Transitional Pass-Through Payments

Medicare reimbursements help give beneficiaries access to innovative technologies

BY THOMAS A. GUSTAFSON, PHD

Transitional pass-through payments—Medicare reimbursement paid on top of an ASC's facility fee for a limited amount of time—were established by Congress to foster innovative medical devices, drugs and biologicals. They can help an ASC give its Medicare patients access to novel therapies without increasing the ASC's costs or overall spending in the US health care system.

Although pass-through status has been in place since 2000, the limited number of products covered under this provision each year might explain why the benefits of transitional pass-through are not well understood. Across all therapeutic categories, only 35 medications have this status in 2015.

Intention and Design

Despite its emphasis on containing costs, Medicare is not opposed to new technologies and, in fact, supports innovation as a way to improve the quality and efficiency of care. Policymakers and legislators, however, recognized that the rigidity of Medicare's payment systems could discourage the use of new medical technologies. Given that payment rates under Medicare's prospective payment systems are based on past claims, a new product coming on the scene is at a disadvantage because its costs will not be reflected in the older claims on which current payments are based.

Congress acted to minimize that problem by setting up a special provision in the law—Social Security Act §1833(t)(6)—to encourage the use of innovative products and help ensure they would be available to Medicare patients by making extra payments, above established facility fees, for new medical products.

Payment for new pharmaceuticals assigned pass-through status is made at wholesale acquisition cost (WAC) + 6 percent for the first two quarters and then at average sales price (ASP) + 6 percent. The national payment rate for each pass-through pharmaceutical is updated and published quarterly on the Centers for Medicare & Medicaid Services (CMS) web site. Pass-through payments for new devices follow the same general scheme but the particulars differ.

The provision is called "transitional" because it is designed to provide a bridge into the regular payment mechanism. Pass-through status is temporary, lasting at least two but not more than three years. In addition to removing financial disincentives to product utilization during this window, thus better enabling clinicians to become familiar with the product's benefits, the provision also allows for the collection of data on utilization to assist CMS in incorporating the product into the service with which it is used when its pass-through status sunsets. At that time, the payment rate for the related service is increased to reflect the utilization of the product during its pass-through period. In this way, use of new technology during the pass-through period helps ensure its accommodation in facility payment rates in the future.

Financing Payments

Each year, CMS estimates Medicare's potential spending in the coming year for all transitional pass-through drugs, biologics and devices and "pays" for anticipated pass-through payments by modestly adjusting all Medicare payments for hospital outpatient department (HOPD) and ASC services. In essence, CMS creates a pool to cover payments for all of the pass-through products for the coming year. This amount is established in advance for the calendar year, so current utilization of pass-through products does not affect the size of the pool for that period. In other words, CMS has already set aside the resources to cover the separate payments for use of new medical technology.

Since the adjustments to Medicare service fees needed to fund these payments have already been taken into account by CMS in setting the payment rates for 2015, whether or not a facility uses a pass-through-designated product now will have no effect on its payment rates this year. To the extent that facilities do not access pass-through payments, the funds that CMS removed from aggregate payments to cover its estimate of pass-through spending for the year will simply be lost to the system.

Fortunately, the adjustments Medicare makes to payments for HOPD and ASC services to contribute funds to the pass-through pool are relatively insignificant. For instance, payment rates in the Outpatient Prospective Payment System (OPPS) for 2015 were reduced by 0.13 percent. Over the past ten years, the total annual adjustment for pass-through spending under the OPPS has ranged from 0.02 percent to 0.22 percent. CMS made similar reductions in ASC payment rates.

The advice and opinions expressed in this column are those of the author's and do not represent official Ambulatory Surgery Center Association policy or opinion.

The utilization of a specific pass-through product will likely have little effect on facility fees during the period it has pass-through status because the reduction taken each year is spread over all services for which Medicare pays under the OPPS and the ASC payment system rather than any single procedure or group of services. In fact, the actual use of a new pass-through product in 2015 will likely not be reflected in the size of the allocation, or the small adjustments to fees to create it, for 2016, because CMS will not have much data on 2015 utilization when it makes its 2016 estimates. When a pass-through product is bundled following expiration of its pass-through status, the associated Ambulatory Payment Classification (APC) reimbursement amount increases in relatively direct correlation to the product's utilization during its pass-through period; therefore, facility fees increase as a result of the product's use during its pass-through status.

The pass-through payments have no effect on physicians' fees, now or in the future. These payment rates are determined on a separate basis under Medicare's Physician Fee Schedule, without reference to payments made to HOPDs or ASCs.

Payments for a pass-through product also have no material effect on overall spending in the US health care system. The pass-through payments are set up to be budget neutral. The bottom line is that Congress has set up Medicare's two payment systems for facilities in a manner that will not materially affect the overall growth in Medicare outlays or in US health care spending.

Although the cost of a pass-through product might seem large relative to the facility fee for the procedure in which it is used, the size of the overall pass-through pool is small in the grand scheme of things. Medicare now pays out more than $500 billion a year, and payments to any one specialty or set of procedures represents a fraction of that total, with pass-through payments accounting for an even smaller portion.

> *"Transitional pass-through payments can help an ASC give its Medicare patients access to novel therapies without increasing the ASC's costs or overall spending in the US health care system."*
>
> *—Dr. Thomas A. Gustafson, Arnold & Porter LLP*

Indeed, despite intense budget pressures, Congress has not rolled back the transitional pass-through provision or other new-technology payment mechanisms. The most recent major Medicare bill, which repealed the sustainable growth rate (SGR) formula for physician payment, left these provisions intact, a testament to Congress's commitment to facilitating access to new technologies for the benefit of Medicare patients.

How It Works

Let's look at one recent example. In 2014, the Food and Drug Administration approved a proprietary combination of phenylephrine and ketorolac as the first product for intracameral delivery during cataract surgery to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative pain. CMS determined that this product was eligible for pass-through payments starting in January 2015 and assigned it a new Health Care Common Procedure Coding System (HCPCS) code, C9447 (*Injection, phenylephrine and ketorolac, 4 ml vial*). Through the end of September 2015, Medicare pays for this product at its WAC+6 percent rate, or $492.90 per vial. Beginning in the fourth quarter of 2015, the payment rate will be ASP+6 percent and will change slightly from quarter to quarter as the product's ASP varies. Patients are not liable for a co-payment when the product is used in the HOPD setting and, although a 20 percent co-payment applies in the ASC, a 2014 report from the Kaiser Family Foundation suggests that the large majority of Medicare Part B patients have some form of supplemental insurance to cover co-payments. Pass-through status for this product is expected to expire on December 31, 2017. At that time, the facility fee for cataract surgery will be increased to reflect the use of the product with the magnitude of the rise depending on the overall utilization of the product during the pass-through period.

Clearing up Billing Misconceptions

Congress established the provision to foster innovation and to remove financial barriers to the utilization of important new products. Reimbursement in Medicare Part B patients is straightforward with proper completion of the billing claim and the use of the pass-through product's unique HCPCS code. Coverage under Medicare Advantage and commercial payers usually follows suit, but facilities are encouraged to contact those payers prior to use of pass-through products to confirm payment rates. Also, most companies marketing pass-through products have reimbursement professionals and/or reimbursement hotlines to answer questions that facilities might have regarding billing and reimbursement.

Performing as it was designed, the transitional pass-through provision benefits Medicare patients and ASCs by facilitating reimbursement for innovative technology now and paving the way for its incorporation into routine use—and standard Medicare reimbursement—later. «

Dr. Thomas A. Gustafson, formerly deputy director of the Center for Medicare Management, is a senior policy adviser at Arnold & Porter LLP in Washington, DC. Write him at Tom.Gustafson@aporter.com.