MEDPAC | Medicare Payment Advisory Commission

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September 6, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8010

Attention: CMS-1809-P

Dear Ms. Brooks-LaSure:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS's) proposed rule entitled "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities," *Federal Register* 89, no. 140, pp. 59186–59581 (July 22, 2024). We appreciate CMS's ongoing efforts to administer and improve Medicare's policies for hospital outpatient and ambulatory surgical center payments, particularly given the many competing demands on the agency's staff. We hope that our comments are helpful in these endeavors.

Our comments address the following provisions in this proposed rule:

- Grant separately payable status under the outpatient prospective payment system (OPPS) for diagnostic radiopharmaceuticals that do not have pass-through status and have costs per day exceeding $630;

- Use provider invoices to determine OPPS payments for separately payable drugs that do not have pricing data (no average sales price (ASP), wholesale acquisition cost (WAC), average wholesale price (AWP), or mean unit cost data); and

- Provide separate payment under the OPPS and ambulatory surgical center (ASC) payment system for non-opioid products (drugs, biologics, and devices) for pain management.

Separately payable status under the OPPS for diagnostic radiopharmaceuticals with costs per day exceeding $630

Since calendar year (CY) 2008, CMS has classified diagnostic radiopharmaceuticals as *policy packaged* in the OPPS. *Policy packaged* means that, unless a diagnostic radiopharmaceutical has pass-through status, its cost is packaged into the payment rate of the related primary service(s).[1] Over the years, CMS has repeatedly stated that packaging costs into a single aggregate payment for a service, encounter, or episode of care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. Packaging the costs of ancillary items and services into the payment for the related primary service encourages hospital efficiencies and enables hospitals to manage their resources with maximum flexibility.

In this rule, CMS considers that situations exist in which the share of the OPPS payment rate for a diagnostic nuclear medicine procedure that reflects the cost of packaged diagnostic radiopharmaceuticals might not adequately account for a high-cost diagnostic radiopharmaceutical. To ensure that Medicare payment policy is not providing a disincentive for use of high-cost, low-volume diagnostic radiopharmaceuticals and to ensure beneficiary access to those radiopharmaceuticals, CMS proposes that diagnostic radiopharmaceuticals with costs per day exceeding $630 would be paid separately and not packaged into the diagnostic nuclear medicine procedure(s) with which the radiopharmaceutical is used.

Comment

The Commission strongly encourages CMS to maintain the current policy-packaged status of diagnostic radiopharmaceuticals. We recognize the need to ensure beneficiary access to costly technologies that improve outcomes while preserving incentives for efficiency, but, in our view, this goal is best achieved by relying on broad payment bundles to the greatest extent possible, particularly given that costly technologies are not required to exhibit superior clinical benefit over other alternatives. Packaging encourages judicious consideration of the items and services provided to beneficiaries. 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. Broader bundles also foster competition between similar items and services, which generates pressure on manufacturers and suppliers to reduce prices. In contrast, providing separately payable status based on cost encourages manufacturers to charge higher prices for products that offer similar clinical benefits to existing products but are not clinically superior. For example, drug cost per day is not

[1] Drugs that are granted pass-through status maintain that status for two to three years after the drug is first launched. The pass-through period allows CMS to collect pricing data for the drug, which allows CMS to determine whether the drug should be separately payable or packaged, and, if the drug is packaged, to incorporate the cost of the drug into the payment rate of the applicable service(s). The OPPS has two categories for packaged drugs: policy packaged and threshold packaged. The costs of policy-packaged drugs are always packaged into the payment rate of the related services unless they have pass-through status under the OPPS. Threshold-packaged drugs are those that do not have pass-through status and have costs per day below the OPPS packaging threshold (proposed to be $140 in 2025). If these drugs have costs above the packaging threshold, they are classified as separately payable and are not packaged.

fixed, but is instead a reflection of market forces and payment policy. Therefore, separately payable status for radiopharmaceuticals that have costs per day that exceed $630 could encourage manufacturers to raise prices above the $630 threshold. Finally, packaging high-cost radiopharmaceuticals does not mean that providers are not reimbursed for the cost of the drugs because the method that CMS uses to set OPPS payment rates results in relatively higher payments for the affected services when the radiopharmaceuticals are packaged.

If CMS determines that concerns about access to costly diagnostic radiopharmaceuticals must be addressed, we strongly encourage the agency to consider alternative approaches before granting separately payable status.

Use provider invoices to determine OPPS payments for drugs that do not have pricing data

Under the OPPS, CMS sets the payment rates for most separately payable drugs and biologics equal to ASP+6 percent. In instances in which ASP data are not available, CMS uses other measures for setting drug payment rates including WAC, AWP, and the drug's mean unit cost. However, situations occur in which none of these sources of drug pricing are available. These drugs do not have payment rates under the OPPS. To provide appropriate payment for the drugs and biologics that do not have pricing data, CMS proposes to use drug invoice data, which CMS currently uses in the Medicare physician fee schedule (PFS).

CMS proposes that the Medicare administrative contractors (MACs) use provider invoice costs to determine the OPPS payments for these drugs. The invoice cost data would be net acquisition cost minus rebates, chargebacks, or post-sale concessions. This policy would not begin until CY 2026 because the policy requires significant operational changes. Before calculating an invoice-based payment rate, the MACs would use the provider invoice to determine that the drug or biologic is not policy packaged and that the per day cost of the drug or biologic exceeds the OPPS packaging threshold amount.

CMS expects that invoice-based payments for a given drug generally would be temporary, lasting two to three quarters for drugs required to report ASP data. For drugs that are not required to report ASP, invoice pricing might be used for a longer time until CMS can calculate a mean unit cost for the drug.

Comment

The Commission supports this proposal. It would help ensure adequate hospital payment for these drugs and biologics, establish a consistent policy across the OPPS and the PFS, and maintain the policies for identifying separately payable and packaged drugs and biologics that CMS has established for the OPPS.

We emphasize that CMS should be attentive to how long drugs are paid at invoice-based payment rates. If CMS finds that the duration of invoice pricing is longer than expected, CMS should consider revising or replacing this policy.

Separate payment for non-opioid pain management products under the OPPS and the ASC payment system

The Consolidated Appropriations Act of 2023 (CAA) provides for temporary separately payable status under the OPPS and the ASC payment system for non-opioid treatments for pain relief that would otherwise be packaged items under both payment systems. The CAA specifies that separately payable status would apply to qualifying non-opioid treatments furnished on or after January 1, 2025, and before January 1, 2028. The intent of this policy is to provide incentive for providers to use non-opioid treatments in place of opioid products.

These separate payments would apply to non-opioid pain management drugs and biologics that do not have pass-through status under the OPPS and are considered supplies to surgical procedures. The separate payments would also apply to medical devices that do not have pass-through status under the OPPS and provide non-opioid treatment for pain relief. These non-opioid drugs, biologics, and devices currently have their costs packaged into the payment rate of a covered OPPS service or group of services. To qualify as a non-opioid treatment, a drug or biologic must have a label indication approved by the Food and Drug Administration (FDA) that the drug or biologic reduces postoperative pain or produces postsurgical or regional analgesia without acting upon the body's opioid receptors. A qualifying device must:

- Be used to deliver a therapy to reduce postoperative pain or produce postsurgical or regional analgesia;

- Have an application under section 515 of the Federal Food, Drug, and Cosmetic Act (FFDCA) that has been approved, been cleared for market under section 510(k) of the FFDCA, or be exempt from the requirements of section 510(k); and

- Have demonstrated—in a clinical trial or through data published in a peer-reviewed journal—the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed.

CMS has identified six drugs or biologics and one device as qualifying for separately payable status under the rules established by the CAA. Following CAA guidelines, CMS proposes that payment rates under both the OPPS and the ASC payment system for qualifying drugs and biologics would be the amount specified in section 1847A of the Social Security Act, which is generally ASP+6 percent. For qualifying devices, the payment rates would be facility charges adjusted to cost using a facility-level cost-to-charge ratio. Note that these are the same payment rates that would occur if these drugs, biologics, and devices had pass-through status under the OPPS.

However, the CAA has a requirement that the separate payment amount for each non-opioid item cannot exceed 18 percent of the OPPS payment rate for the service or group of services with which the item is furnished. CMS proposes to satisfy this requirement by applying an 18 percent payment limitation per date of service billed rather than per dosage unit. That is, when a provider uses a non-opioid item with an OPPS-covered service,

the total payment for the item on the date of the service cannot exceed 18 percent of the service's OPPS payment rate.[2]

Comment

The Commission has commented on CMS proposals that are similar to this one but narrower in scope.[3,4,5] In each comment, the Commission expressed reservations about proposals to pay separately for non-opioid pain management drugs that function as supplies in a surgical procedure. The Commission has the same reservations about the policy proposed in this rule. Paying separately for non-opioid items that function as supplies in surgical procedures runs contrary to CMS's efforts to increase the size of payment bundles in the OPPS in order to increase incentives for efficient delivery of care.

However, the Commission recognizes that CMS must implement the provisions in the CAA that require separately payable status for these non-opioid items under the OPPS and the ASC payment system. The Commission supports the method that CMS proposes for implementing the CAA requirements, including the proposed method for meeting the requirement to limit payment for a non-opioid item to 18 percent of the payment rate of the applicable service or services.

Conclusion

MedPAC appreciates your consideration of these issues. The Commission values the ongoing collaboration between CMS and MedPAC staff on Medicare policy, and we look forward to continuing this relationship. If you have any questions regarding our comments, please contact Paul B. Masi, MedPAC's Executive Director, at 202-220-3700.

Sincerely,

Michael E. Chernew, Ph.D.
Chair

MC/dz/pm

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[2] For example, if a provider uses a non-opioid drug that has an OPPS payment rate of $1 per unit with a surgical procedure that has an OPPS payment rate of $1,000 and the provider uses 50 units of the drug, the total payment for the drug would be $50 because it does not exceed 18 percent of the payment rate for the service ($180). Conversely, if the provider had instead used 200 units of the drug with this service, the total payment for the drug would be capped at $180.
[3] Medicare Payment Advisory Commission. 2018. MedPAC comment on CMS's proposed rule on the payment systems for hospital outpatient departments and ambulatory surgical centers for 2019. September 21.
[4] Medicare Payment Advisory Commission. 2019. MedPAC comment on CMS's proposed rule on the payment systems for hospital outpatient departments and ambulatory surgical centers for 2020. September 13.
[5] Medicare Payment Advisory Commission. 2021. MedPAC comment on CMS's proposed rule on the payment systems for hospital outpatient departments and ambulatory surgical centers for 2022. September 10.