CHAPTER 4

Value-based incentives for managing Part B drug use

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Chapter summary

Medicare's payment policies for Part B drugs do not always provide beneficiaries or taxpayers the best value because the policies do not consider evidence of a drug's clinical effectiveness compared with its alternatives. Federal agencies—the Department of Health and Human Services (HHS) Office of Inspector General and the Congressional Budget Office—have shown that linking Part B payment for drugs and biologics to comparative evidence of clinical effectiveness would reduce spending for beneficiaries and taxpayers.

Several types of value-based incentives have been implemented or proposed that seek to obtain a better price for Part B drugs and biologics for beneficiaries than under the current fee-for-service (FFS) system in traditional Medicare:

- ***The least costly alternative (LCA) and functional equivalence policies*** that Medicare used from 1995 to 2010. Under this approach, the program set the payment rate for a group of drugs with similar health effects (but assigned to different payment codes) based on the payment rate for the least costly product in the group.

In this chapter

- ***A consolidated payment code approach*** that Medicare used from 2007 to 2008. Under this approach, the program grouped drugs with similar health effects into a single payment code and set payment based on the volume-weighted average of the program's payment (average sales price) for each product.
- ***A bundled approach,*** which would cover drugs and their administration costs across all settings and providers as well as related services (e.g., inpatient admissions, emergency department visits) during a defined period under one payment (or a benchmark price across multiple providers). With the availability of a large evidence base and regularly updated clinical guidelines, oncology is a clinical area that might be amenable to bundling. Design issues associated with constructing oncology bundles in FFS Medicare are complex but important since Medicare spending for oncology drugs and biologics is substantial, accounting for about half of 2013 spending on Part B drugs administered in physicians' offices.

These three approaches are intended to improve efficiency by creating incentives for providers to choose lower cost products among a category of products with similar health effects. Under LCA and consolidated payment policies, Medicare would judge the comparative clinical effectiveness of a drug relative to its alternatives. By contrast, under bundled approaches, clinicians would judge the clinical effectiveness of alternative treatment approaches. Depending on the design, bundling has the potential to encourage providers' accountability across the spectrum of care and lead to positive downstream effects such as reduced hospital admissions and emergency department visits.

The Secretary of HHS would need the Congress to restore her authority to establish LCA or consolidated payment code policies. For LCA and consolidated payment code approaches, Medicare would need to consider and address a number of design questions and issues, including defining groups of products that treat a given condition with similar health effects, standardizing units and frequency of drug administration, and calculating and updating the payment rate. By contrast, the Center for Medicare and Medicaid Innovation (CMMI) could develop and test bundling approaches that include Part B drugs, or the Congress could mandate that CMS implement an oncology bundling initiative. Issues associated with implementing a bundled oncology approach include the bundle's scope of services, the duration of the treatment bundle, the event that triggers the use of the payment bundle, and the type of payment.

Other approaches that seek to pay efficiently for oncology services while improving care quality are currently in place. They include oncology medical homes and the use of clinical pathways. The Community Oncology Medical Home (COME

HOME) is a three-year oncology medical home model that CMMI funded in 2012 with seven oncology practices. The practices offer enhanced services for Medicare and Medicaid beneficiaries and commercially insured patients who have been newly diagnosed with or relapsed in seven cancer types. Clinical pathways, which in this context are evidence-based treatment protocols that commercial payers and providers use to standardize anticancer drug regimens, seek to reduce unnecessary variation, improve quality of care, and reduce costs. ■

Introduction

Since 2005, in accord with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Medicare pays physicians and suppliers the average sales price (ASP) + 6 percent for most Part B–covered drugs and biologics.[1] CMS, through regulation, has also established a payment rate of ASP + 6 percent for separately payable Part B drugs reimbursed through the hospital outpatient prospective payment system (OPPS). Under the Patient Protection and Affordable Care Act of 2010 (PPACA), a biosimilar biologic product is paid 100 percent of its ASP, plus 6 percent of the ASP for the reference biologic. Chapter 3 explains in more detail how Medicare pays for Part B drugs and biologics.

Medicare spending for Part B drugs and biologics paid under ASP is substantial. In 2013, Medicare spending (program payments and beneficiary cost sharing) for Part B drugs paid under ASP amounted to over $19 billion dollars (with more than $15 billion of Medicare program payments and nearly $4 billion of beneficiary cost sharing). Of that spending, physician offices accounted for over $11 billion, hospital outpatient departments accounted for nearly $7 billion, and suppliers accounted for over $1 billion.

Medicare's payment policy for Part B drugs does not always provide beneficiaries and taxpayers the best value because the policies do not consider evidence of a drug's clinical effectiveness compared with its alternatives. Concerns raised by the Department of Health and Human Services (HHS) Office of Inspector General (OIG) and researchers that the 6 percent add-on to ASP may incentivize the use of higher priced drugs are summarized in a text box (p. 92). Least costly alternative (LCA), consolidated payment code, and bundling approaches have the potential to improve value by creating incentives for providers to choose lower cost products from a category of products with similar health effects. Under LCA and consolidated payment code approaches, Medicare would develop groups of drugs that are used to treat a given condition and result in similar health effects. By contrast, under bundling, providers would make decisions on the value of services included in the bundle.

Concern has also been expressed that, under fee-for-service (FFS) payment systems, providers are not accountable for the total cost of services across an episode of care, and care is often fragmented and uncoordinated. According to Bach (2007), the fragmented FFS payment system is a poor fit for cancer care because patients require different services that should be integrated seamlessly (physician services, laboratory tests, and multimodality regimens that include infusion of cancer drugs, administration of radiation oncology, and surgery) (Bach 2007).

As the Commission discussed in its June 2013 report, bundling could achieve several goals. First, bundling would encourage providers to make clinically appropriate decisions about the most efficient mix of services beneficiaries receive. It might also reduce variation in total spending. For broader bundles, care could be less fragmented because the provider(s) would be accountable for all care furnished during an episode, which might result in fewer hospitalizations and emergency department visits. Last, bundling could give providers experience managing care across a continuum that is likely to be required in broader payment initiatives (Medicare Payment Advisory Commission 2013).

Previously, the Commission has considered and made recommendations on bundled payment approaches for certain services. For example:

- In its June 2013 report, the Commission considered design aspects of a bundled payment that would begin with an initial hospital stay; span 90 days after discharge; and include any potentially avoidable readmissions, post-acute care (PAC), and physician services furnished during the hospital stay and during any institutional PAC care (Medicare Payment Advisory Commission 2013).
- In its June 2008 report, the Commission recommended that the Congress require the Secretary to create a voluntary pilot program to test the feasibility of bundled payments for services around a hospitalization for select services; PPACA included a provision that directed the Secretary to test the bundling concept (Medicare Payment Advisory Commission 2008).
- In its March 2001 report, the Commission recommended that the Congress direct the Secretary to expand the dialysis payment bundle to include dialysis drugs, laboratory tests, and other items and services related to end-stage renal disease that were previously separately billable (Medicare Payment Advisory Commission 2001); the Medicare Improvements for Patients and Providers Act of

Does the 6 percent add-on create an incentive to use high-cost drugs?

Some researchers and stakeholders have raised concerns that the 6 percent add-on to average sales price (ASP) may create incentives to use higher priced drugs and biologics (Emanuel 2014, Hutton et al. 2014, Sanghavi et al. 2014). Since 6 percent of a higher priced drug generates more revenue for the provider than 6 percent of a lower priced drug, selection of the higher priced drug has the potential to generate more profit, depending on the provider's acquisition costs for the two drugs.

One study looking at oncologists' prescribing patterns for lung cancer suggests that drug choice may to some degree be influenced by the higher add-on (Jacobson et al. 2010). Looking at five chemotherapy drugs for lung cancer, these researchers found a modest increase in use of the most expensive cancer drug after Medicare began paying for Part B drugs based on ASP in January 2005 (9.2 percent of beneficiaries used the most expensive drug in the 10 months before the payment change, and 11.0 percent of beneficiaries used that drug in the 10 months after).

Other researchers surveyed medical oncologists about their perceptions of the impact of prescribing practices on their income, including how their income would most likely change as a result of prescribing and administering more chemotherapy. A multivariate analysis found that, compared with medical oncologists who were paid a fixed salary, those who were in fee-for-service Medicare practices or were paid a salary with a productivity incentive were more likely to report that their income would increase by "administering more chemotherapy" (Malin et al. 2013).

The Department of Health and Human Services Office of Inspector General reported that a shift in utilization patterns toward costlier products coincided directly with the removal of the least costly alternative (LCA) policy for prostate cancer drugs (Office of Inspector General 2012). After the LCA was rescinded in April 2010, between the beginning of the second quarter of 2010 and the end of the second quarter of 2011, use of the two costlier products increased by 31 percent while use of the least costly product declined by 74 percent.[2]

As discussed in Chapter 3, for the 6 percent add-on to create the incentive to use a higher priced drug, there must be alternative drugs with different prices available to treat a particular patient's condition. Researchers have not quantified the amount of total Part B drug spending accounted for by drugs for which differently priced substitutes are available. Thus, it is difficult to know the extent to which the percentage add-on to ASP has the potential to affect drug prescribing patterns and the resulting spending levels. ■

2008 included such a provision for the Secretary to implement.

Applying least costly alternative and consolidated payment code policies to Part B drug payment

Between 1995 and 2010, Medicare implemented policies—the LCA and functional equivalence (FE) policies—that improved the value of care provided to Medicare beneficiaries by linking payment to comparative clinical effectiveness evidence. Under these policies, a group of drugs with similar health effects but assigned to different payment codes was paid based on the least costly product in the group. The LCA and FE policies are strategies in which a single payment rate is set for a group of products that result in similar health effects.

LCA and FE policies, which are types of reference pricing policies, work best for products and services that exhibit wide variation in prices but only small differences in quality or outcomes (Robinson 2013). While LCA and FE policies set the payment based on the lowest cost product, alternative ways to calculate a reference price include basing it on the mean, median, or the volume-weighted average of the prices for the individual products in a category.

Federal agencies have shown that applying LCA policies to Part B drug payment improved the value of Medicare

spending for beneficiaries and taxpayers. OIG estimated one-year savings of nearly $7 million for beneficiaries and nearly $27 million for Medicare if an LCA policy was used for a group of drugs that treat prostate cancer (Office of Inspector General 2012). OIG also found that if Medicare had set the payment rate for drugs that treat wet age-related macular degeneration (a cause of vision loss) on the least costly one, beneficiaries would have saved $275 million and the program would have saved $1.1 billion in 2008 and 2009 (Office of Inspector General 2011). The Congressional Budget Office estimated savings of almost $500 million between 2010 and 2019 if an LCA policy was used for drugs that treat osteoarthritis of the knee (Congressional Budget Office 2008).

The Secretary would need the Congress to restore her authority to implement LCA or consolidated payment code approaches. At present, the Secretary's lack of flexibility to apply these approaches stems from the MMA, which requires that biologics (both reference products and biosimilars) and single-source drugs (without generic competition) be paid based on their own ASP and not averaged with other products. Consequently, these products receive their own payment code.

Medicare's application of least costly alternative policies

Between 1995 and 2010, the medical directors associated with the Medicare administrative contractors (MACs), which process and pay Medicare FFS claims, established LCA policies to set the payment rate for certain Part B drug classes based on guidance contained in CMS's Benefit Policy and Program Integrity Manuals.[3] The contractors' medical directors generally based LCA determinations on the premise that "if two services are clinically comparable, then Medicare does not cover the additional expense of the more costly service, when this additional expense is not attributable to that part of an item or service that is medically reasonable and necessary" (National Government Services 2009). The medical directors implemented LCA policies in local coverage decisions that applied to a defined geographic jurisdiction. LCA policies were established based on the statutory provision (1862(a)(1)(A)) that states that "no payment may be made under Part A or Part B for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Simply put, LCA policies were applied under the premise that Medicare should not pay for the additional cost of a more expensive product if a less costly product produces a comparable clinical outcome. Although the statutory platform for making LCA determinations was based on Medicare's reasonable and necessary authority for medical services, the policy affected the payment rate of drugs. In addition, in one instance, Medicare applied an LCA-type policy—referred to as the FE policy—on the national level to set the payment rate for anti-anemia drugs paid for under the OPPS. The text box (p. 94) describes the circumstances in 2002 under which CMS implemented the FE policy under the OPPS rule-making process.

In applying LCA policies to Part B drugs, the MACs' medical directors generally followed these steps:

- determined that the product was a Medicare-covered benefit,
- determined that the product was "reasonable and necessary" for the treatment of an illness or injury,
- reviewed clinical evidence from the Food and Drug Administration and other sources and determined that the clinical effects of two or more products were comparable,
- displayed draft and final policies online and provided for a notice and comment period (Centers for Medicare & Medicaid Services 2010), and
- established the payment rate for each product covered under the LCA policy under the prevailing Medicare payment policy—based on ASP since 2005—and set the payment rate for all the products based on the product with the lowest ASP.

In some instances, the MACs' medical directors would pay the higher rate for the more costly product when the physician could document that the more costly product was medically necessary to treat a specific patient. In addition, there was an opportunity for the beneficiary to choose the more costly product. Specifically, if the physician informed the beneficiary in advance and in writing that Medicare was likely to deny payment for the more costly product and if the beneficiary signed an advance beneficiary notice for the product, then the beneficiary could pay an additional sum if the beneficiary and physician chose a more costly service. Under these circumstances, the beneficiary's liability would include the 20 percent coinsurance and the difference in the Medicare payment between the more costly and least costly product.

Applying a national least costly alternative policy: The functional equivalence standard

The functional equivalence (FE) standard is similar to the least costly alternative (LCA) policy under which payment for clinically comparable products assigned to separate payment codes is based on the least costly item. The FE policy was established in the national payment (rule-making) process and applied nationally. By contrast, LCA policies were established in the local coverage process and applied in specific geographic regions.

In 2003, in the rule-making process for the hospital outpatient prospective payment system (OPPS), CMS nationally set the payment rate for a new biologic (darbepoetin alfa) at the rate of an existing, less costly product (epoetin alfa) after concluding that both anti-anemia products were functionally equivalent because they used the same biological mechanism to produce the same clinical result—stimulation of the bone marrow to produce red blood cells (Centers for Medicare & Medicaid Services 2002a).

CMS did not initially set the payment rate for the new product by using the FE standard. Rather, in the 2003 OPPS proposed rule, CMS said that it would continue the new biologic's transitional (higher) pass-through payments (Centers for Medicare & Medicaid Services 2002b). In response, a product developer argued that because both the old and the new biologic are substitutes (with the same clinical effects) for each other, they should be paid at the same rate. In the final rule, CMS reviewed the clinical evidence, concluded that both biologics were functionally equivalent, and set the payment rate of the new biologic at the same rate as the older one (Centers for Medicare & Medicaid Services 2002a). CMS contended that it would not be equitable or an efficient use of Medicare funds to pay for these two functionally equivalent products at greatly different rates and used its authority under the Social Security Act (1833(t)(2)(E)) to make an adjustment it determined "necessary to ensure equitable payments."

This policy withstood a lawsuit from the product developer of the new biologic. An appeals court dismissed the case, concluding that CMS's statutory rationale for the decision was not subject to judicial review (U.S. Court of Appeals 2004).[4] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) limited future use of the FE standard. The Congress prohibited use of this standard for drugs and biologics in the hospital outpatient setting unless the standard was in place before the law's enactment (the law did not prevent the use of the FE policy for erythropoiesis-stimulating agents—typically used to treat anemia—paid under the OPPS).

Medicare continued to use the FE standard in 2004 and 2005. In response to passage of the MMA, each biologic's payment rate was set under the ASP policy in 2006. ■

In 2008, a beneficiary and the manufacturer of a particular inhalation drug challenged the proposed application of an LCA policy for that drug, arguing that the statute requires that if the drug is reasonable and necessary, Medicare must pay the statutorily defined payment rate for the drug—ASP + 6 percent.[5] The government argued that the reasonable and necessary statutory provision confers great discretion on the Secretary and that the LCA policy was permissible because the provision explicitly addresses payment and expenses.

Two federal courts agreed with the beneficiary and ruled that Medicare cannot use LCA policies to pay for that particular Part B inhalation drug, asserting that the statute's provision that sets the payment rate for Part B drugs based on its ASP precludes Medicare from applying LCA policies. These rulings apply to instances in which CMS has set a drug's payment based on the ASP of the least costly product. Effective April 2010, the MAC's medical directors rescinded the LCA policies applied to Part B drugs, and since then, Medicare's payment rate for products previously paid for under an LCA policy (including luteinizing hormone-releasing hormone agonists for prostate cancer) is 106 percent of the product's ASP.

TABLE 4–1 **Grouping two inhalation products with similar health effects in a single payment code**

Coding strategy	Medicare payment based on 106 percent of ASP for each drug*			Medicare payment based on volume-weighted average (106 percent of ASP) for both drugs**		
	2005: 1st quarter	2006: 1st quarter	2007: 2nd quarter	2007: 3rd quarter	2007: 4th quarter	2008: 1st quarter
Separate payment code						
Albuterol	$0.07	$0.06	$0.08			
Levalbuterol	1.28	1.34	1.54			
Combined payment code						
Albuterol				$0.53	$0.42	$0.44
Levalbuterol				0.53	0.42	0.44

Note: ASP (average sales price). Albuterol is unit dose, 1 milligram. Levalbuterol is unit dose, 0.5 milligram.
*Between the first quarter of 2005 and the second quarter of 2007, Medicare payment was based on 106 percent of ASP for each drug.
**Between the third quarter of 2007 and the first quarter of 2008, payment for the single code that included albuterol and levalbuterol was based on the volume-weighted average (106 percent of ASP) for both drugs.

Source: MedPAC analysis of CMS's Medicare Part B drug ASP data files available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.

Medicare's application of the consolidated payment code approach

Between July 1, 2007, and March 31, 2008, Medicare used a single payment code for two drugs used to treat asthma and chronic obstructive pulmonary disease—levalbuterol (which was a single-source drug until 2008) and albuterol (a multisource drug) (Food and Drug Administration 2014). Medicare covers such inhalation drugs under Part B when they are administered through a nebulizer in a patient's home. Combining both products into a single payment code essentially sets the payment amount based on the volume-weighted ASP for these products. CMS established a single payment code for the two products to comply with the MMA provisions concerning payment for drugs (Table 4-1).[6] In contrast, between January 1, 2005, and June 30, 2007, CMS used separate Level II Healthcare Common Procedure Coding System (HCPCS) codes and payment amounts for both products. The text box (p. 97) describes how Medicare establishes Level II HCPCS codes for drugs and other medical services.

Including products with divergent acquisition costs in a single payment code could initially result in Medicare's payment rate not reflecting each product's acquisition cost. After both drugs were included in the same code (in the third quarter of 2007), the payment rate for albuterol (which was multisource) increased by 563 percent, while the rate for levalbuterol (which was single source in 2007) decreased by 66 percent. In the following two quarters (the fourth quarter of 2007 and the first quarter of 2008), the combined payment rate declined by about 17 percent.

To determine whether shifts in utilization patterns for albuterol and levalbuterol coincided with changes in Part B payment and coding policy, OIG conducted a survey of suppliers and physicians for 312 beneficiaries who had used albuterol, levalbuterol, or both products between January 2003 and December 2007. OIG found that between January 2005 and June 2007, with each drug assigned to separate payment codes, Medicare payment favored levalbuterol; one-quarter of beneficiaries who were using albuterol were changed to levalbuterol. From July 2007 through December 2007, Medicare payment favored albuterol; two-thirds of the beneficiaries in OIG's sample who had been using levalbuterol were changed to albuterol (Office of Inspector General 2009).

The Medicare, Medicaid, and SCHIP Extension Act of 2007 essentially reestablished separate codes for both albuterol and levalbuterol. Effective April 1, 2008, the law calculates each product's payment as the lower of (1) the volume-weighted average of 106 percent of the ASP for both drugs, or (2) the payment rate based on 106 percent of the ASP for the individual drug. CMS implemented this statutory provision by establishing separate payment codes for each product effective April 1, 2008 (Office of

TABLE 4–2

Effective April 1, 2008, statutory change in payment and coding for two inhalation products

Coding strategy	Medicare payment based on the lower of volume-weighted average of 106 percent of ASP for both drugs or 106 percent of ASP for the individual drug*			
	2008: 2nd quarter	2010: 1st quarter	2012: 1st quarter	2014: 1st quarter
Separate payment code				
Albuterol	$0.04	$0.05	$0.06	$0.05
Levalbuterol	0.28	0.20	0.26	0.09

Note: ASP (average sales price). Albuterol is unit dose, 1 milligram. Levalbuterol is unit dose, 0.5 milligram.
*Since the second quarter of 2008, Medicare payment is based on the lower of (1) the volume-weighted average of 106 percent of the ASP for both drugs, or (2) the payment rate based on 106 percent of ASP for the individual drug.

Source: MedPAC analysis of CMS's Medicare Part B drug ASP data files available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.

Inspector General 2009). Between the first and second quarters of 2008, this policy resulted in payments that dropped 91 percent for albuterol and 36 percent for levalbuterol (Table 4-2). Another factor affecting the payment for levalbuterol was the Food and Drug Administration approval of this product's generic versions.

Issues in implementing LCA and consolidated payment code approaches

Key to implementing LCA and consolidated payment code approaches successfully would be to develop a transparent and predictable process that permits opportunities for public comment. CMS would need to establish processes for:

- defining groups of products that achieve comparable clinical outcomes;
- obtaining public comment from a wide range of stakeholders, including beneficiaries, providers, product developers, insurers, and researchers; and
- reconsidering comparative clinical effectiveness evidence and the payment policy over time.

Ensuring beneficiary access either for medical necessity or preference (i.e., not medical necessity) would also have to be addressed in applying these approaches to Part B drug payment.

Under these approaches, beneficiary access to the more costly product could be addressed in Medicare's appeals process.[7] As was the case under prior LCA policies, the process could permit beneficiaries to gain access to a more costly product when not medically necessary by permitting the beneficiary to pay the difference (in the cost between the more costly and least costly service) if that is his or her preference.

Options for ensuring transparency include consulting with the public on an issue-by-issue basis or establishing an advisory group. An example of a way for CMS to gain technical expertise from the public is the Medicare Evidence Development & Coverage Advisory Committee. Established in 1998, it provides independent guidance and expert technical advice to CMS on specific clinical topics considered in the national coverage determination process.

CMS also could consult with the Evidence-Based Practice Centers (EPCs), an initiative launched by the Agency for Healthcare Research and Quality (AHRQ) in 1997 to promote evidence-based practice. The EPCs are located at universities, medical centers, and research institutions across the country and provide technology assessments for CMS, provide comparative effectiveness reviews for AHRQ's Effective Health Care Program, and support the work of the U.S. Preventive Services Task Force.

Bundling oncology services

Bundled payments set a fixed (or benchmark) price for a group of related items and services. Bundling oncology services could achieve several goals. Developing

Medicare's coding of health care services: The Healthcare Common Procedure Coding System

The Healthcare Common Procedure Coding System (HCPCS) was established in 1978 to provide a standardized coding system for the items and services provided in the delivery of health care. Initially, use of the codes was voluntary, but with the implementation of the Health Insurance Portability and Accountability Act of 1996, use of the HCPCS for transactions involving health care information became mandatory. Public and private insurers were required to be in compliance with the August 2000 regulation by October 1, 2002.

The HCPCS is divided into two principal subsystems, referred to as Level I and Level II. The Level I system consists of the Current Procedural Terminology–4 (CPT–4), a numeric coding system maintained by the American Medical Association to identify medical services and procedures. The Level II HCPCS is a standardized coding system that is used primarily to identify drug, biologics, supplies, and services not included in the CPT–4 codes.

Since 2003, CMS maintains the Level II HCPCS, which involves assigning new codes, modifying existing codes, or deleting codes (Centers for Medicare & Medicaid Services 2012). The CMS HCPCS Workgroup, which includes representatives from Medicaid state agencies and the Medicare administrative contractors, evaluates requests from interested parties for modifying the HCPCS Level II set (e.g., seeking a new code or a change to an existing code). In addition, coding decisions are coordinated with public and private payers. The workgroup considers factors such as whether or not an existing code adequately describes the item in a coding request. National codes are updated on an annual basis. CMS hosts annual public meetings that provide a forum for interested parties to provide additional input about requests to modify the HCPCS code set. ■

oncology bundles that include Part B oncology drugs and biologics—defined as anticancer drugs and supportive-care drugs given with anticancer drugs—might help address potential incentives under Medicare's current Part B payment method for providers to furnish more costly regimens when therapeutically equivalent drugs exist.

A primary rationale for bundling is to address the concern that, under FFS payment systems, providers are not accountable for the total cost of services across an episode of care, and care is often fragmented and uncoordinated. Specific to oncology care, according to the Institute of Medicine (IOM) and others, FFS payment systems can have the following effects:

- create incentives to use more costly interventions—oncology-related drugs, radiation, and surgery—that lack evidence of improved clinical effectiveness compared with other treatment options (Balogh et al. 2011, Institute of Medicine 2013, Sanghavi et al. 2014). For example, use of proton beam therapy for prostate cancer has increased among Medicare beneficiaries despite the lack of evidence showing that the intervention is better than other, less costly radiation alternatives such as three-dimensional conformal radiation therapy and intensity-modulated radiation therapy (Jarosek et al. 2012, Ollendorf et al. 2014, Yu et al. 2013).
- lead to the overuse of oncology-related interventions (Institute of Medicine 2013). For example, one study reported that many patients with metastatic non-small-cell lung cancer receive a greater number of treatments or higher doses of palliative radiation than is supported by current evidence (Chen et al. 2013). According to the IOM, use of chemotherapy near the end of life is another example of overuse.
- do not facilitate cancer care coordination, which can lead to duplication of care and result in patient complications, which is particularly problematic for patients who have comorbidities that should be managed by both the cancer care team and other specialist care teams (Sanghavi et al. 2014).
- lead to unnecessary emergency department (ED) visits and hospitalizations for potentially avoidable conditions such as nausea following chemotherapy administration (Sanghavi et al. 2014).

TABLE 4–3

Medicare spending for beneficiaries newly diagnosed with breast, colon, or lung cancer during a six-month oncology episode, 2011–2012

Type of service	Mean total spending per beneficiary	Percent of beneficiaries receiving service type
Physician/supplier	$18,752	99.9%
Institutional outpatient	12,062	91.6
Inpatient	8,221	45.7
Home health	844	24.2
Hospice	761	14.5
All of above	$40,640	100.0

Note: This table reports Medicare spending for 180 days following the first administration (between January 1, 2011, and June 30, 2012) of a Part B–covered oncology drug for beneficiaries newly diagnosed with breast, colon, or lung cancer. Medicare spending in this table includes program payments and beneficiary payments. Inpatient spending includes services provided under the inpatient prospective payment system and by critical access hospitals. This analysis does not include Medicare spending for Part D drugs, durable medical equipment, skilled nursing facilities, inpatient rehabilitation facilities, long-term care hospitals, and inpatient psychiatric hospitals. The number of beneficiaries included in the analysis is 61,039.

Source: MedPAC analysis of 2011–2012 100 percent claims from inpatient, institutional outpatient, physician/supplier, hospice, and home health files.

According to some researchers, medical oncology care is amenable to bundling because management of cancer care is supported by a large evidence base and regularly updated guidelines from numerous organizations, and the guidelines address the most costly components of care—anticancer drugs, supportive-care drugs, and their attendant administration fees (Bach et al. 2011, Emanuel 2014). The same researchers concluded that it is possible to assess the quality of care by measuring whether the published evidence-based guidelines are followed (Bach et al. 2011, Emanuel 2014).[8]

The implementation of oncology payment bundles in FFS would need to address multiple design issues. For instance, inherent in establishing a bundled payment amount is a judgment on what the treatment of a condition should cost. There are also trade-offs associated with deciding what is and is not included in the bundle. A bundled approach also has implications for beneficiaries, with respect to how much they pay for care. In addition, bundling could create incentives for undesirable provider behavior, such as the underprovision of care. A bundled payment may be a fixed price paid to the provider (e.g., clinicians and/or organizations furnishing care) prospectively, and this provider would be responsible for paying all providers furnishing care to the beneficiary during the bundle window. Alternatively, Medicare could continue to pay each provider under its FFS systems, and a benchmark would then be used to adjust net payments to providers retrospectively. Bundling could also require providers to have an infrastructure to make payments to other providers and receive payments on their behalf. Our study of these issues—an analysis of Medicare spending for certain cancer diagnoses requiring Part B oncology drugs, commercial payers' experience with bundling payment for oncology services, and other approaches to oncology care—suggests a combination of design features that could address these issues.

Medicare spending for oncology services: Findings of an exploratory analysis

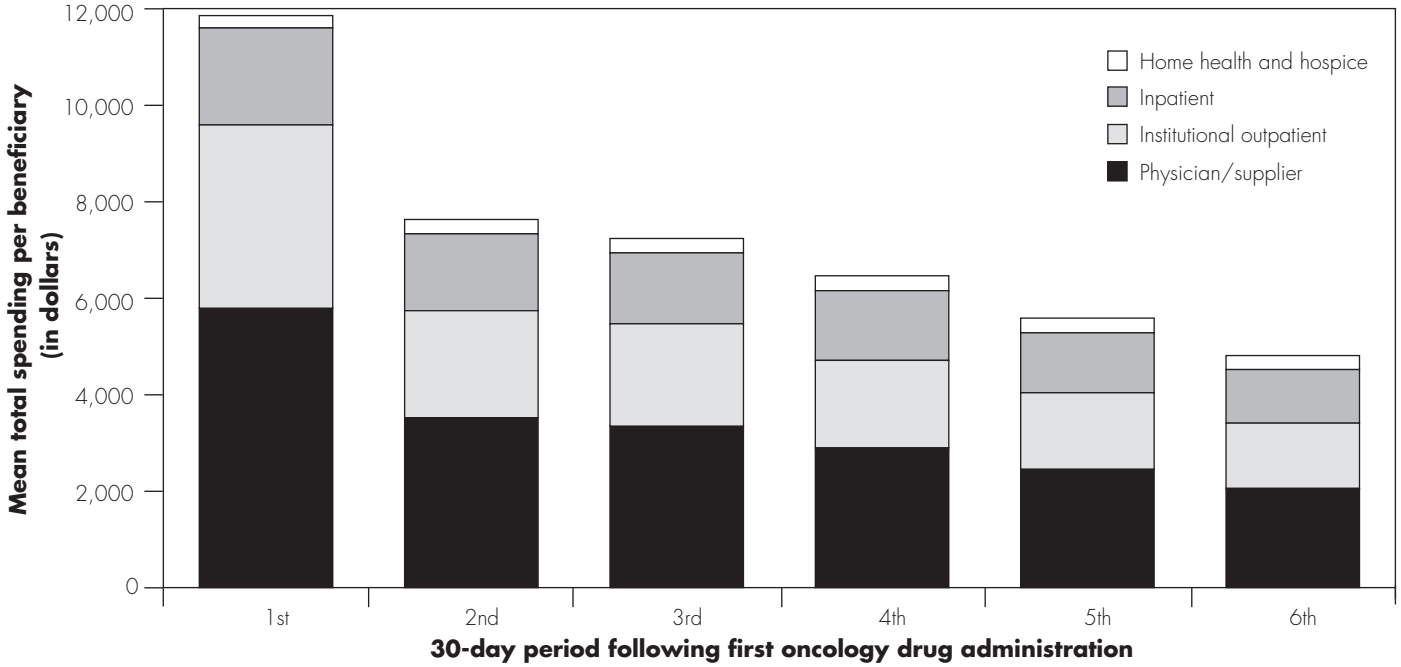
As a first step in considering oncology bundles, we sought to understand spending patterns for beneficiaries with cancer. To do so, we examined Medicare spending for newly diagnosed beneficiaries with breast, colon, or lung cancer who received an oncology drug (which includes anticancer drugs and supportive-care drugs) in 2011 or 2012. We found that in an episode—defined as 180 days following an initial oncology drug paid under Part B—oncology drugs and their administration costs accounted for nearly half (46 percent) of total Part A and Part B spending. Oncology-related radiation services accounted for an additional 9 percent of total spending during the 180-day follow-up period.

Specifically, we analyzed the spending patterns for 61,039 beneficiaries with newly diagnosed (incident) breast, colon, or lung cancer who received outpatient chemotherapy in 2011 or 2012. This analysis used CMS's 2010–2012 Master Beneficiary Summary file to identify and classify the study population by cancer type and CMS's 2011–2012 100 percent claims files to determine Medicare spending (program and beneficiary payments). For each beneficiary, we constructed an episode that started the first day that the beneficiary first received a Part B–covered oncology drug and ended 180 days later or at the beneficiary's death. Each beneficiary's episode of care was divided into six 30-day periods. During the episode of care, 21 percent of beneficiaries died (12,689 beneficiaries). The study population had the following characteristics:

- Twenty-eight percent were diagnosed with breast cancer, 52 percent with lung cancer, and 23 percent with colon cancer (total does not sum to 100 percent

FIGURE 4–1

Medicare spending for beneficiaries newly diagnosed with breast, colon, or lung cancer for the six 30-day periods of an oncology episode, 2011–2012



Note: "Medicare spending" in this figure is for 180 days following the first administration (between January 1, 2011, and June 30, 2012) of a Part B–covered oncology drug for beneficiaries newly diagnosed with breast, colon, or lung cancer. Beneficiaries are included in a given period if they were alive at any point during that period. Medicare spending includes program payments and beneficiary payments. Inpatient spending includes services paid under the inpatient prospective payment system and by critical access hospitals. This analysis does not include Medicare spending for Part D drugs, durable medical equipment, skilled nursing facilities, inpatient rehabilitation facilities, long-term care hospitals, or inpatient psychiatric hospitals.

Source: MedPAC analysis of 2011–2012 100 percent claims from inpatient, institutional outpatient, physician/supplier, hospice, and home health files.

because beneficiaries may have had more than one type of cancer).

- Nine percent were under age 65, 43 percent were 65 to 74 years old, 23 percent were ages 75 to 79 years, 15 percent were ages 80 to 84 years, and 10 percent were 85 years or older.
- Forty percent were male and 60 percent were female.
- Eighty-seven percent were White, 9 percent were African American, 1 percent was Asian American, and the remainder (3 percent) were all other races or race unknown.
- Twenty-five percent resided in rural areas.

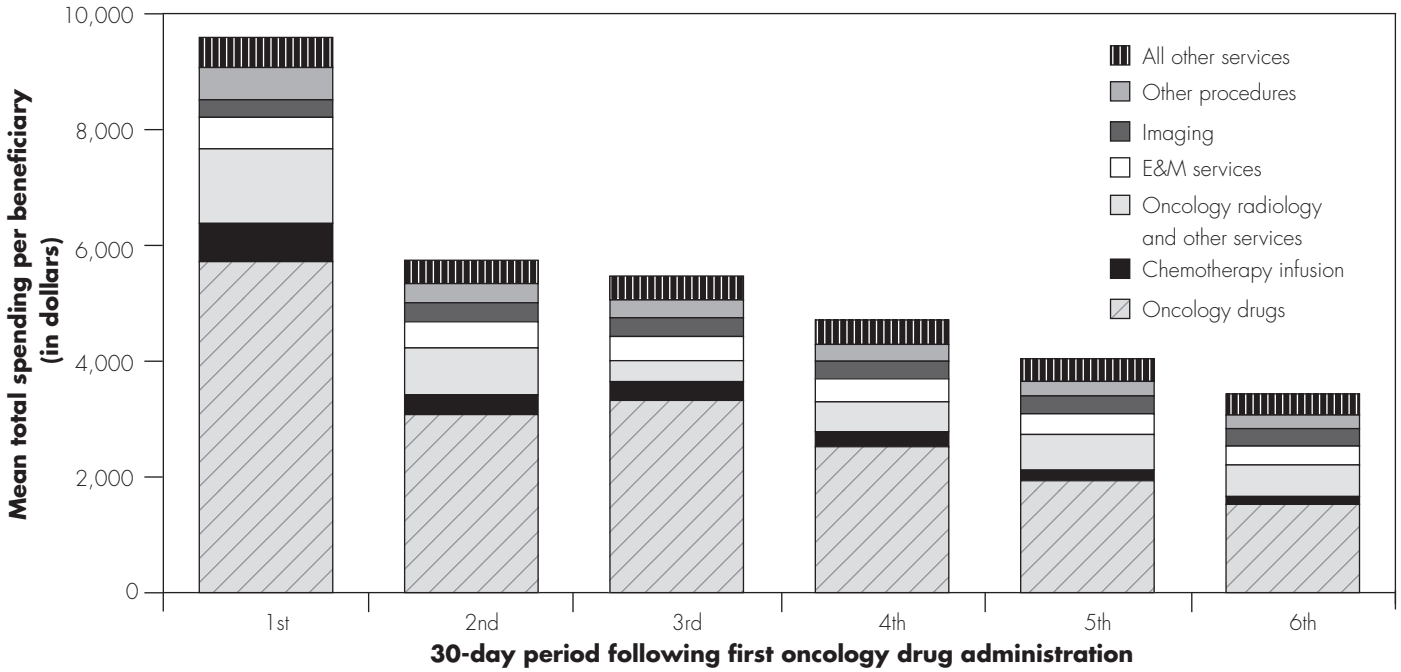
During the 180-day episode, spending for physician/supplier, institutional outpatient, inpatient, home health, and hospice services averaged $40,640. Outpatient services—physician/supplier and institutional outpatient services—accounted for 76 percent of this total (Table 4-3).[9] During the episode, 46 percent of beneficiaries in the study population were hospitalized, 24 percent received home health services, and about 15 percent elected hospice. Part A and Part B total spending during the 180-day episode varied by cancer type, ranging from nearly $35,000 per beneficiary with breast cancer to nearly $42,000 per beneficiary with lung cancer and nearly $46,000 per beneficiary for colon cancer.

Medicare also pays for oncology drugs under Part D. Nearly 60 percent of the study population was enrolled in Part D, and roughly one-quarter of enrolled beneficiaries received an oncology drug during the 180-day episode. For enrolled beneficiaries, Part D spending for oncology drugs averaged about $700 per beneficiary during the 180-day episode.

Figure 4-1 shows mean total spending for the six 30-day periods of the episode. For this analysis, the denominator consists of all beneficiaries who were alive at any point during that period. Mean total spending per beneficiary

FIGURE 4–2

Medicare spending for physician/supplier and institutional outpatient services for the six 30-day periods of an oncology episode, 2011–2012



Note: E&M (evaluation and management). "Medicare spending" in this figure is for 180 days following the first administration (between January 1, 2011, and June 30, 2012) of a Part B–covered oncology drug for beneficiaries newly diagnosed with breast, colon, or lung cancer. Beneficiaries are included in a given period if they were alive at any point during that period. Medicare spending includes program payments and beneficiary payments. Inpatient spending includes services provided by inpatient prospective payment system hospitals and critical access hospitals. This analysis does not include Medicare spending for Part D drugs, durable medical equipment, skilled nursing facilities, inpatient rehabilitation facilities, long-term care hospitals, or inpatient psychiatric hospitals.

Source: MedPAC analysis of 2011–2012 100 percent claims for institutional outpatient and physician/supplier files.

gradually decreased during the episode, from nearly $11,900 per beneficiary in the first 30-day period to about $4,800 per beneficiary in the last 30-day period.

Figure 4-2 highlights outpatient spending for physician/supplier and institutional outpatient services per 30-day period. We assigned outpatient services to mutually exclusive categories (e.g., chemotherapy and other cancer drugs, chemotherapy infusion, etc.) based on the Berenson-Eggers code and procedure code reported on the physician/supplier and institutional outpatient claims. The services in the "all other" category include non-oncology drugs, laboratory services, other tests, major procedures, and ED services. Between the first 30-day period and the last 30-day period, mean total spending per beneficiary declined from nearly $9,600 per beneficiary to $3,400. Overall, oncology drugs and their administration costs accounted for 61 percent of total oncology episode outpatient spending, and oncology-related radiation services accounted for an additional 13 percent of spending. Across the six 30-day periods, oncology drugs and their administration costs and oncology-related radiation services ranged between 65 percent and 80 percent of total outpatient spending. The study population's 2011 spending for oncology drugs accounted for roughly 8 percent of 2011 Part B drug spending in physician offices and hospital outpatient departments (data not shown).

We also looked at spending between each beneficiary's initial cancer diagnosis in 2011–2012 and the first oncology drug furnished to the beneficiary. The number of days between the initial cancer diagnosis and first oncology treatment averaged 67 days, and total spending averaged about $14,200 per beneficiary during this period for physician/supplier, institutional outpatient, inpatient hospital, home health, and hospice services.

TABLE 4–4

Summary of five case studies illustrating alternative approaches to bundling oncology services

Payer or provider	Design summary	Status and results
Case 1: Bach et al. (2011) proposal for FFS Medicare	Prospective payment covering anticancer and support drugs and their administration. Length of episode varies for colon, breast, and lung cancer.	Proposed in *Health Affairs* article.
Case 2: UnitedHealthcare–MD Anderson pilot	One-year episode with prospective payment covering surgery, chemotherapy, and imaging. Bundles vary based on treatment for newly diagnosed head and neck cancer.	Began December 2014; expected to run for three years.
Case 3: Blue Cross and Blue Shield of Florida pilot with Mobile Surgery International	Prospective payment covers care furnished for a minimally invasive laparoscopic radical prostatectomy for localized prostate cancer, including physician, hospital, and pathology services and drugs.	Ongoing since 2011.
Case 4: UnitedHealthcare pilot (completed) with five physician practices	Practices paid FFS for nondrug services, ASP (no add-on) for anticancer drugs, and an episode payment at the initial visit. Episode payment and length varies for lung, colon, and breast cancer. Performance-based payment based on reducing total spending and meeting quality metrics.	October 2009 to December 2012. Compared with control group, participating practices had lower total spending but higher drug spending.
Case 5: CMMI proposal for physician practices	Practices paid FFS plus $160 per beneficiary per month for enhanced services. One-sided risk for first two years, optional two-sided risk for last three years. Performance-based payment based on reducing total spending and meeting quality metrics; six-month episode begins at first chemotherapy administration for all cancer types.	Seeking applications from physician practices and other payers; expected to begin spring 2016 and run five years.

Note: FFS (fee-for-service), ASP (average sales price), CMMI (Center for Medicare & Medicaid Innovation).

Source: Bach et al. 2011; Blue Cross Blue Shield of Florida 2011; Centers for Medicare & Medicaid Services 2015a; MD Anderson 2014; Newcomer et al. 2014.

Five case studies illustrating alternative bundling approaches for oncology services

Several approaches to bundling payment for oncology services have either been proposed for FFS Medicare or implemented by commercial payers. In studying five such approaches summarized in Table 4-4, we found that the bundling designs varied based on:

- the specificity of services covered by the bundle, with the narrowest bundle consisting of oncology drugs and their administration costs, and the broadest bundle consisting of all services—oncology and non-oncology—and by cancer type, with the narrowest bundle including one cancer type and the broadest bundle including all cancer types;
- the duration of the bundle, spanning from a 1-month (30-day) bundle to a 1-year bundle;
- the trigger event, including chemotherapy administration and cancer diagnosis; and
- the type of payment—for some, a fixed prospective payment, and for others, payment using an FFS mechanism with net payments adjusted retrospectively based on achieving cost and quality benchmarks.

Case 1: Proposals for FFS Medicare to bundle oncology services

In 2011, Bach and colleagues (2011) described a proposal for Medicare FFS to pilot a bundled payment for cancer care that would include chemotherapy, supportive drugs, and their administration for a predetermined period of time (Bach et al. 2011). The length of an episode would vary based on cancer type and treatment; for example, a one-month episode was proposed for metastatic non-small-cell lung cancer. The pilot would encompass the more common cancers such as metastatic lung cancer, breast cancer, and

colon cancer. Payment would be based on the average cost of caring for all patients grouped by their specific cancer diagnosis. According to Bach and colleagues, such a payment method would encourage providers to select lower priced regimens from among those deemed equally appropriate, an incentive not present in the current FFS system.[10] Program savings would be achieved by recalibrating FFS and bundled payments periodically to account for cost reductions in earlier episodes. To ensure quality, Medicare would establish standards of care, with an exceptions process, based on already existing public guidelines. The authors acknowledged the potential for backlash against the notion of Medicare's establishing care standards. Bach and colleagues pointed out that issues such as changes in treatment protocols, cost shifting, upcoding, and stinting on care would need to be addressed for this model to work. Widespread adoption of episode payments could, according to the authors, pressure drug manufacturers to lower their prices. To date, FFS has not implemented this bundled approach.

Case study 2: UnitedHealthcare–MD Anderson pilot for head and neck cancer

In December 2014, UnitedHealthcare and MD Anderson Cancer Center announced a three-year pilot that pays MD Anderson a fixed annual amount for the care of up to 150 patients (enrolled in employer-sponsored health plans) with certain types of head and neck cancer. According to MD Anderson, the prospective payment provides an incentive to focus on the essential elements of care and to avoid unnecessary steps; the program is expected to improve patient outcomes, lower costs, and improve patients' quality of life (MD Anderson 2014). The annual payments are expected to cover nearly all of a patient's cancer care for a year, including surgery, chemotherapy, and radiation services. This approach uses eight different bundles of care, which differ based on the types of oncology care (e.g., surgery, radiation, chemotherapy) that patients require. MD Anderson does not receive increased payments for patients who experience complications and need additional treatments. Because the costs of care are priced upfront, patients know the cost of care early in their treatment regimen, and MD Anderson bills patients only once for their cancer treatment.

Case study 3: Blue Cross and Blue Shield of Florida bundled payment with one provider for localized prostate cancer

In 2011, Blue Cross and Blue Shield of Florida and Mobile Surgery International implemented a bundled payment pilot for prostate cancer patients treated with minimally invasive laparoscopic radical prostatectomy surgery (Bandell 2011, Blue Cross Blue Shield of Florida 2011). The bundle is intended to cover all care surrounding a radical prostatectomy and related procedures and includes the services of the surgeon, surgeon's assistant, and operative technical team; anesthesia and pathology services; hospital services; medications; and patient education.[11] The provider is responsible for paying the hospital and all other providers that furnish care under the bundle and will retain as profit any funds left over after the patient is treated. From the payer's perspective, the pilot provides an incentive for participating physicians to operate effectively and work cooperatively to prevent complications. It also simplifies the billing process for patients, who receive a single bill instead of separate bills from each provider, and for the payer, who no longer incurs the administrative cost of processing bills from multiple providers.

Case study 4: UnitedHealthcare episode-of-care pilot with five oncology practices

Between October 2009 and December 2012, UnitedHealthcare implemented an oncology payment pilot with 19 distinct types of clinical episodes. Five large oncology physician practices were paid ASP (instead of ASP plus the negotiated add-on amount) for chemotherapy drugs, an episode fee at the initial visit that was based on the contracted drug add-on amount to ASP, and FFS payments for most other services (e.g., office visits, drug administration, diagnostic radiology, and laboratory). The five participating practices were eligible for shared savings if, compared with physician practices in a national payer registry, quality (as measured by survival) improved or total episode costs decreased (or both). The pilot's objectives were to decrease total medical costs by aligning financial incentives supported by use and quality data and remove the link between drug selection and medical oncology income (Newcomer et al. 2014).

The pilot included 810 patients with breast, colon, and lung cancer. The 19 clinical episodes varied based on type of cancer, clinical stage (stage 0 through stage IV), and tumor histology. The duration of episodes spanned from 4 months to 12 months. At the time of the initial patient presentation, participating practices reported clinical information—such as clinical stage, histology, and intent of treatment (curative or palliative)—to the payer to determine the correct episode type.

To arrive at the episode payment for each of the 19 cancer episodes, the national drug margin for each episode was calculated by subtracting the aggregate ASP from the aggregate amount paid for chemotherapy drugs, then dividing by the total number of patients in each episode. Practices were also paid a small fee for each episode for case management that included physician hospital care services. Participating services continued to be paid FFS for physician office visits, chemotherapy administration, and diagnostic radiology. To compensate providers for furnishing palliative care services, the episode payments continued every four months for patients with metastatic disease no longer receiving chemotherapy or enrolled in hospice (Newcomer et al. 2014, UnitedHealthcare 2014).

At the beginning of the pilot, each participating practice selected a preferred drug regimen for each episode.[12] The participating practices were free to change their preferred drug regimen at any time during the three-year pilot. New studies and new drug releases resulted in changes in the preferred regimens during the pilot's implementation (Newcomer et al. 2014). Thus, providers had the flexibility to customize the regimen to individual patients, and, by paying for drugs at ASP, had less revenue-based incentive to use higher cost drugs. The episode payment was not adjusted to account for new drug selections during the course of the pilot.

The participating practices collaborated with the payer to develop quality, cost, and use measures, and the practices met annually to review their outcomes. These outcomes included total cost of care; rates of emergency room and hospitalization use; use of laboratory, diagnostic radiology, surgical services, and durable medical equipment; time to first progression for relapsed patients; hospice days for patients who died; days from last chemotherapy to death; and rate of febrile neutropenia occurrence. During the meeting, providers discussed potential solutions for variation in performance (e.g., in rates of hospital admission and use of diagnostic radiology).

UnitedHealthcare found their overall spending declined during the pilot, while drug spending increased. Specifically Newcomer and colleagues (2014) reported a 34 percent reduction in total actual spending compared with predicted total spending ($64.8 million vs. $98.1 million) and a 179 percent increase in actual drug spending compared with predicted drug spending ($21.0 million vs. $7.5 million) (Newcomer et al. 2014). The authors did not expect the increase in drug spending and did not provide the specific components of drug spending. According to a *Washington Post* write-up of the pilot, the participating practices collectively received about one-third of the $33 million in total savings (Millman 2014).

Although the Newcomer analysis was not designed to determine the drivers of the differences in total medical spending, a subset analysis did demonstrate a statistically valid decrease in hospitalization and therapeutic radiology usage for the episode model. Most quality outcomes had insufficient numbers for statistical analysis, but the authors reported that Kaplan-Meier survival curves were monitored for all patients with metastatic disease; lung cancer survivors were the only evaluable subgroup, and there was no significant survival difference between patients in the pilot and the control groups (Newcomer et al. 2014).

Case study 5: Center for Medicare and Medicaid Innovation's Oncology Care Model

In 2015, the Center for Medicare and Medicaid Innovation (CMMI) released a request for applications for a demonstration to improve care coordination with an episode-based payment model for oncology, titled the Oncology Care Model (OCM). The model will last five years and is scheduled to begin in spring of 2016. The model's aim, through upfront payments to individual oncologists and group practices for practice transformation and care management, is that by improving the quality of care for beneficiaries with cancer, practices will lower total Medicare costs for their oncology patients and will then be eligible for performance-based payments. An episode of care lasts for six months and begins at receipt of Part B or Part D chemotherapy administration for cancer. During the episode, practices continue to receive FFS payments (including ASP + 6 percent for Part B drugs), plus a $160 per beneficiary per month (PBPM) payment to support practice transformation and coordinated care. Practices bill each month for the $160 PBPM using a HCPCS code (created for the OCM) unless a beneficiary enters hospice. The PBPM is included in the calculation of six-month episode expenditures.

Oncology practices willing to engage in practice redesign to promote care coordination and better quality outcomes are eligible to apply for the model. Practices must include at least two physicians or nonphysician providers under a single legal entity to qualify. Applicants will be screened for size, primarily to reduce random variation in the benchmarking process, and screened for past program integrity violations.

CMMI intends for this model to be a multipayer demonstration. While the practice transformation requirements must be aligned across all payers, individual payers will have discretion in designing the financial incentives to support their insured population.

Definition of episode Under the OCM model, an episode that lasts for six months and can be renewed for the demonstration's duration is triggered with an initial chemotherapy claim either in Part B or Part D. Topical formulations of chemotherapy drugs are excluded because they do not require the same intensity of management from the oncologist. The episode will not be shortened in cases when chemotherapy lasts fewer than six months; PBPM payments continue to be made for the duration of the six-month episode or until the beneficiary enters hospice.

CMMI intends for the OCM to be as broad as possible but recognizes that some cases are not amenable to being covered under the model. Beneficiaries who are not eligible for the OCM include those not enrolled in Part A and Part B, those with end-stage renal disease (ESRD), and those for whom Medicare is not the primary payer. Beneficiaries participating in other CMS models like accountable care organizations (ACOs) and those participating in clinical trials remain eligible. Beneficiaries without Part D are eligible, but their episodes are triggered only from Part B claims, and benchmarks include only Part A and Part B spending.

Beneficiary attribution In the OCM model, for payment and quality monitoring purposes, each eligible beneficiary treated at a participating practice will be aligned to the practice actively managing the beneficiary. According to CMMI, beneficiaries will be retrospectively attributed to practices after the completion of each episode (Centers for Medicare & Medicaid Services 2015b). Until the end of the demonstration in 2021, beneficiaries are eligible for new episodes of care as long as they continue to receive chemotherapy. Currently, CMMI intends to inform beneficiaries that they are in the model and they cannot opt out, but only administratively speaking. In practice, beneficiaries' can seek care from any willing provider.

Practice requirements PBPM payments in the OCM are contingent on compliance with the following practice transformation requirements: 24/7 access to a clinician with real-time access to medical records; use of a certified electronic health record system; use of data for quality improvement; available patient navigation services; development of a care plan that includes the 13 components of an IOM Care Management Plan; and adherence to national clinical guidelines for use of therapies.

Benchmarking To measure savings gained under the OCM, total Medicare expenditures in the performance period will be compared with a benchmark based on a historical baseline period, divided into six-month episodes. The benchmark includes all Medicare expenditures for eligible beneficiaries for a participating practice. The benchmark will then be adjusted for risk and geographic variation and trended forward to the performance period. Performance-year Medicare expenditures (including PBPM payments) will be compared with the baseline-year expenditures for each practice.

If a practice does not have enough eligible beneficiaries for reliable benchmarking, national and regional data will be used in conjunction with practice-level data to increase precision. Practices have the option of being pooled with other practices to further increase benchmarking precision. Other payers are free to develop a different benchmarking methodology, but it must be shared with CMMI.

A risk-adjustment methodology has not yet been finalized. Factors under consideration include beneficiary characteristics such as age, comorbidities, type of cancer, number of episodes, and types of concurrent therapies (radiation, endocrine therapy, etc.). At least for the first year, risk-adjustment data will be limited to that which can be gleaned from administrative claims. CMMI could consider collecting clinical data from practices treating oncology beneficiaries, including data on cancer stage and tumor histology.

Performance-based payment Under the OCM model, risk sharing includes a one-sided arrangement and an optional two-sided arrangement. To calculate eligibility for performance-based payment, a discount rate is applied to the baseline amount to arrive at the target spending amount (4 percent for one-sided risk sharing, 2.75 percent for two-sided risk sharing). Under one-sided risk, practices that reduce spending below the target amount are eligible for a performance-based payment. Under two-sided risk, practices are also financially responsible for Medicare spending that exceeds the target amount. The two-sided risk option will be available in the demonstration's third year, after which practices can switch between the two risk-sharing arrangements on a semi-annual basis. Performance-based payments are not made for beneficiaries with low-volume cancers for which it is not possible to calculate reliable benchmarks.

Payments will be adjusted based on performance on quality measures in the domains of care coordination, communication, patient- and caregiver-centered experience and outcomes, and clinical quality. The quality measures are intended to balance the incentives for cost reduction by ensuring that participating practices meet the OCM's goals of patient-centered, coordinated, and clinically appropriate care. CMMI limits expenditure reductions to 20 percent of the baseline expenditure amount to prevent practices from stinting. In the two-sided risk arrangement, a 20 percent maximum loss percentage also applies. Practices that have been pooled together to create a benchmark will also receive shared savings as a group; one practice is designated to receive any shared savings from CMS and distribute the savings to the other practices in the pool.

Practices participating in the OCM are not precluded from participating in other models, including shared-savings models. In cases where oncology practices are also in a Medicare ACO, oncology spending counts toward the ACO benchmark. CMS intends to recoup the OCM's discount amounts from the ACO's shared-savings amount.

Quality measurement CMMI intends to measure quality both for the purposes of performance-based payment and monitoring to prevent stinting on care. Measures include, among others, number of ED visits per beneficiary per episode, score on patient experience survey, share of beneficiaries with very short hospice stays, and share of visits that include medication reconciliation. At this time, CMMI plans to send quarterly reports to practices to aid in management of their populations.

Simulation results from RAND Under contract with CMS, RAND estimated the OCM's potential impact on spending using 2010 data inflated to 2016 dollars. It assumed that only practices with more than 50 eligible chemotherapy episodes per year would consider participating and, of those, about 10 percent of practices would do so. For these practices, RAND simulated the total spending on care management payments ($160 PBPM), baseline spending, and the spending target, assuming different levels of behavioral response (that is, changes to treatment decisions).

Spending estimates were simulated based on three scenarios: no behavioral change, 5 percent reduction in spending, and 10 percent reduction in spending. These reductions were not tied to particular actions the practices might take, but instead assumed aggregate reductions in spending at the practice level. In the scenario of no behavioral change, total spending increased by 4 percent because all practices receive PBPM payments and some receive unearned performance-based payments.[13] The 5 percent reduction scenario resulted in spending slightly below the baseline, meaning the program would roughly break even. The 10 percent reduction scenario resulted in about 5 percent savings relative to the baseline.

Further, RAND projected the effect of the OCM payments on practice-level revenue to be significant relative to current Medicare revenue for physician services (which accounts for about 7 percent of total spending on oncology care). According to RAND, for most practices, the OCM is expected to augment existing revenue from evaluation and management services (E&M) by between 20 percent and 60 percent, and, for some practices, their E&M revenues could double, triple, or more.

Possible behavioral responses The effect that the OCM will have on Medicare spending is dependent on the degree to which practice patterns (e.g., use of inpatient hospital and ED services) change in response to the practice transformation requirements and quality measures. The OCM is not designed to specifically address the incentive under the Part B ASP payment method to use higher priced drugs. While the OCM may encourage more active management of patients, and thus fewer ED visits and hospitalizations, the model could also induce unintended behaviors.

First, if the financial incentives to change behavior and lower spending are not strong enough, practices in the one-sided risk model might not change their practice patterns. Despite the practice transformation requirements, some practices might not effectively furnish care coordination and enhanced patient care. Second, to receive the PBPM payments, some practices might offer chemotherapy to patients who would not have been offered such treatment before the OCM. Some practices could increase the number of episodes per beneficiary to generate more PBPM payments (to the extent clinically possible) (Colla et al. 2012, Elliott et al. 2010, Jacobson et al. 2010). Given the size of the PBPM payment relative to practice revenue, there seems to be a significant incentive to engage in these behaviors. Finally, to keep spending below the benchmark, some practices might select less intensely ill patients to reduce the level of management they would need to provide, or they could use less costly treatment regimens, regardless of their appropriateness for an individual patient (to the extent clinically possible).

Issues in designing oncology bundles

In its June 2013 report, the Commission discussed several approaches and design issues associated with bundling post-acute care (PAC) services. Similar challenges exist with respect to a payment bundle for oncology services. Among the design issues are decisions about the services in the bundle, the duration of the bundle, payment arrangements, and incentives to encourage more efficient provision of care. Each decision involves trade-offs between increasing the opportunities for care coordination and requiring providers to accept risk for care beyond what they furnish.

In principle, under some forms of bundled payment, providers would not have an incentive to furnish more expensive drugs to generate revenue; instead, they would deliver a mix of treatments that would enable them to improve the quality of their care while keeping Medicare spending low. However, as the Commission discussed in the June 2013 report on PAC bundling, the scope and duration of the bundle and the quality incentives linked to payment would shape the financial pressures providers experience to change their current practice patterns.

From the granularity with which the condition is defined, to the triggering event, to the length of time the bundle covers, to which services are included, a bundle could be either narrowly or broadly defined. There are advantages and disadvantages to each approach, and it may be that different conditions lend themselves to different bundling structures. In general, more narrowly defined bundles are more straightforward to implement but also have the disadvantage of fewer opportunities to gain efficiencies from the clinician's choice of services prescribed. In contrast, a broader bundle is desirable because of the flexibility it gives clinicians in choosing the appropriate treatment regimen for each patient and might result in positive downstream effects. However, the broader bundle is challenging to implement because as services are added, more providers may need to be involved, and designating the accountable provider (or providers) becomes more complex. Underlying the general concept of a narrow or broad bundle are several specific design issues that must be addressed. A discussion of these issues follows.

What triggers an episode? For oncology episodes, the triggering event could be based on the diagnosis of the patient, the initiation of chemotherapy treatment, or the initiation of some other oncology-related treatment option (e.g., surgery or radiation services).

What services are included in the bundle? Bundles that require providers to be accountable for a wide number of services create greater incentives for care management and coordination than narrowly defined bundles would. The proposal by Bach and colleagues (2011) is for a narrow bundle that consists of anticancer drugs and their administration. In contrast, CMMI's OCM proposes a broad bundle in which the episode includes both cancer and noncancer services.

How specific is the bundle? Another quality inherent in the nature of bundling is that the beneficiaries covered in the bundle must be sufficiently similar such that their costs can be estimated. Creating a bundle with a small enough scope (i.e., for beneficiaries with similar illnesses) that costs are within a predictable range is a challenge in the current environment, particularly if claims data are to be used to establish the appropriate bundle for the patient. Neither the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM) nor ICD–10 coding differentiates between different stages of cancer. This lack of differentiation is important because, just as different cancer types require different mixes of services to treat, different stages of the same cancer vary in the intensity and type of treatment. For bundles to accurately reflect the services provided, the information used to assign patients to a bundle may have to be further refined.

Who gets paid, and how? Depending on the bundle's scope, one or multiple providers may be implicated. As shown by the five cases we studied, a bundled payment can be a fixed price paid to the provider prospectively or a benchmark that is used to adjust net payments to the providers retrospectively. Emanuel (2014) argued that an episode should be based on the total cost of care, with oncologists as the accountable providers, and that payments should be transitioned from a retrospective payment design to a prospective two-sided risk design.

In a narrow bundle, like Bach and colleagues' (2011) approach, the medical oncologist is the accountable provider who receives the bundled reimbursement and is responsible for patients' outcomes. By contrast, under a broader approach, determining who is designated the accountable provider may be more complex. This issue is particularly relevant for beneficiaries furnished more than one treatment regimen (e.g., oncology drugs, radiation oncology, and surgery). It would be necessary to identify the accountable provider, who could be the medical oncologist, radiation oncologist, surgeon, some other type of clinician, hospital, or type of group. In certain cases,

clinicians may be able to affect service use that is not directly under their control. And increasingly, providers act in teams to care for patients. In these situations, who is ultimately held accountable? Large provider groups and ACOs may have formalized these relationships to facilitate team-based care within bundles, but smaller providers may not have the infrastructure to do so.

What span of time does the bundle cover? The length of the bundle establishes the number of days when service utilization will be included. As the Commission noted in June 2013, longer (and broader) bundles improve the incentives for care coordination and give providers the flexibility to consider the mix and timing of services they furnish. On the other hand, compared with bundles of relatively short duration, longer bundles increase the risk that the services furnished during the episode are unrelated to the triggering event. Long (and broad) bundles require providers to assume greater financial risk. CMS's OCM and the approach proposed by Bach and colleagues (2011) addresses financial risk by setting a maximum loss threshold.

What is the best way to adjust for risk? The model should take into account differences in patient severity and other factors, particularly if they affect prognosis. How will these be accounted for in the bundle? The three commercial pilot programs and the proposal by Bach and colleagues (2011) take into account the type of cancer, cancer stage, tumor histology, and treatment. By contrast, all cancers are included in the OCM.

How to counter the incentive to stint on care? Bundled payments create an incentive to furnish fewer services than medically necessary. Options to limit such behavior include (1) requiring providers to report their use of one of the nationally recognized published clinical guidelines and provide reasons if their treatment protocol varies from national standards; (2) tying rewards to quality requirements (and keeping spending below the benchmarks); and (3) placing providers at risk for the care that is considered to result from stinting (by, for example, measuring the rate of readmissions and ED use). The OCM will use all three of these approaches to ensure quality.

How are efficiencies gained? A motivation for bundling is that, if clinicians make judicious decisions about the treatment of their patients, they may be able to reduce costs while maintaining or improving quality. The scope of the bundle determines the degree to which providers may change the mix of services to reduce costs.

In a narrower bundle, there is less flexibility in gaining efficiencies. Particularly for cancer care, for which clinical guidelines and pathways (evidence-based treatment protocols that providers use in developing a treatment plan for a patient's particular type and stage of cancer) are available, providers may have few opportunities to deviate from standard treatment. For example, in a bundle that includes only oncology drugs, the providers' effect on spending is limited to the selection of drugs. Compared with narrower bundles, larger prospective bundles may give providers more flexibility in modifying a patient's treatment plan to furnish second and third lines of chemotherapy that may be more costly than first-line regimens.

In a broad bundle, more services included mean more choices that the provider can make to deliver care most efficiently. Efficiencies could be gained not just by drug or procedure choice but also by reducing complications like unplanned hospitalizations. The UnitedHealthcare bundle illustrates this point. In its pilot program, in which financial incentives on chemotherapy drugs were reduced by omitting the drug add-on (see p. 102 for full description), overall spending decreased while drug spending increased. If the practices' performance were measured by drug spending only, it would appear that they were unsuccessful in controlling costs. However, the total cost of care shows that efficiencies were gained by reducing hospitalizations and radiology use. Broader bundles are able to capture these shifts in patterns of care.

How is the bundle updated to address changes in evidence and technology? And how does the bundle account for price growth outside the providers' influence? Clinical evidence can change rapidly. Once a bundle is established, the process of incorporating changes in recommended clinical protocols needs to be determined.

How to protect against "unbundling"? If the bundle accounts for some particular treatment regimen, it is important that it also includes its substitutes. For example, if Part B oncology drugs were included in an oncology bundle, but Part D drugs were paid outside the bundle, there might be an incentive to prescribe more (i.e., substitute) Part D drugs in place of comparable Part B drugs.

This problem was addressed in the implementation of the broader ESRD bundle in 2011. Patients on dialysis need a variety of drugs, most commonly erythropoietin-stimulating agents, vitamin D agents, iron agents, and antibiotics. Some of these drugs have both injectable and oral formulations. To prevent shifting prescribing behavior to favor drugs outside the Part B bundle, the ESRD bundle

includes both the injectable and oral formulations of these dialysis drugs. In addition, the ESRD bundle includes Part D oral ESRD-related drugs with no injectable equivalent (oral-only drugs include phosphate binders and calcimimetics).

Treatment patterns in medical oncology are similar in that they require the use of Part B and Part D drugs and procedural care, which suggests that oncology may lend itself well to a broader bundle, which can account for the broad array of services that may be required. Since a primary aim of bundling is to allow clinical decision making to reside at the level of the clinician and remove some of the revenue incentives at play in pure FFS, the bundle must be wide enough to allow clinicians to make those decisions and not leave opportunities for simultaneous reimbursement through the bundle and FFS billing.

What are the implications for beneficiaries? A bundled approach in which Medicare continues to pay individual providers under FFS (and uses a benchmark to adjust net payments to providers retrospectively) would not affect beneficiary cost sharing. By contrast, under prospective bundled approaches, beneficiary cost sharing would be tied to the bundle amount rather than FFS transactions. This arrangement might result in beneficiaries paying either more or less than they otherwise would for the same treatment under traditional FFS, which might create equity issues among beneficiaries (or at least the perception of such issues). Designing bundles specific to a given treatment and condition might help mitigate this issue. For example, the UnitedHealthcare–MD Anderson pilot uses eight different prospective bundles that vary based on the treatment regimen for head and neck cancer. Applying risk adjustment to the payment rate might also mitigate this issue.

Finally, particularly with regard to oncology care, it is appropriate to consider including end-of-life care in the bundle. The presence of the bundle should not discourage clinicians from recommending hospice or palliative care for those beneficiaries for whom it is appropriate. In fact, a well-constructed bundle may facilitate those conversations.

Other approaches to improve the efficiency of oncology care

Medicare and commercial payers have considered and implemented various approaches to address some or all of these concerns about payment for and quality of oncology care. A review of the literature and discussions with stakeholders suggest that their efforts fall under two general approaches: (1) increasing use of medical homes and (2) wide use of clinical pathways by providers and commercial payers.

Oncology medical homes

The medical home builds on the concept of patient-centered care under which a designated provider is responsible for complying with requirements for integrated or coordinated care, evidence-based medicine and performance measurement to ensure quality and safety, and enhanced access. In 2010, the first oncology practice was recognized by the National Committee for Quality Assurance as a Level III patient-centered medical home (Sprandio 2012). The adoption of an oncology medical home by providers and payers appears to be increasing over the past five years (Aetna 2013, Fox 2013).

Beginning July 2012, CMMI provided a grant for seven oncology practices to implement a three-year oncology patient-centered medical home. The Community Oncology Medical Home (COME HOME) model offers enhanced services to newly diagnosed or relapsed Medicare and Medicaid beneficiaries and commercially insured patients with one of seven cancer types (breast, lung, colon, pancreas, thyroid, melanoma, and lymphoma). These services include patient education and medication management counseling, team-based care, and enhanced practice access through triage pathways, which help manage patient symptoms on a 24/7 basis through a triage phone line, extended night and weekend office hours, and on-call providers. CMMI provided a $19.8 million grant to the participating practices to fund the enhanced services; the grant funding could not be used for services billed with an E&M service (to ensure that CMS would not be paying twice for the same service) (Centers for Medicare & Medicaid Services 2015a). According to CMS, the estimated three-year savings of this initiative is $33.5 million. The program's aim is to reduce the costs associated with ED visits by 52 percent and hospital admissions by 21 percent through enhanced symptom management, increased access to care, use of pathways, improved decision support, and improved capacity to collect and use data (McAneny 2012).[14] This demonstration is expected to conclude in 2015.

In a preliminary analysis, CMS's contractor examined whether longer patient participation in the COME HOME model in 2013 lowered Medicare FFS spending and use of hospital and ED services (NORC at the University of Chicago 2014). (This analysis did not compare cost and use data of patients who participated in the model

with a comparison group.) The contractor found that longer patient participation in the model in 2013 (i.e., more than one calendar quarter) was associated with statistically significant lower total Medicare spending per beneficiary and lower rates of all-cause hospitalizations per beneficiary. The contractor did not find a statistically significant relationship between length of patient participation and rates of ambulatory care–sensitive hospitalizations and ED visits. The contractor concluded that the reduction in cost and utilization over greater lengths of program enrollment could be a consequence of the model or a consequence of regression to the mean in the care trajectory of patients newly diagnosed with cancer.

Clinical pathways

Clinical pathways are evidence-based treatment protocols that payers and providers are adopting to standardize drug treatment, reduce unnecessary variation, and improve quality of care (DeMartino and Larsen 2012). Although pathways are generally consistent with publicly available clinical guidelines such as the National Comprehensive Cancer Network guidelines, they narrow treatment options and suggest when these options are appropriate. Most pathways began by focusing on chemotherapy, but some have broadened to include other oncology-related services (e.g., radiation oncology services) (DeMartino and Larsen 2012). Pathways typically evaluate competing regimens for a given condition based on efficacy, side effects (toxicity), strength of national guideline recommendations, and cost. One payer explicitly stated that in selecting a particular therapy as a pathway, cost is considered only after consideration of all other factors (Anthem 2014).

Clinical pathways are widely used in oncology care. One survey estimated that over half of responding practices used clinical pathways, and about 90 percent used guidelines (Barr and Towle 2011). Various companies—including eviti, New Century Health, P4 Pathways (Cardinal Health), US Oncology, Innovent Oncology (McKesson Specialty Health), Kew Group, and Via Oncology (UPMC)—have developed proprietary pathways (DeMartino and Larsen 2012). In addition, some clinician practices and large cancer centers have developed their own pathways. There are two common pathway business models (DeMartino and Larsen 2012). In the first model, a payer sponsors a company to develop pathways. The payer then provides incentives to the payer's oncologists to use the pathways. In the second model, oncologists work directly with vendors to develop pathways (Sanghavi et al. 2014). The oncologists then work with their payers to develop incentives the payers will offer for oncologists to follow the pathways. In most instances, pathways are proprietary, that is, available only to payers and clinicians.

Payers and providers have implemented various approaches that link compliance to clinical pathways to financial incentives, including providers receiving a higher reimbursement rate on drugs or other services (e.g., E&M services), an add-on per patient, and a lower risk of denied or delayed reimbursement (DeMartino and Larsen 2012). Under these approaches, providers typically have to meet a certain level of pathway compliance but can go "off pathway" to accommodate patient preferences and variation in disease development. For example, one commercial payer increases the add-on to the drug payment rate if clinicians meet a 60 percent compliance threshold (*Oncology Business Review* 2008). Another commercial payer links additional payment for each patient who receives treatment as specified by the pathways for breast, lung, and colorectal cancer. If a practice follows the pathways, it receives a $350 one-time fee at the onset of treatment and payments of $350 per patient per month while the patient is actively in therapy and treated in compliance with a pathway (Anthem 2014). The notion is that the additional payments will offset the amount of revenue the practice could gain from administering more-costly drugs (Nelson 2013).

Compared with bundled payments, payment for pathway adherence limits flexibility and (depending on the design) may not remove the incentive for some clinicians to furnish higher priced products when therapeutic equivalents exist. Compared with bundling approaches that require providers to be accountable for a wide range of care, use of pathways may not necessarily lead to more coordinated care or enhanced access for beneficiaries.[15] Because pathways are typically proprietary, it might be difficult for FFS Medicare to adopt such an approach.

Conclusions

In this chapter, we discussed the lack of value-based incentives for managing Part B drug use. Medicare's payment policy for Part B drugs does not always provide beneficiaries and taxpayers the best value because the policies do not consider evidence of a drug's clinical effectiveness compared with its alternatives. LCA, consolidated payment codes, and bundling approaches have the potential to improve value by reducing the

payment system's incentive to encourage the use of more costly drugs and biologics. These value-based approaches could be designed to reduce beneficiary and Medicare spending while maintaining quality. Alternatively, these approaches could be designed to use existing resources to improve quality of care. Bundling, in particular, has the potential to encourage providers to make clinically appropriate decisions about the most efficient mix of services beneficiaries receive and has the potential to improve care coordination and result in positive downstream effects, such as reduced hospital admissions and ED visits. CMS could consider conducting an oncology bundling demonstration that is designed to use existing Medicare resources to improve beneficiaries' quality of care and address potential incentives under FFS that might lead to the use of more-costly drugs and other interventions, increased service volume without regard to quality or value, potentially avoidable hospital admissions and ED visits, and fragmentation of care. ■

Endnotes

1 Certain vaccines, certain blood products, and home infusion drugs requiring durable medical equipment are paid based on 95 percent of the average wholesale price instead of ASP + 6 percent.

2 In April 2010, CMS directed its contractors to discontinue all LCA policies for Part B drugs.

3 Medicare's contractors are currently referred to as Medicare administrative contractors and previously were referred to as carriers and fiscal intermediaries.

4 To implement the functional equivalence standard, CMS used its authority (under section 1833(t)(2)(E)) to adjust the hospital outpatient prospective payment system's transitional pass-through payments that the agency determines are "necessary to ensure equitable payments." By contrast, CMS implements LCA policies under a different authority (under section 1862 (a)(1)(A)) to pay the expenses of reasonable and necessary services.

5 Ilene Hays, a beneficiary, was prescribed DuoNeb, an inhalation treatment for chronic obstructive pulmonary disease. Originally, Hays filed the motion together with the manufacturer of DuoNeb. The court held that the manufacturer had no standing because the relevant statute allows only beneficiaries to challenge contractors' local coverage determinations and dismissed the manufacturer from the case (Akin Gump 2008).

6 CMS established a single Healthcare Common Procedure Coding System (HCPCS) code for both products to comply with a provision in the MMA that the Secretary treat single-source drugs that were within the same billing code as of October 1, 2003, as if the products were multiple-source drugs. Before 2005, Medicare paid for albuterol and levalbuterol under the same Level II HCPCS code.

7 The Medicare appeals process includes five levels: (1) redetermination by a Medicare administrative contractor; (2) reconsideration by a qualified independent contractor; (3) hearing by an administrative law judge; (4) review by the Medicare Appeals Council; and (5) judicial review in district court.

8 Concerns raised about the development of clinical guidelines include the following: (1) guidelines developed by specialties often have a financial interest in having broad or permissive guidelines; (2) physicians and researchers who sit on guideline committees frequently have relationships with drug manufacturers, and organizations that sponsor guideline development also have industry relationships; (3) guidelines developed by different groups and specialties may differ in their recommendations; and (4) guidelines often focus on a single disease, and older patients usually have multiple diseases.

9 Institutional services are furnished by institutional outpatient providers such as hospital outpatient departments, rural health clinics, and dialysis facilities. Physician/supplier services are furnished by noninstitutional providers such as physicians, physician assistants, clinical social workers, nurse practitioners, and certain freestanding providers (e.g., independent clinical laboratories, ambulance providers, and freestanding ambulatory surgical centers).

10 In the initial period of the pilot, providers would be paid according to FFS policies. In Period 2 of the pilot, Medicare would use a single payment based on the average of the costs of the bundled services furnished in Period 1. In subsequent periods, payment would be recalibrated based on average utilization in the previous period.

11 According to the American Cancer Society, radical prostatectomy is the main type of surgery for prostate cancer, which involves removing the entire prostate gland plus some of the tissue around it (American Cancer Society 2015).

12 The practices committed to at least 85 percent compliance with their chosen therapies; exceptions were allowed (e.g., for medical contraindications). The groups could change the preferred regimen at any time, but they had to achieve the same level of compliance (Newcomer et al. 2014).

13 Ninety percent of this increase is due to PBPM payments, and 10 percent is due to "noise bonuses."

14 Through the COME HOME model, each practice paid $125,000 to collaborate on pathway development for seven tumor types.

15 Limited studies are available to show the clinical and financial outcomes of using pathways. One study showed that for patients with non-small-cell lung cancer over a one-year period, outpatient costs were 35 percent lower for patients on clinical pathways than for patients who received nonpathway treatment (Neubauer et al. 2010). Another study found that, for adjuvant treatment for colon cancer, the mean per patient per month treatment costs were lower for patients on pathways compared with patients not on pathways ($5,907 versus $9,121, $p \leq 0.001$) (Hoverman et al. 2011). For metastatic colon cancer patients, the lower per patient per month cost for patients on pathways compared with patients not on pathways did not reach statistical significance. The authors also found that survival for patients on pathways was comparable with patients not on pathways. Wellpoint estimates the company's program will reduce treatment costs between 3 percent and 4 percent per year (Sanghavi et al. 2014). Other programs have reported more aggressive cost reductions (15 percent on cancer-related costs) (Nelson 2013).

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