CHAPTER 6

Separately payable drugs in the hospital outpatient prospective payment system

CHAPTER 6

Separately payable drugs in the hospital outpatient prospective payment system

Chapter summary

CMS has defined the unit of payment in the hospital outpatient prospective payment system (OPPS) as a primary service (the reason for the visit) coupled with the ancillary items provided with the primary service. That is, the OPPS typically packages the cost of ancillary items into the payment rate of the related primary service. This approach contrasts with a fee schedule in which each service (both primary and ancillary) has a separate payment. Combining a primary service and related ancillary items into a single payment unit encourages efficiency because the combination of inputs used to treat a patient determines whether the provider experiences a financial gain or loss. In this chapter, we consider an exception to this general policy in the OPPS: separately payable drugs. Although we are focusing on separately payable drugs, the issues we consider in the chapter have broader implications.

Although packaging ancillary items has the benefit of encouraging efficiency, not all ancillary items should be packaged. If the OPPS packaged ancillary items that are costly or infrequently provided with a particular primary service, the financial risk to hospitals could be excessive. By volume, the OPPS treats most drugs as packaged items. However, the OPPS provides payments for some relatively high-cost drugs that are separate from primary services. The OPPS has two distinct policies for paying for these drugs: pass-through drugs and separately payable non-pass-through (SPNPT) drugs. The pass-through program is intended to provide adequate payment to hospitals

In this chapter

for drugs that are relatively costly and new to the market. In contrast, the SPNPT program is intended to provide adequate payment for relatively high-cost drugs that are already established in the drug market. Total Medicare spending (combined program spending and beneficiary cost sharing) for pass-through drugs and SPNPT drugs has grown rapidly, increasing from $5.1 billion in 2011 to $12.9 billion in 2018. Most of that growth in drug spending—82 percent—was for cancer treatment drugs.

For a drug to be granted pass-through status, it must be new to the market, and it must have costs that exceed several thresholds relative to the OPPS payment rate of the associated service. By statute, drugs can have pass-through status for two to three years. For a drug to have SPNPT status, it must have costs per day that exceed a threshold ($130 in 2020) and it cannot be a "policy-packaged" drug, which is a drug in a category that CMS has determined is always packaged with the associated service. The categories of policy-packaged drugs include anesthesia drugs; drugs, biologics, and radiopharmaceuticals that function as supplies in diagnostic tests or procedures; and drugs and biologics that function as supplies in surgical procedures.

Packaging drugs into payment bundles provides a strong incentive for providers to be efficient. However, packaging all drugs can put providers at excessive financial risk, which can lead them to avoid infrequently used or high-cost drugs and adversely affect access to treatments that may improve patient care, which, in turn, can adversely affect incentives for drug innovation. At the same time, paying separately for drugs creates distortions in payments, and these distortions can lead to overuse of high-cost drugs and shift financial pressure from providers to Medicare. In addition, separate payments for drugs reduce price competition among manufacturers, which can lead to greater drug price inflation. Therefore, Medicare must be judicious concerning separately payable drugs and balance the desire to promote innovation with the need to maintain pressure on providers to be efficient.

The current criteria for both pass-through drugs and SPNPT drugs have been in place for more than 15 years. The Commission is concerned that the criteria for eligibility under both policies do not strike an appropriate balance between promoting access to innovative treatments and maintaining pressure on providers to be efficient. In particular, we are concerned about the rising cost of Part B drugs, and these policies for separately payable drugs do little to discourage high launch prices set by drug manufacturers or excessive use by providers. Both policies use cost criteria to identify drugs for program eligibility. The cost criteria are different between the programs, but we are concerned that both allow eligibility for drugs that could be packaged without placing excessive financial risk on hospitals. Also, neither policy requires drugs to be clinically superior to competing drugs, even

though a requirement for clinical superiority implicitly encourages innovation. As a result, Medicare could pay separately for a drug no more effective than an existing product, even when the cost of the existing product is reflected in the OPPS payment. This possibility could result in Medicare paying twice for a drug.

We reviewed criteria used to identify separately payable drugs in several payment systems for hospital services: the Medicare OPPS, the Medicare inpatient prospective payment system, and the ambulatory patient group system developed by 3M™ Health Information Systems. Taken together, these three systems use four criteria for identifying separately payable drugs:

- The drug must be new to the market.
- The cost of the drug must be high in relation to the payment rate of the associated procedure.
- The dollar cost of the drug must be high.
- The drug must show clinical superiority over other drugs with a similar therapeutic use.

All of these criteria could be used in the OPPS. However, no payment system combines the use of all four of these criteria, and the use of all four could be overly stringent.

We emphasize that the purpose of this analysis is to evaluate potential criteria for identifying drugs that should be separately payable in the OPPS. The Commission will provide further analysis to determine the specific criteria that should be used and the parameters of those criteria. At the present stage, we are certain that an effective system of separately payable drugs should have two features:

- Some drugs should be paid separately because they are not ancillary. These drugs are the purpose for a visit, are high cost, treat a condition, and are usually administered by infusion. Many of these drugs are for cancer treatment, but some, such as infliximab for treatment of autoimmune disorders, treat other conditions. Separate payment for these drugs is consistent with the policy in the ambulatory patient group system.
- Drugs should show clinical superiority over other drugs to have separately payable status. A clinical superiority requirement is vital. Without one, as noted above, Medicare could pay separately for a drug no more effective than an existing product, even when the cost of the existing product is reflected in the OPPS payment. This situation results in double payments by Medicare.

In future work, we will perform analyses to determine other criteria for identifying drugs that should be separately payable. We will also perform analysis to determine the parameters for those criteria. ■

Background

The unit of payment in the hospital outpatient prospective payment system (OPPS) is the primary service (the service that is the reason for the visit, such as a clinic visit or a device implant) coupled with the ancillary items that are provided with and adjunctive to the primary service (such as a diagnostic X-ray during a clinic visit). The OPPS packages the ancillary items with the related primary service into a single payment bundle. The rationale for packaging ancillary items rather than paying separately for them is to create an incentive for hospitals to identify the most efficient way to provide a primary service. The packaging of ancillary items contrasts with a fee schedule in which providers receive a separate payment for each service provided—the primary service and the ancillary items.

The packaging of ancillary items does not mean that OPPS payments do not reflect the cost of packaged ancillaries because the payment rates for primary services reflect the costs of the packaged items. For example, if a packaged ancillary costs $20 and is provided 50 percent of the time for patients who receive a particular primary service, then $10 (50 percent of $20) is included in the estimated cost for the primary service when setting the payment rate. A simple example of how packaging works under the OPPS is a case of someone having a bad cough with chest discomfort and congestion. If this person goes to an outpatient clinic of a hospital, the physician might order a chest X-ray to check for pneumonia. In this case, the visit to the clinic would be the primary service, while the chest X-ray, an ancillary service, would be packaged with the primary service.

In the OPPS, CMS identifies services using Healthcare Common Procedure Coding System (HCPCS) codes. CMS creates a payment bundle by combining the HCPCS code of the primary service with the HCPCS codes of the packaged ancillary items. CMS collects the HCPCS codes of the primary services into ambulatory payment classifications (APCs), which are groups of services that have similar clinical characteristics and costs. For each APC, CMS determines a payment rate that is based on the geometric mean cost of all the services in the APC.[1] All of the primary services in an APC have the same payment rate.

Although packaging ancillary items encourages efficiency by giving hospitals a financial incentive to consider all of the input costs related to the delivery of primary services, not all ancillary items should be packaged. If the OPPS packaged ancillary items that are expensive or infrequently provided with a particular primary service, the financial risk to hospitals (and the risk of stinting on care) would be excessive. For example, if the OPPS packaged a $500 drug that is provided 1 percent of the time with the primary services in an APC, the payment rate for this primary service would include only $5 for this drug. That is, the difference between the cost of the drug and how much of its cost is reflected in the payment rate of the related service would be $495.

A category of ancillary items that has grown in importance in the OPPS is drugs covered under Medicare Part B. By volume, the OPPS treats most drugs as packaged items because their cost is low enough that packaging does not pose a high financial risk. However, through statute and through CMS regulatory action, the OPPS has two policies for paying some drugs separately from primary services: pass-through drugs and separately payable non-pass-through (SPNPT) drugs. At times, we refer to these two groups collectively as "separately payable drugs." Each pass-through drug and each SPNPT drug has its own APC and payment rate. From 2011 to 2018, total Medicare spending (combined program spending and beneficiary cost sharing) for pass-through and SPNPT drugs increased from $5.1 billion to $12.9 billion.[2] Most of that growth in drug spending—82 percent—was for cancer treatment drugs, and the growth reflects strong increases in volume and prices.

As we consider which drugs should be paid separately and which should be packaged, we should be aware that not all drugs are ancillary items. In situations in which receiving a drug is the reason for the patient visit, the drug is not ancillary. These drugs are usually very expensive, are used to treat medical conditions, and are usually administered by infusion. Many of these drugs are used to treat cancer. Because of their high cost and because they are not ancillary, these drugs should be separately payable.

Existing policy for pass-through drugs

The Congress established pass-through drugs through Section 1833(t)(6) of the Social Security Act. Before CMS implemented the OPPS, there was concern that data on the cost of new drugs would not be available when setting the APC payment rates. Consequently, providers could be underpaid for these new drugs because the cost

TABLE 6–1 **The programs for pass-through drugs and separately payable non-pass-through drugs have important differences, but neither requires clinical superiority**

Program feature	Pass-through drugs	Separately payable non-pass-through drugs
New to market	Required	Not required
Time limit	Two to three years	No limit
Cost	Cost must exceed three thresholds related to primary service	Cost must exceed $130 per day
Clinical superiority	Not required	Not required

Source: Final rule regulations on the hospital outpatient prospective payment system from CMS.

of those drugs would not be reflected in the APC payment rates, which could adversely affect the use of those drugs and, thus, be a disincentive to innovation. As a result, the Congress established pass-through payments for new drugs that have high costs relative to the payment rates of their associated primary services' APCs. Pass-through payments are additional payments that providers receive above the value of the drugs that are packaged into the payment rate of a service when the providers use a pass-through drug. To implement the statute, CMS established requirements for a drug to have pass-through status:

- The item must be new, meaning that payment for the drug was not being made as of December 31, 1996.
- The cost of the drug is not insignificant in relation to the OPPS payment rate for the related service (or group of services). CMS has determined that drug costs are not insignificant if they meet all of these thresholds:
  - The estimated average reasonable cost of the drug exceeds 10 percent of the APC payment amount for the service related to the drug.
  - The estimated average reasonable cost of the drug exceeds the drug portion of the APC payment amount for the related service by at least 25 percent.
  - The difference between the estimated reasonable cost of the drug and the drug portion of the APC payment amount for the related service must exceed 10 percent of the APC payment amount for the related service.

Because the purpose of the pass-through program is to provide adequate payment for new, relatively costly drugs while CMS collects the necessary cost data for including the cost of these drugs in the APC payment rates of the related service, pass-through status is time limited. A drug can have pass-through status for two to three years. Despite requirements that pass-through drugs meet three cost thresholds, it is possible that relatively low-cost drugs, which arguably pose minimal financial risk to hospitals, can become pass-through drugs. For example, Lumason—a contrast agent used in ultrasound imaging—has pass-through status and costs about $23 per day.

Existing policy for separately payable non-pass-through drugs

The program for SPNPT drugs exists from a combination of legislation and a regulatory decision by CMS. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) defined specified covered outpatient drugs (SCODs) and mandated separate payment for them in the OPPS. The MMA defined SCODs as drugs that had pass-through status before January 1, 2003. The MMA also requires that payment for SCODs from 2006 forward be equal to the average acquisition cost for the drug, subject to adjustments for overhead costs. CMS has used average sales price (ASP) as the basis of payment for SCODs, with adjustments to account for overhead costs that CMS has varied over time.

Through regulation, CMS established a policy that created SPNPT drugs: SCODs plus other drugs that are not SCODs but have costs per day that exceed a cost threshold ($130 in 2020). CMS adjusts this cost threshold each year using the producer price index for pharmaceutical preparations. However, CMS has established that certain

drugs must be packaged if they do not have pass-through status, which means they cannot be SPNPT drugs. CMS refers to these drugs as policy-packaged drugs. These drugs include anesthesia drugs; drugs, biologics, and radiopharmaceuticals that function as supplies in diagnostic tests or procedures; and drugs and biologics that function as supplies in surgical procedures.

The SPNPT program is distinct from the pass-through program in three important ways (Table 6-1). First, the SPNPT program is for established drugs, while the pass-through program is for new drugs. Second, the SPNPT program has no limit on how long a drug can hold SPNPT status, while the pass-through program limits eligibility to two to three years. Third, the cost requirements are very different between these two programs because pass-through drugs have to have costs that exceed three thresholds related to the payment rate of the associated service and SPNPT drugs simply have to exceed a cost per day threshold. Neither program requires drugs to show clinical superiority over other drugs.

Identifying drugs that should be separately payable in the OPPS

Packaging drugs into payment bundles provides a strong incentive for providers to be efficient. However, packaging all drugs can put providers at risk for substantial financial loss, which can lead them to avoid rarely used or high-cost drugs and adversely affect access to treatments that may improve patient care, which, in turn, can adversely affect incentives for drug innovation. At the same time, overly lenient criteria for separately payable status can lead to overuse of separately payable drugs and shift financial pressure from providers to Medicare. In addition, separate payments for drugs reduces price competition among manufacturers, especially new, separately payable drugs versus established drugs that may be packaged, which can lead to greater drug price inflation. Therefore, Medicare must be judicious concerning separately payable drugs and must balance a desire to promote access to innovative treatments with the need to maintain pressure on providers to be efficient.

The current criteria for both pass-through drugs and SPNPT drugs have been in place for 15 years. We are concerned that the criteria for eligibility in both programs do not strike an appropriate balance between promoting innovation and maintaining appropriate pressure on providers. Both programs use cost criteria to identify drugs for program eligibility, but we are concerned that both can allow separately payable status to drugs that could be packaged without placing excessive financial pressure on hospitals. In particular, the Commission is concerned about the rising cost of Part B drugs, and these policies for separately payable drugs do little to discourage either high launch prices set by drug manufacturers or excessive use by providers. In part, our concern stems from the fact that Medicare spending on separately payable drugs in the OPPS has rapidly increased, from $5.1 billion in 2011 to $12.9 billion in 2018.

Under the pass-through program, there is a risk of allowing separately payable status for low-cost drugs that could be packaged because there is no requirement that a drug's cost must exceed a dollar threshold to be a pass-through drug. There is evidence that low-cost drugs do become pass-through drugs, such as the example of Lumason discussed earlier. Under the SPNPT program, there is no requirement that a drug's cost must be high in relation to the payment rate of the associated service. We are also concerned that neither program requires drugs to be clinically better than competing drugs, even though a requirement for clinical superiority implicitly encourages innovation. As a result, Medicare could pay separately for a drug no more effective than an existing product, even when the cost of the existing product is reflected in the OPPS payment. This situation results in Medicare making a double payment.

We seek to develop a program for separately payable drugs in the OPPS that improves on the two current programs. To identify criteria that could be used to determine which drugs should be separately payable, we assessed the criteria for separately payable drugs used in several payments systems. These payment systems include the OPPS, the inpatient prospective payment system (IPPS) in the Medicare program, and the ambulatory patient group (APG) system developed by 3M™ Health Information Systems (3M HIS). Referring to this assessment, we discuss whether each of these criteria would be appropriate for the OPPS.

Payment systems for hospital services use four criteria to identify separately payable drugs

We reviewed papers by analysts at 3M HIS that describe the features of the APG system, which served as a model

for the APC system that CMS uses in the OPPS (3M Health Information Systems 2019, Averill et al. 1993, Goldfield et al. 2008). These papers indicate that, during the development of the APG system, 3M HIS considered, but did not implement, an elaborate system in which decisions to package ancillary items (including drugs) would be based on the cost of the ancillary item in relation to the cost of the associated service and how often the ancillary item is used with the associated service (Averill et al. 1993). 3M HIS also considered, and implemented, a less complicated system that paid separately for ancillary items that 3M HIS considered costly without consideration of the cost of the associated service. This system has resulted in the packaging of all drugs except those that are administered by means of infusion and constitute the reason for a visit, which are paid separately. The separately paid drugs are predominantly chemotherapy drugs.

We have already discussed the criteria for eligibility for the two programs for separately payable drugs in the OPPS, pass-through drugs and SPNPT drugs. A summary of these criteria includes the following:

- Pass-through drugs—Must be new to the market; must have costs relative to the payment rate of the associated service that exceed three thresholds
- SPNPT drugs—Must have cost per day that exceeds $130; cannot be policy-packaged drugs (largely drugs that function as supplies in a primary service)

In the IPPS, the new-technology add-on payment (NTAP) program provides separate payment for new drugs and devices that meet several criteria. For a drug to qualify for NTAP status, it must be new to the market, its cost relative to the payment rate of the applicable diagnosis related group must exceed a threshold determined by CMS, and it must show substantial clinical improvement (clinical superiority) over other drugs.[3]

In summary, the criteria that the APG system, the OPPS, and the IPPS use or considered using to determine whether drugs should be separately paid include the following: the drug's cost must be high in relation to the payment rate of the associated service, the drug has a high dollar cost, the drug must be new to the market, and the drug must show clinical superiority over competing drugs. We will consider each of these criteria in our effort to identify the criteria that drugs should meet to be eligible for separate payment under the OPPS.

Cost of drug relative to the payment rate of the associated service: Precise but complicated

The benefit of using the cost of a drug relative to the payment rate of the associated service or services as a criterion is that, for a given drug, there are situations for which packaging is reasonable and other situations for which separate payment is beneficial. Using the cost of the drug relative to the payment rate of the associated service, we can identify these different situations. If a drug is used frequently with different services, the cost of the drug relative to the payment rates of the associated services can vary. In some cases, the cost of the drug may be high relative to the payment rate. In these cases, it may be beneficial to pay separately. In other cases, the cost of the drug may be relatively low. In these cases, packaging the drug is likely to be reasonable.

A disadvantage of using cost relative to the payment rate of the associated service is the potential for complication and confusion. A drug could be packaged when used with some services and paid separately when used with others, which could be confusing for hospital staff and for claims processors.

Calculation of the cost of a drug in relation to the payment rate of the associated service uses the price of the drug, how frequently the drug is used with the associated service, and the payment rate of the associated service. Consider a situation in which a drug has a cost of $300 and is used with a service that would have a payment rate of $300 if the drug is paid separately:

- If this drug is used 5 percent of the time with this service, packaging the drug would add $15 (0.05 × $300) to the payment rate for the service (for a total payment of $315). In this case, it is reasonable to pay separately for the drug because, if the drug is packaged, the difference between the cost of the drug and the amount of the drug cost included in the payment rate of the associated service is $285, which is 95 percent of the payment rate for the service.
- Conversely, if this drug is used 95 percent of the time with this service, packaging the drug would add $285 to the payment rate for the service (for a total payment of $585). In this case, it is reasonable to package the drug because the difference between the drug cost and the amount of the drug cost included in the payment rate of the associated service is just $15, which is only 5 percent of the payment rate for the service.

This example suggests a formula that could be used to determine whether hospitals face excessive risk if a drug is packaged:

> [(cost of drug) – (percentage of time drug used with service) × (cost of drug)]/(payment rate for service).

If the result of this formula is greater than some percentage, such as 10 percent, then it would be reasonable to pay separately for the drug. If it is less than the percentage, then it would be reasonable to package the drug.

This formula is similar to the formula that the Commission uses to calculate margins for evaluating appropriate updates to Medicare payment rates. The numerator is the difference between the cost of a drug and the portion of the payment for a service that is for that drug. The denominator is the total payment for the service. The formula indicates the loss that a hospital would experience each time it used a drug that is packaged. Note that because the drug cost is packaged into the payment rate of the associated service, the provider would receive an implicit payment for the drug even when the drug is not used with the service.

High dollar cost per day: Straightforward but can be imprecise

The benefit of a requirement that a drug have a high cost is that it is straightforward and uncomplicated. If a drug is determined to be high cost—for example, the cost per day exceeds a dollar threshold—it is paid separately. Otherwise, it is packaged. This criterion presents a dichotomous situation, which is different from a criterion that requires a drug to have high cost in relation to the associated service, which can produce situations in which a drug is sometimes packaged and sometimes paid separately.

One disadvantage of a requirement that a drug be high cost is that it can be somewhat imprecise. Some drugs would have separately payable status even though packaging the drug would not put excessive financial pressure on hospitals. For example, if the OPPS paid separately for all drugs that have a cost of more than $130 per day, a drug that cost $140 per day would be paid separately. If this drug were packaged with a procedure that had a $10,000 payment rate, the hospital would not be under excessive financial risk because the cost of the drug would be small relative to the payment rate of the procedure.

A second disadvantage of this cost requirement is that it encourages manufacturers to set high prices or at least prices just above the cost per day requirement.

New to the market: Ensures adequate payment for new drugs and supports innovation

Being new to the drug market is a requirement for a drug to be eligible for the pass-through drug program and the NTAP program (which includes both drugs and devices). The purpose of these programs is to ensure adequate payment for new technology because of concerns that the necessary cost and use data are not available to include new drugs in the payment rates of the associated services. If the cost of new drugs is not reflected in payment rates, hospitals could choose not to use these new drugs, and patients' access to innovative new treatments could be diminished. Therefore, a program of separate payment for some new drugs is beneficial for adequate payment and access to innovative products. However, the duration of separate payment should be limited to the length of time needed to collect the necessary data for including the cost of new drugs in the payment rates of the associated services, generally two to three years. When the necessary cost and use data are available for including new drugs in the payment rates for the associated services, whether these drugs should be packaged or separately payable should be reconsidered along with the other established drugs.

Clinical superiority: Prevents double payments and increases incentives for innovation

Given the high threshold for reducing the financial incentives of bundled payments by carving out drugs (or other items or services), an important factor in determining whether a drug should be separately payable is that it shows clinical superiority over drugs that have similar therapeutic uses. Without a clinical superiority criterion, the Medicare program could pay separately for drugs that are not clinically better than drugs that are packaged. This situation would result in double payments by Medicare: a payment for the cost of the packaged drug and a distinct payment for the separately payable drug. Also, incentives to produce innovative drugs would be increased if drugs had to show clinical superiority to obtain separately payable status.

In the NTAP program, a drug demonstrates clinical improvement if it meets any one of the following criteria:

- The drug offers a treatment option for a patient population unresponsive to, or ineligible for, other available treatments.
- The drug offers the ability to diagnose a medical condition in a patient population for which that

medical condition is otherwise undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by other methods, and use of the drug affects the management of the patient.

- Use of the drug improves clinical outcomes relative to other drugs, such as:
  - a reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication;
  - a decreased rate of at least one subsequent diagnostic or therapeutic intervention (for example, due to reduced rate of recurrence of the disease process);
  - a decreased number of future hospitalizations or physician visits; or
  - a more rapid beneficial resolution of the disease process including, but not limited to, a reduced length of stay or recovery time, an improvement in one or more activities of daily living, an improved quality of life, or a demonstrated greater medication adherence or compliance.
- The totality of the circumstances otherwise demonstrates that the drug substantially improves, relative to other drugs, the diagnosis or treatment of Medicare beneficiaries.

CMS established a similar list for pass-through devices in the OPPS, which includes two additional possibilities: (1) decreased pain, bleeding, or other quantifiable symptom and (2) reduced recovery time.

The clinical superiority criteria from both the NTAP and pass-through device programs could be used in the OPPS to determine clinical superiority for drugs, and we believe that drugs that meet the requirements under either program would demonstrate true innovation.

However, implementing a clinical superiority criterion necessitates addressing what to do when drugs with similar therapeutic purposes are clinically beneficial in different ways. Consider a situation where two different drugs (Drug A and Drug B) treat the same condition, but Drug A is better than Drug B in a particular clinical attribute (perhaps it results in fewer adverse events) while Drug B is better than Drug A in a different clinical attribute (more rapid resolution of the disease process). There are at least two approaches for addressing this issue:

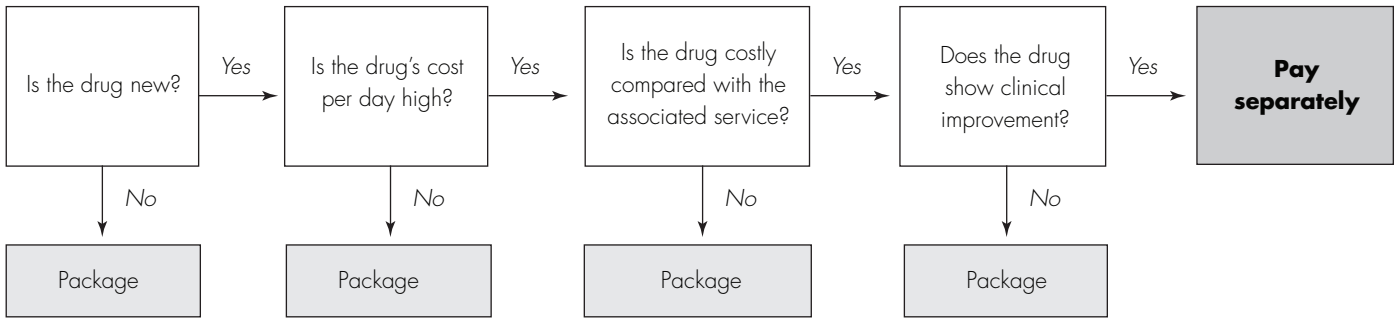
- Among drugs that have similar therapeutic uses, identify one and only one drug as being clinically better than the others. This approach would provide clarity about which drug in a given class is considered the best drug, but it may create situations where a drug has been identified as the best in its class while other drugs in the same class perform better in some clinical aspects.
- If a drug is clinically better than other drugs in its therapeutic class in *at least one clinical measure*, allow it to have separately payable status even if another drug in the same class is better in a different clinical measure. This approach would allow both Drug A and Drug B from the above example to be separately payable drugs.

Considering the criteria used in various Medicare payment systems for the OPPS

If a payment system required a drug to satisfy all four criteria that we discussed in the previous section to qualify for separately payable status, Figure 6-1 illustrates how the decision for separately payable status would work in practice. We do not know of a payment system that requires a drug to meet all four of these criteria to qualify for separately payable status. Therefore, a payment system that requires a drug to meet all four of these criteria would likely be more restrictive than any policy currently in use.

As a starting point in identifying drugs that should be separately payable in the OPPS, recall that the OPPS creates payment bundles by packaging the cost of ancillary items into the payment rates of primary services. While most drugs are ancillary items, some drugs are the reason for outpatient visits and are not ancillary. These drugs are expensive, dominate the cost of the visit, are used to treat medical conditions, and are usually administered by means of infusion techniques. Many of these drugs treat cancer, but some, such as infliximab for autoimmune disorders, treat other conditions. Because these drugs are not ancillary items, they should be separately payable. Paying separately for these drugs would be similar to the policy under the Enhanced Ambulatory Patient Group (EAPG) system—the most recent version of the APG system—

FIGURE 6–1 **Possible decision criteria for identifying separately payable drugs**



which pays separately for all infused drugs and packages all other drugs (3M Health Information Systems 2019).[4]

For the other drugs that are ancillary, the Commission intends to develop a program of separately payable drugs under the OPPS that is different from the two programs currently in use. The four criteria that we discussed in the previous section can serve as a starting point for identifying the criteria for an effective system, but we need to determine which of those criteria to use, then determine the parameters for the criteria selected.

Drug must be new to the market

The benefit of a requirement that a drug has to be new to the market is that it can increase incentives for drug manufacturers to produce innovative new products. However, allowing separate payments only for new drugs could adversely affect use of expensive drugs that are already on the market. Therefore, an important question related to this criterion is, what should be done about drugs that are already on the market? Options include:

- Implement a "new" criterion but let established drugs keep their current status; they are either packaged or paid separately under existing rules.
- Implement a "new" criterion and package all drugs that are already on the market. This option could be implemented immediately or a transition period could be used in which established drugs keep their current status for a limited period (two to three years), then package them.
- Do not use a "new" criterion and subject established drugs to the same criteria for separately payable status as new drugs.

Analysis is needed to determine the best option. If we find that most of the established drugs that are currently separately payable would be in the category of the expensive, nonancillary drugs that we have already designated as separately payable, then a "new" requirement for ancillary drugs would be reasonable because there would be few existing separately payable ancillary drugs affected by the policy.

Drug must have a high dollar cost

Drugs that have a low cost per day should be packaged because packaging them would not expose hospitals to excessive financial risk. Therefore, we assert that a separately payable drug should have a cost per day that exceeds a dollar threshold. A question that obviously must be answered is: At what level should we set the cost per day threshold?

The program for SPNPT drugs has a threshold of $130 per day for 2020, and CMS updates this threshold for drug price inflation each year. The Congress established the initial threshold for SPNPT drugs at $50 per day for both 2005 and 2006 in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. CMS has updated the initial $50 threshold for drug price inflation each year beginning in 2007. At this time, we are not sure whether the threshold used by CMS is appropriate because

it is not based on empirical evidence. The Commission will do an empirical analysis to determine an appropriate threshold. The threshold that is selected should be adjusted each year based on inflation.

Drug's cost must be high relative to the payment rate of the associated service

CMS applies this criterion in the pass-through drug program by requiring pass-through drugs to have costs that exceed three thresholds in relation to the payment rate of the associated service. In relation to the cost per day criterion, drug cost in relation to the associated service is more complex because it includes three variables rather than one: cost of the drug, payment rate of the associated service, and how frequently the drug is used with the associated service. A useful method for determining whether the cost of a drug is high in relation to the payment rate of the associated service is to calculate the difference between the cost of the drug and how much of that cost would be reflected in the payment rate of the associated service if the drug were packaged. This difference indicates the loss a hospital would experience each time it uses the drug (note that because the drug is packaged, the provider receives an implicit payment for the drug when it does not use it). That difference would be compared with the payment rate of the associated service. A formula that represents this comparison is the following:

> [(cost of the drug) – (percentage of time drug is used with associated service) × (cost of the drug)] / (payment rate of associated service)

If the result of this equation is greater than some percentage, such as 10 percent, then it would be reasonable to pay separately for the drug. If it is less than the percentage, then it would be reasonable to package the drug.

Drug must show clinical superiority

The Commission asserts that clinical superiority is a necessary requirement for a new drug to be granted separately payable status. Without a clinical superiority requirement, a new drug could become separately payable even though it has no clinical benefit over packaged drugs that have similar therapeutic uses. Under this scenario, Medicare would make double payments when a hospital uses the separately payable drug, one for the packaged drug and one for the separately payable drugs. Moreover, requiring clinical superiority for new drugs would provide incentive for drug innovation.

A clinical superiority requirement would compare the performance of a drug with drugs that have similar therapeutic uses. If the drug is clinically better in some way, such as it resolves the disease process faster, then the drug can be separately payable. The NTAP in the IPPS and the pass-through device program in the OPPS have clinical superiority requirements, and the two programs have similar, but slightly different, options for an item to indicate clinical superiority. Because the NTAP program encompasses both devices and drugs while the pass-through program encompasses only devices, the options for showing clinical superiority in the NTAP program are likely a better fit for determining clinical superiority among drugs in the OPPS.

While use of a clinical superiority criterion is straightforward to apply if only new drugs can be separately payable, it becomes more complicated if established drugs also are allowed to be separately payable, for two reasons. First, a clinical superiority requirement is intended to spur innovation (stated earlier), and it would be logically inconsistent to apply such a requirement to drugs that have already been introduced to the market. Second, it would make the assessment of which drugs are clinically superior more costly and complicated. Consider a class of drugs that has one new drug and five established drugs. If only new drugs can be separately payable, an assessment for clinical superiority would require only a comparison of the new drug with each of the five established drugs. In contrast, if both new drugs and established drugs can be separately payable, an assessment for clinical superiority would require each drug to be compared with all the other drugs in the class.

How long should a drug be separately payable?

Should there be a time limit for how long a drug can be separately payable, or should drugs be allowed to hold separately payable status indefinitely? The two programs for separately payable drugs in the OPPS have different rules on this issue. The pass-through program limits a drug to pass-through status for two to three years, while the SPNPT program allows a drug to hold that status indefinitely. Possible approaches for a new program of separately payable drugs in the OPPS include:

- Allow only new drugs to be separately payable and limit their time. After their time expires, they are

packaged. This approach can spur incentives for innovation.

- Allow only new drugs to be separately payable, but allow them to hold that status until manufacturers produce a new drug that is clinically superior. This approach may further spur incentives for innovation because the length of time as separately payable is not definite.
- Allow both new drugs and established drugs to have separately payable status. We could classify drugs by therapeutic use. In each therapeutic class, we would determine whether each drug is better than the other drugs in its class in at least one measure of clinical performance. This approach would allow for more than one drug in a therapeutic class to be separately payable.

Summary

Because of the benefits of packaging, the Commission encourages packaging drugs to the fullest extent without subjecting hospitals to excessive financial loss. In other words, the Commission would like a system that limits separately payable drugs to those drugs that would pose an excessive financial risk to hospitals if they are packaged.

To develop such a system, we will make decisions about each of the four criteria that we discussed in this report. The Commission is certain that an effective system of separately payable drugs should have two features:

- Some drugs should be paid separately because they are not ancillary. These drugs are the purpose for a visit, are high cost, treat a condition, and are usually administered by infusion. Many of these drugs are for cancer treatment, but some, such as infliximab for treatment of autoimmune disorders, treat other conditions. Separate payment for these drugs is consistent with the policy in the APG system.
- Drugs that are ancillary items should show clinical superiority over other drugs to have separately payable status. A clinical superiority requirement is vital. Without one, Medicare could pay separately for a drug no more effective than an existing product, even when the cost of the existing product is reflected in the OPPS payment. This situation would result in a double payment by Medicare.

If we determine that no drugs should be paid separately other than those that are not ancillary, the result would be a system of separately payable drugs that is similar to the EAPG system.

If we determine that some drugs other than the nonancillary drugs should be separately payable, then we would have to determine whether only drugs that are new to the market should be allowed to be separately payable or whether established drugs also should be allowed. Irrespective of that decision, we would also have to make decisions about the two cost-related criteria:

- *Cost per day must exceed a dollar threshold.* It is not clear whether the $130 per day threshold that CMS uses in the program for SPNPT drugs is the appropriate level. Empirical analysis is needed.
- *Cost of the drug relative to the payment rate of the associated service exceeds a threshold.* When a drug is packaged, the difference between the cost of the drug and the amount of the cost that is reflected in the payment rate of the associated service is the loss a hospital faces each time it uses that drug with that service. We would have to determine the point at which that loss in relation to the payment rate of the associated service places excessive risk on hospitals.

In future work, we will perform analyses to determine other criteria for identifying separately payable drugs and determine the parameters for those criteria. ■

Endnotes

1 The formula for the geometric mean differs from the formula for the more common arithmetic mean. The formula for the geometric mean of a sample of N numbers is $(\prod Y_i)^{(1/N)} = (Y_1 * \times Y_2 \times \ldots \times Y_n)^{(1/N)}$. The formula for the arithmetic mean of a sample of N numbers is $(\sum Y_i)/N = (Y_{1+}Y_{2+}\ldots+Y_n)/N$. An important difference between the geometric mean and the arithmetic mean is that outliers (unusually high or unusually low values) have a smaller effect under the geometric mean.

2 The level of program spending and beneficiary cost sharing in 2018—$12.9 billion—was mitigated by a policy that CMS instituted in 2018 that reduces the OPPS payment rate for SPNPT drugs obtained through the 340B Drug Pricing Program from 106 percent of the average sales price (ASP + 6 percent) to ASP – 22.5 percent. We estimate that if the OPPS payment rate for SPNPT drugs had been ASP + 6 percent in 2018, combined program spending and beneficiary cost sharing would have been $14.8 billion in 2018.

3 For 2020, CMS has changed the NTAP criteria for meeting substantial clinical improvement. For products that have received a designation as a breakthrough device from the Food and Drug Administration, CMS does not require the standard clinical improvement criteria. All other items must still meet the standard criteria for clinical improvement.

4 The EAPG system collects separately paid cancer treatment drugs into several categories on the basis of drug cost. All drugs in the same category have the same payment rate. The EAPG system does the same thing for all separately paid noncancer drugs. In contrast to the EAPG system, the OPPS provides a distinct, separate payment rate for each separately paid drug. The EAPG method can be thought of as a technique of consolidated billing.

References

3M Health Information Systems. 2019. 3M enhanced ambulatory patient grouping systems: Methodology overview. https://apps.3mhis.com/docs/Groupers/Enhanced_Ambulatory_Patient_Grouping_EAPGS/methodology_overview/grp403_eapg_meth_overview.pdf.

Averill, R. F., N. I. Goldfield, M. E. Wynn, et al. 1993. Design of a prospective payment patient classification system for ambulatory care. *Health Care Financing Review* 15, no. 1 (Fall): 71–100.

Goldfield, N., R. Averill, J. Eisenhandler, et al. 2008. Ambulatory patient groups, version 3.0—A classification system for payment of ambulatory visits. *Journal of Ambulatory Care Management* 31, no. 1 (January–March): 2–16.