it works to establish efficient and effective policies for specialty pharmaceuticals.

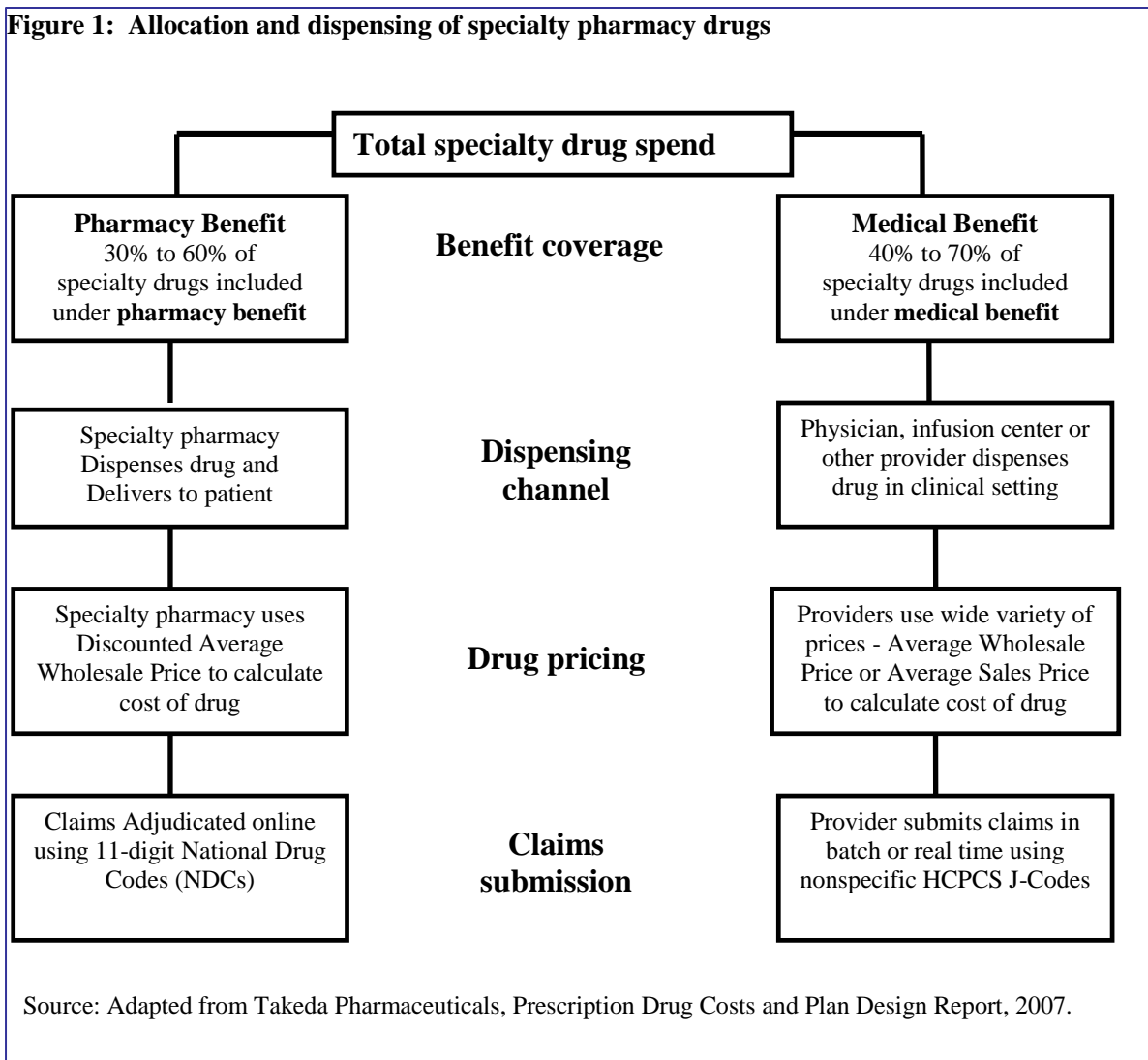
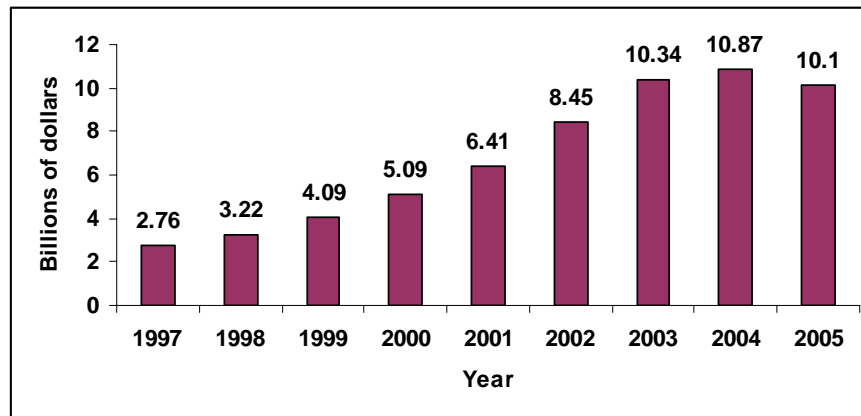


Figure 2: Medicare spending for Part B specialty drugs



Source: Centers for Medicare and Medicaid Services, Medicare Payment Advisory Commission

CMS coverage decisions for specialty drugs lack standard, evidence-based criteria, and vary across location.

Because of the high cost and limited evidence of effectiveness for specialty pharmaceuticals, there are compelling reasons to adopt policies that encourage use of the most cost-effective products. Medicare coverage decisions are, by law, based on a service being “reasonable and necessary,” and do not consider cost. In most cases, coverage decisions for specialty drugs (determining what is reasonable and necessary), are made at the local level by individual carriers, rather than through national coverage determinations. While Medicare coverage of specialty drugs follows FDA-approved indications, the program has no formal criteria for determining which off-label uses are reasonable and necessary. This is important, as 50-75 percent of cancer treatments are off-label use. Local Medicare carriers often decide on a case-by-case basis, with off-label use for cancer drugs guided by recognized national clinical treatment guidelines, or compendia.⁶ Numerous case studies of biologic treatments for cancer and other serious diseases illustrate the uneven nature of Medicare coverage decisions.⁷

Medicare is now taking steps toward developing an evidence base for coverage decisions. Medicare’s Coverage with Evidence Development (CED) program, a national policy in which Medicare will cover certain specialty drugs within clinical trials, is an effort to standardize criteria for coverage, while developing evidence of effectiveness.

There are major challenges to more standard coverage criteria, including: a lack of consensus about the standards and quality of evidence needed for decision making; funding for data collection and analysis under CED; and the ethical implications of linking coverage with clinical trial participation.⁸ In addition, the fact that CMS is unable to consider cost-effectiveness (value) in its coverage decisions limits its use of economic analyses, a practice widely used in other countries, and that is becoming more common for private insurers in the United States.

Medicare covers specialty drugs under separate and distinct medical (Part B) and outpatient drug (Part D) benefits. This prevents coordinated patient management, and encourages provision of services in more costly settings.

Medicare Part B (the medical benefit) covers the following categories and specific specialty medications:

- Injectables and infusions when administered incident to a physician's service.
- Oral cancer drugs that replace injectables.
- Erythropoietin for renal dialysis patients with anemia, when administered in a dialysis facility.
- Pneumococcal and influenza vaccines and hepatitis vaccine in high-risk patients.
- Drugs requiring administration with medical equipment.
- Immunosuppressant drugs for post transplant patients.

Payment for these medications is no different from other Part B services, and is administered through local insurance carriers. Medicare Part B covers eighty percent of the drug and service, and patients, or their supplemental insurers, pay twenty percent. Because Medicare Part B does not limit patient out-of-pocket costs (includes no catastrophic coverage), beneficiary cost for a Part B drug can be thousands of dollars per month for a patient without supplemental (Medigap) coverage.

In 2006, with implementation of Medicare Part D, Medicare covered additional specialty medications (e.g., self-administered injectables, certain oral chemotherapy agents, and vaccines not covered under Part B). **Figure 3** shows the different specialty drug coverage rules for Medicare Part B and Part D as of October 2007.

Medicare Part D is administered through many private prescription drug plans (PDPs), with a wide array of cost sharing structures, separate administrative systems, distinct geographic markets, and unique provider networks. Because of Part D's catastrophic coverage, patient cost sharing for high cost drugs can be more, less, or similar to that of Part B, depending on the full cost of the drug, the Part D plan characteristics, and a beneficiary's Part B supplemental benefit.

Medicare Part B and Part D remain disconnected. The divided coverage of specialty drugs under two disparate systems creates obvious challenges in coordinating clinical care, and drug cost management. It is typical for high risk or critically ill patients to obtain specialty pharmaceuticals through a combination of physician offices and retail pharmacies. Since not all Part D plans cover all specialty drugs, patients may seek injections at a physician's office (covered under Part B) when a self-administered injectable would be medically appropriate and less costly, if their Part D plans do not cover the medication.

In addition, hundreds of drugs may be covered under both the medical (Part B) and the outpatient drug benefit (Part D), depending on setting, patient diagnosis, timing of treatment, and associated use of durable medical equipment (**Figure 3**).⁹ For example:

- Immunosuppressant drugs are covered under Part B post transplant, and under Part D if used for other purposes such as rheumatoid arthritis, or if the beneficiary was not Medicare-covered at the time of the transplant.
- Hepatitis B vaccine is covered under Part B for high-risk individuals (e.g., people with renal disease or hemophilia), and under Part D for other beneficiaries.

Figure 3: Medicare Part B and Part D coverage of specialty drugs

Part B Coverage Categories	Part B Coverage Description	B/D Coverage Determinations That Must Be Made	Other Issues That Arise
Always Part D at Retail Pharmacy			
Injected or intravenous drugs	Injectable/intravenous drugs 1) administered "incident to" a physician service and 2) considered "not usually self-administered".	Always Part D at retail pharmacy.	Medicare does not cover supplies and professional services associated with Part D covered infusion therapy.
Erythropoietin (EPO)	Treatment of anemia for persons with chronic renal failure who are undergoing dialysis when given in the dialysis center or when given "incident to physician's service" for other approved uses.	Always Part D at retail pharmacy. For Part B coverage for dialysis patients, the claim must be submitted by the ESRD facility.	
Always Part B			
Influenza/Pneumococcal Vaccines	Influenza and Pneumococcal vaccines are covered for all beneficiaries.	Always Part B.	
Coverage Depends on Beneficiary's Diagnosis or History			
Oral Anti-Cancer Drugs	Oral drugs used for cancer treatment that contain same active ingredient (or pro-drug) as drugs that would otherwise be covered incident to a physician's service.	Part B for cancer treatment; Part D for all other indications	Participating Part B pharmacies must bill the DMERC in their region when these drugs are covered under Part B.
Vaccines	Hepatitis B vaccine for intermediate- to high-risk beneficiaries. Other vaccines if "incident to" physician service, only for injury or direct exposure.	Hepatitis: Part B if beneficiary is intermediate- to high-risk; Part D if low-risk. All other vaccines: Part B if related to injury or exposure; otherwise Part D.	Medicare does not cover professional services associated with Part D covered vaccines.
Immunosuppressant Drugs	Drugs used in immunosuppressive therapy for a Medicare-covered transplant.	Part B when drugs used in relation to Medicare-covered transplant; Part D when drugs used for rheumatoid arthritis, other non-transplant use, or a transplant not covered by Medicare.	Participating Part B pharmacies must bill the DMERC in their region when these drugs are covered under Part B.
Parenteral Nutrition	Prosthetic benefit for individuals with "permanent" (or long and indefinite) dysfunction of the digestive tract.	Part B if "permanent" dysfunction of digestive tract, Part D for all other situations.	Medicare does not cover supplies and professional services associated with parenteral nutrition or other Part D covered infusion therapy.
Coverage Depends on Beneficiary's Diagnosis and Timing			
Oral Anti-emetic Drugs	Oral anti-emetic drugs used as full therapeutic replacement for IV anti-emetic drugs within 48 hours of chemotherapy.	Part B if used within 48 hours of chemotherapy; Part D if used beyond 48 hours of chemotherapy or for any non-chemotherapy-associated use.	Participating Part B pharmacies must bill the DMERC in their region when these drugs are covered under Part B.
Coverage Depends on Location and Use of DME			
Durable Medical Equipment (DME) Supply Drugs	Drugs that require administration via covered DME (e.g. nebulizer, infusion pump) in the beneficiary's home.	At retail pharmacy Part B coverage depends on use of DME; usually Part D in LTC facilities because most LTC facilities are not considered a beneficiary's "home."	Medicare does not cover supplies and professional services associated with Part D covered infusion therapy.

Source: Hargrave, E and Hoadley J. Coverage and pricing of drugs that can be covered under Part B and Part D. MedPAC, October 2007.

Determining which program to bill is administratively cumbersome for providers and pharmacists.¹⁰ Medicare has recently clarified coverage of some drugs to facilitate payment, but this issue remains for others. Simplifying reimbursement and management of specialty drugs by covering all specialty drugs under either the medical or pharmacy benefit is one potential approach, but can result in inefficiencies if, for instance, all injectables were covered under Part D and dispensed at retail pharmacies. Private payers have increasingly placed specialty drugs in the outpatient benefit, but as noted in several highly publicized cases, patients then may face prohibitively high cost sharing.¹¹

The divided coverage of specialty drugs under the medical and outpatient benefit is not unique to Medicare, but private payers have instituted a number of innovative approaches to coordinate patient care and manage these medications.¹² These include: contracting out specialty pharmacy services or creating an internal specialty pharmacy; management of medications covered in medical benefit by plan pharmacists; creating a distinct or hybrid benefit for specialty drugs, not based on site of service; multiple specialty tiers; tiering of providers; and limiting networks for prescribing and drug administration services. Most of these options are not currently used in fee-for-service Medicare.

Medicare Part B reduced reimbursement for specialty pharmaceuticals in 2005 to eliminate high provider profits. Critics argue that this policy adversely affects physicians and may diminish beneficiary access to specialty drugs.

Medicare Part B pays for specialty drugs through a “buy and bill” payment system. Through buy and bill, physicians are reimbursed for Part B drugs that they administer, as well as a drug administration fee. Before 2005, Medicare reimbursed physicians for medications based on the average wholesale price (AWP). A major problem is that AWP, an industry-wide benchmark, is a list price set by manufacturers, allowing them to provide discounts, resulting in considerable provider profits. By 2001, Medicare reimbursement for Part B brand drugs was estimated to be \$600 million more than providers paid,¹³ due to discounts.

The Medicare Modernization Act of 2003 included two payment reforms targeting the inefficiencies inherent in buy and bill. First, reimbursement based on AWP was changed to 106 percent of average sales price (ASP), a number based on actual transactions reported to CMS. The second was a voluntary competitive bidding program (CAP) for distribution of Part B medications.

Moving Part B drugs to ASP payment resulted in an eight percent decrease in total Part B drug spending from 2004 to 2005 (\$10.9 billion to \$10.1 billion).¹⁴ Part B drugs decreased as a percentage of Medicare allowed charges and volume of services. Some physicians report providing fewer drug treatments to Medicare patients, and referring patients to outpatient clinics more often, raising concerns about access. There are also continuing administrative challenges inherent in ASP, such as: the six month lag time in calculation of ASP; price differentials between what providers pay and what manufacturers charge, due to markups in the supply chain; and incentives for physicians to purchase discounted bundled products.¹⁵

Medicare’s competitive acquisition project (CAP) is an alternative to the ASP methodology for acquiring certain Part B drugs, in which physicians obtain medications from a CMS-approved vendor who bills Medicare directly, thereby eliminating buy and bill. CAP has had limited impact, as enrollment is low due in part to administrative requirements and limited choice of drugs.¹⁶ While these programs are not without problems, they represent attempts to move toward more rational reimbursement.

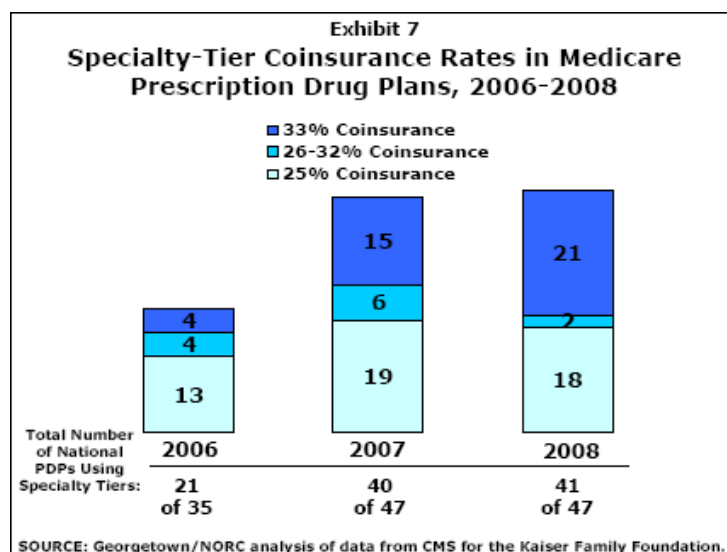
Medicare Part D has expanded coverage for specialty pharmaceuticals, but patient cost sharing can be substantial. Plans vary widely in their coverage of specialty drugs.

There is little doubt that Medicare Part D has expanded access to specialty medications, but cost sharing is considerable. The standard Part D prescription drug plan in 2008 requires that beneficiaries pay a deductible of \$265, twenty-five percent of drug costs from \$265 to \$2510, 100 percent of drug costs between \$2510 and \$5726 (the coverage gap), and five percent after \$5726 (catastrophic coverage). The conditions of coverage, including high cost sharing and prior authorization, may pose barriers for beneficiaries taking specialty drugs. At the same time, Part D catastrophic coverage shields covered beneficiaries from the high outpatient cost sharing that may occur under Part B for beneficiaries with no supplemental coverage, and that is often seen in commercial insurance.

Medicare's definition of specialty drugs under Part D underscores its payment-based approach to coverage. Specialty drugs are defined as any drug for which the negotiated price is \$600 per month or more. Any drug fitting this definition may be placed on a specialty tier, requiring higher patient cost sharing. CMS guidelines recommend Part D cost sharing for the specialty drug tier to be set no higher than 25 percent, but higher cost sharing is allowed if it is offset by lower deductibles. More drugs are being placed on specialty tiers each year. In 2007, of all Medicare drug plans with a specialty tier, twelve percent of covered drugs were on that tier.¹⁷

As shown in Figure 4, 41 of 47 Medicare national prescription drug plans now have a specialty tier. The number of Medicare drug plans that require 33 percent coinsurance for the specialty tier increased from four in 2006 to 21 in 2008. Based on average Medicare drug plan cost sharing, for a drug that costs \$600 per month, placement on a specialty tier could increase patient copayments from \$30 (if preferred) or \$60 (if non-preferred), to \$180 per month at 30 percent coinsurance, and \$600 in the coverage gap. This is not trivial: in an unrelated survey, Medicare Advantage plans report that 80 percent of members on a specialty medication reach the Part D coverage gap.¹⁸

Figure 4: Medicare prescription drug plan (PDP) specialty tier coinsurance rates



Source: Hoadley J, Hargrave E, Cubanski J, and Neuman T. Medicare prescription drug plans in 2008 and key changes since 2006. Kaiser Family Foundation, April 2008. (Summary of findings available at <http://www.kff.org/medicare/upload/7762.pdf>).

Part D drug plans also have a wide range of specialty drug availability and cost sharing requirements.¹⁹ CMS requires that drug plans cover “all or substantially all” drugs for six therapeutic classes, including some associated with specialty drugs (e.g., anti-neoplastics, immunosuppressants). An early analysis of Part D 2006 formularies indicated most cancer drugs were covered by drug plans and Medicare Advantage plans, with relatively low cost sharing,²⁰ but a later analyses revealed an evolution to more utilization controls and higher cost sharing by 2008.²¹

Can Medicare evolve to value-based payment for specialty drugs?

In both the public and private sectors, pay for performance is seen as one of the most promising approaches to health care reimbursement. Medicare has developed performance-based payment for hospitals, placing them at risk for the cost of preventable errors, and has implemented a voluntary reporting initiative for physicians. However, as Rosenthal and others note,²² moving performance-based payment beyond the initial demonstration and hospital care, will be a challenge, but broadening this approach is clearly a goal for the near future.

Medicare’s Physician Quality Reporting Initiative (PQRI) is a program that pays providers for reporting to Medicare on their use of quality-based measures. Several cancer treatments using specialty pharmacy are included in this program (e.g., multiple myeloma, chronic lymphocytic leukemia, colon cancer). In 2008, physicians who submit quality measures data for services receive an incentive payment of 1.5 percent of their total allowed charges. Although providers are paid for reporting and not for performance, this is an important step in development and application of pay for performance for high cost treatments.

The example of Velcade in the British system is a provocative example of pay-for-performance for specialty drugs, although in the extreme.²³ When cost effectiveness analysis by the British health program evaluation agency National Institute for Clinical Excellence (NICE) refused to support coverage of bortezomib (Velcade) for multiple myeloma, the manufacturer offered to be paid only for individuals with an “adequate response.” Defining response and adequate payment, and identifying appropriate patients for the treatment remain major issues.

There are clear challenges in instituting pay-for-performance and outcomes-based payment systems for high risk patients using specialty medications. Particularly when prescribing these medications for off-label use, protocols vary, and individualized treatments are the rule. Finally, as with any performance-based payment, the current lack of comprehensive patient records, standardized reporting systems, and agreement on appropriate end points as outcomes all serve as barriers to effective implementation.

SUMMARY

Because of the growing importance of specialty pharmaceuticals for Medicare beneficiaries, the program must use its coverage and payment policies to promote appropriate, efficient, high quality care. Taking steps to address the high cost of specialty pharmaceuticals while balancing the needs of patients and providers will be challenging. Although many of the issues described here are not unique to Medicare, they are more difficult to resolve within the constraints of Medicare’s legal and statutory requirements. Medicare recently has enacted a more rational reimbursement policy for physician-administered drugs and has implemented a more sophisticated process for coverage determinations. Nevertheless, as new products and potential uses for specialty pharmaceuticals expand, managing specialty pharmaceuticals will continue to be an important challenge for Medicare in the coming years.

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