



OFFICE OF INSPECTOR GENERAL

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Update: Xolair Prefilled Syringes Likely Meet Part B Coverage Criteria

Why OIG Did This Review

- Congress requires [OIG](#) to conduct periodic studies to identify billing codes for which both noncovered self-administered versions and covered provider-administered versions of a drug are used to set Part B payment amounts.
- In general, statute also states that [CMS](#) shall, to the extent deemed appropriate, remove noncovered self-administered versions identified by OIG from payment amount calculations in subsequent quarters if the exclusions would result in lower payment amounts.
- In a [November 2023 issue brief](#) to CMS, OIG found that prefilled syringes of Xolair met the criteria for exclusion from Part B coverage.
- In response, in accordance with regulations, CMS removed the prefilled syringes from the Part B payment calculation for Xolair beginning April 1, 2024.
- Genentech, the manufacturer of Xolair, subsequently raised concerns to OIG and asserted that prefilled syringes meet Part B coverage requirements and thus should be included by CMS when setting payment.
- Determining whether certain versions of drugs meet Part B coverage requirements can be a challenging process given (1) the complex criteria set by CMS, (2) a lack of granularity in the billing codes used to identify versions being administered in professional settings, and (3) frequently changing prescribing patterns among health care providers.
- In light of this dynamic environment and Genentech's concerns, OIG obtained and analyzed additional and more recent data beyond what was examined for the earlier issue brief. This included fourth-quarter 2023 Part B claims data, Part C encounter data, and Part D prescription records for Xolair. We also accessed sales data reported to CMS by Genentech under statutory ASP requirements.

What OIG Concluded

According to the results of the additional analysis we performed using new and updated data, at least half of Xolair prefilled syringes paid under Medicare in the fourth quarter of 2023 were administered by health care professionals, meaning the syringes meet important criteria for Part B coverage.

As a result, OIG no longer identifies Xolair prefilled syringes as being self-administered drugs for which payment is not made under Part B.

We have provided CMS with supplemental information, which includes proprietary sales data, that supports our conclusion.

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