

# **Is Your Hospital Drug Really ASP+?**



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## The Changing Policy Landscape for Drug Payments in Hospital Outpatient Departments and Ambulatory Surgical Centers

### These are the three main ways in which CMS encourages cost efficiency in the OPPTS:

- Threshold packaging
- Policy/surgical packaging
- Denying permanent J-codes for drugs that do not have any physician office-setting utilization

Publication of the Centers for Medicare & Medicaid Services' (CMS) 2020 Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System final rule in November 2019 offers a finalized perspective on CMS' hospital outpatient payment approach and its ASC payment system, effective Jan. 1, 2020.

While not new, packaging payment in the prospective payment system may pose potential market access hurdles for manufacturers. Historically, many drugs used in the facility setting were paid for using a "buy and bill" method where the provider purchases, stocks, administers to the patient, and then bills for separate reimbursement to recoup drug cost at average sales price plus (ASP+) some add-on amount.

In an effort to encourage cost efficiencies in outpatient settings such as hospitals and ASCs, CMS has implemented several policies to capitate financial exposure and limit separate drug payment outside of transitional pass-through status. By introducing a "packaged" pricing model, a product at steady-state will be wrapped into the payment for the primary procedure and not paid separately. CMS' packaging policies "support the strategic goal of using larger payment bundles in

the OPPTS to maximize hospitals' and ASC's incentives to provide care in the most efficient manner."<sup>1</sup> Considering that the inpatient payment system packages drugs using DRG-based fixed payments, this structure encourages hospitals to negotiate with suppliers and manufacturers to explore alternative group purchasing arrangements, or reduce prices, and may result in both insufficient reimbursement for the outpatient facility and an additional barrier to drug adoption.

### 1. Threshold Packaging — Implications for Low-Cost Drugs and Supplies

In 2014, CMS expanded the products and services that are subject to "packaging" policies from just ancillary services and diagnostic tests to include all drugs, biologicals, and radiopharmaceuticals that do not qualify for pass-through status and separate payment. In the CY 2020 OPPS final rule, CMS proposed the new threshold for packaging to be set at \$130 per day. Now, drugs with expiring pass-through payment status with a daily cost below the \$130 threshold will be packaged into the payment for the larger associated procedure. Only when a drug costs more than the \$130 threshold would it be paid using the traditional outpatient ASP+6% payment rate. With the intent of encouraging hospitals to negotiate and

1. Centers for Medicare & Medicaid Services, "CY 2020 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule," November 2019, <https://www.cms.gov/newsroom/fact-sheets/cy-2020-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-0>.

explore alternative group purchasing arrangements or to reduce prices, threshold pricing cutoffs may impact reimbursement for lower-cost products when used in the hospital outpatient department (HOPD) and ASC settings.

As a manufacturer, having a strong sense of the specific costs that a facility must account for to perform a procedure is crucial to understanding the potential impact on your product's utilization. There are also additional implications to consider even earlier in the drug development process. Assessing the product's anticipated positioning in setting of care, the appropriate dosing schedule, and a targeted value proposition will all be crucial in understanding these cost offsets, demonstrating substantial clinical benefit, and ensuring appropriate payment for a product under the OPPS.

## **2. Policy/Surgical Packaging — Implications for Ambulatory Payment Classification Structure**

Another way that CMS encourages cost efficiency in the OPPS is through surgical or policy packaging, which is intended to combine entire categories of drugs, biologics, and radiopharmaceuticals into the procedure with which they are associated, regardless of the product cost.

CMS “considers all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging

policy.”<sup>2</sup> This category is quite extensive, with all items related to the surgical outcome packaged into the cost of the surgery, including post-surgical pain management drugs and implantable biologics. Even high-cost products, including anesthesia, surgical supplies, and drugs that function as supplies when used in a diagnostic test or surgical procedure, may be effectively considered part of the surgery.

In addition, in 2015, CMS established comprehensive Ambulatory Patient Classifications to provide all-inclusive payments for certain secondary services given in conjunction with a primary procedure. This policy combines payment for all items and services typically packaged under the OPPS. For a drug subject to surgical packaging, facility payments may not always account for both the procedure and product costs. In strategic planning for reimbursement, manufacturers may also consider the way in which code descriptors are framed such that products are not limited to use in a surgical setting. A key example of this scenario can be seen with Exparel, Omidria, and many other drugs. Significant investments in strategic planning are required to navigate the potential implications for product pricing and customer financials.

## **3. The HCPCS Workgroup — Blocking Administrative Infrastructure for Buy-and-Bill**

In May 2019, the CMS Healthcare Common Procedure Coding System (HCPCS) workgroup assessed permanent J-code applications for a number of drugs and biologics, noting

2. Hart Health Strategies, Inc., “A Summary of the Centers for Medicare and Medicaid Services Calendar Year 2019 OPPS & ASC Payment System Proposed Rule,” 2019, <https://www.aans.org/-/media/Files/AANS/Advocacy/PDFS/Hart-Health-Strategies-CY-2019-OPPS-ASC-Proposed-Rule-Summary.ashx?la=en&hash=32BB570719F4E1C46D650CC0316077C48CF19548>.



that a permanent J-code will only be established for products that have some physician office utilization.<sup>3</sup> If a permanent J-code is not established, not only is in-office utilization precluded, but opportunities for permanent separate payment post-pass-through are unattainable. To avoid packaging under HOPD in this scenario, pharma manufacturers may consider driving physician office use and securing eligibility for a permanent J-code.

CMS packaging implications should be considered as part of a product's prelaunch clinical, regulatory, and commercial strategy to anticipate potential pricing barriers and consequences, and understand likely reimbursement in the HOPD and ASC settings. While ASP+ may be expected given outpatient use, the ability to secure long-term separate payment in the outpatient setting will be contingent on avoiding policy packaging and establishing a unique HCPCS J-code early in the product development process. If this cannot be avoided, a well-designed Current Procedural Technology/HCPCS coding and payment policy strategy will be even more critical. Transient payment with transitional pass-through may provide a short-term solution for Medicare fee-for-service but may not be turnkey for other payer segments.

In addition to specific elements of coding and payment strategy, innovators should consider how several overarching market access activities may influence strategic considerations for securing adequate payment:

- Evidence and health economics and outcomes research considerations, such as payer and provider evidence planning, budget impact/provider economic modeling, and real-world evidence generation
- Reimbursement and pricing activities, such as product-pricing strategy, stakeholder economics, payer mix, and forecasting
- Strategic accounts planning, such as payer collateral building and positioning relative to other procedures, and building hospital pharmacy and therapeutics strategy and toolkits
- Policy and government affairs considerations, such as coding and payment policy, and society advocacy engagement
- Distribution and channel mix planning, such as assessing anticipated site-of-care mix across HOPD, ASC, and physician offices
- Patient and provider support activities, such as customer targeting, education, and providing hub services

3. Centers for Medicare & Medicaid Services, "CY 2020 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule."



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