



DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



February 15, 2022

TO: Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services

FROM: Suzanne Murrin
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Date: 2022.02.15 11:17:38
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On behalf of Suzanne Murrin

SUBJECT: *Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Third Quarter of 2021, OEI-03-22-00190*

This memorandum summarizes the results of the Office of Inspector General's (OIG's) comparison of average sales prices (ASPs) and average manufacturer prices (AMPs) for the third quarter of 2021. By law, OIG must notify the Secretary of Health and Human Services if the ASP for a particular drug exceeds the drug's AMP by 5 percent or more. If that threshold is met, the Secretary may disregard the drug's ASP when setting the reimbursement amount and substitute the lesser of either the widely available market price or 103 percent of the AMP.

In April 2013, the Centers for Medicare & Medicaid Services (CMS) began making price substitutions in accordance with the November 2012 final rule specifying the circumstances under which AMP-based price substitutions occur. Pursuant to the rule, CMS substitutes 103 percent of the AMP for the ASP-based reimbursement amount when OIG identifies a drug code that exceeds the 5-percent threshold for 2 consecutive quarters or 3 of the previous 4 quarters. CMS lowers reimbursement amounts only when ASP and AMP comparisons are based on the same set of drug products (i.e., based on complete AMP data). To prevent CMS from inadvertently raising the Medicare reimbursement amount, a price substitution is not implemented if the substituted amount would exceed the ASP-based payment amount for the quarter in which the price substitution would take effect. In addition, price substitutions are not implemented for drugs that the Food and Drug Administration (FDA) identifies as being in short supply.

OIG found that in the third quarter of 2021, 8 drug codes met CMS's price-substitution criteria by exceeding the 5-percent threshold for 2 consecutive quarters or 3 of the previous 4 quarters, on the basis of complete AMP data. OIG found 6 additional drug codes that, on the basis of complete AMP data, exceeded the 5-percent threshold. However, at the time of our analysis, FDA identified these drugs as being in short supply. Another 14 drug codes had ASPs that

exceeded the AMPs by at least 5 percent in the third quarter of 2021, on the basis of complete AMP data, but these drug codes did not meet other CMS price-substitution criteria.

In addition, on February 11, 2022, OIG sent an early alert to CMS informing you that the ASPs used to set the Part B payment amount for Aduhelm in the first quarter of 2022 exceeded the widely available market price by more than 5 percent. In future quarters, OIG will continue to provide early alerts to CMS when we identify similar instances involving Part B drugs.

We will provide you with the results of our pricing comparison for the third quarter of 2021, the results for the three previous quarters, and pricing information for Aduhelm from the February 2022 early alert. This information will be transmitted via our secure file transfer system.