Effective January 1, 2019—Changes to Part B Drug Pricing

Medicare Part B covers drugs administered in physician offices and hospital outpatient departments by infusion or injection—such as drugs to treat cancer, macular degeneration, and rheumatoid arthritis. From 2011 to 2016, Medicare Part B drug spending grew from $17.6 billion to $28 billion, representing a compound annual growth rate of 9.8%.

Back in May, the Department of Health and Human Services published its *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, which includes several proposed changes to Medicare Part B drug policies. However, only one of these changes—pricing for new drugs—could be accomplished through rulemaking; all others would require congressional action.

Medicare reimbursement for most Part B drugs is based on the drug’s average sales price (ASP) plus 6%. However, due to sequestration cuts, the actual markup amount is 4.3%. ASP is computed using manufacturers’ actual sales, i.e., list price minus all price concessions (e.g., volume discounts, prompt pay discounts, cash discounts, free goods, chargebacks, rebates).

When ASP data is not available for a specific drug, reimbursement is based on the manufacturer-reported wholesale acquisition cost (WAC) for that drug (i.e., the manufacturer’s list price for the drug, paid by wholesalers or direct purchasers in the U.S.) plus 6%. For a new drug, the Centers for Medicare & Medicaid Services (CMS) uses WAC until there is a full quarter of ASP data available, with a two-quarter lag. Thus, Medicare reimbursement for a new drug may remain at WAC plus 6% for up to nine months following the initial release of that drug.

In 2017, the Medicare Payment Advisory Commission (MedPAC) compared the initial WAC to the subsequent ASP for several new, high-expenditure Part B drugs and found that these drugs’ WACs were significantly higher than their ASPs. MedPAC attributed this price difference to the fact that WACs do not take manufacturers’ price concessions into account. MedPAC noted these findings were consistent with a *2014 Office of Inspector General report* regarding manufacturers’ reporting of ASP data. Based on these findings, MedPAC recommended reducing the payment rate from “WAC plus 6%” to “WAC plus 3%.” Again, due to sequestration cuts, WAC plus 3% is actually WAC plus 1.35%.

In the *2019 Medicare Physician Fee Schedule Final Rule*, CMS has implemented the aforementioned recommendation effective January 1. Although payment for single-source drugs is also based on WAC plus 6%, this new reimbursement applies only to new drugs. Changing payment for single-source drugs would require Congress to amend Section 1847(b) of the Social Security Act, which sets payment for
these drugs at 106% of the lesser of ASP or WAC.

Many objected to CMS’ proposal to reduce reimbursement for new drugs, claiming it would discourage innovation. CMS, however, believes the change “strike[s] a balance between concerns about providers’ overhead costs and concerns about addressing financial incentives that may lead to excessive drug use.” Others commented that the 6% markup was necessary to cover administrative complexity, handling, storage, and other overhead costs incurred by the physician administering the drug. CMS also found this argument unconvincing, noting there was no correlation between the 6% add-on and actual overhead costs. In most cases, CMS noted, the costs associated with the administration of new drugs is no different than the costs associated with drugs reimbursed at the lower ASP rate.

In the Regulatory Impact Analysis accompanying the Proposed Rule, CMS admits it cannot quantify the savings from reducing reimbursement for new drugs. The agency, however, “do[es] not anticipate this change will result in payment amounts that are below acquisition cost or that the proposals will impact providers’ or patients’ access to Part B drugs.”

Beginning January 1, 2019, physicians administering drugs previously reimbursed at WAC plus 6% will see an immediate decrease in reimbursement. Once reimbursement for that drug moves to ASP plus 6% (which would happen in no more than nine months from the first full quarter that ASP data is available for the drug), there would be no further reimbursement impact to the provider. Whether this limited change in reimbursement will discourage physicians from administering new drugs remains to be seen.

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