GAO Highlights

Highlights of GAO-16-12, a report to the Ranking Member, Committee on the Budget, House of Representatives

October 2015

MEDICARE PART B

Expenditures for New Drugs Concentrated among a Few Drugs, and Most Were Costly for Beneficiaries

Why GAO Did This Study

Questions have been raised about the effects of newly approved drugs on spending by the Medicare Part B program and its beneficiaries. Medicare Part B pays for drugs that are commonly physician-administered. In 2013, the Medicare program and its beneficiaries spent $20.9 billion on Part B drugs.

GAO was asked to review newly approved Part B drugs. This report (1) describes drugs newly approved by FDA and paid for by Medicare Part B and compares them to drugs newly approved and not paid for by Part B and (2) analyzes spending and utilization patterns for new Part B drugs.

To describe new Part B drugs, GAO obtained a list from FDA of the 250 drugs approved from 2006 through 2013, including chemically synthesized drugs and biologics. This list was limited to new drugs defined by FDA officials as innovative products that were significantly different from previously approved products. GAO cross-referenced the list with Medicare pricing files to identify 83 new Part B drugs. GAO analyzed the drugs' use of FDA's expedited programs and uses for which they were approved. GAO then compared these Part B drugs to new drugs not paid for under Part B. To analyze the spending and utilization patterns of new Part B drugs, GAO used claims files from CMS to calculate for each drug total Medicare Part B expenditures, spending per beneficiary, and number of unique beneficiaries who received it. GAO identified expenditures in 2013 for 75 of the 83 new Part B drugs.

View GAO-16-12. For more information, contact James Cosgrove at (202) 512-7114 or cosgrovej@gao.gov.

What GAO Found

New Medicare Part B drugs were more likely than new drugs not paid under Part B to be biologics, that is, products derived from living sources; be approved to treat a narrower range of conditions; and to have used a Food and Drug Administration (FDA) program to expedite their development and review. Sixty-one percent of the 83 new Part B drugs approved by FDA from 2006 through 2013 were biologics, compared to 16 percent of new non-Part B drugs. Biologics are more likely to be physician-administered and therefore paid for by Part B because they are usually injected or infused, their administration requires monitoring and individualized dosing, and they have unique storage requirements. Fifty-three percent of new Part B drugs were used to treat cancer or blood diseases, or were used in diagnostic imaging. New Part B drugs were more likely than new non-Part B drugs to have used an FDA expedited program or to have received an orphan designation, which applies to drugs that treat rare conditions and are received by a relatively small number of people.

Expenditures for new Part B drugs were concentrated among a small number of drugs and conditions, and most new Part B drugs were costly for beneficiaries. GAO identified expenditures in 2013 for 75 of the 83 new Part B drugs. Expenditures for these 75 drugs in 2013 were concentrated among 3 drugs—Lucentis, Eylea, and Prolia—which accounted for 53 percent of the $5.9 billion Medicare and its beneficiaries spent on new Part B drugs. The 20 highest expenditure drugs accounted for 92 percent of 2013 expenditures on new Part B drugs and for 26 percent of total expenditures for Part B drugs. Nearly two-thirds of new Part B drugs had expenditures per beneficiary in excess of $9,000 in 2013. Beneficiaries' share of the cost of these drugs ranged from $1,900 to $107,000 per drug in 2013, though many of these drugs received orphan designation and had low utilization. Total Part B drug expenditures grew at an average annual rate of 4.4 percent from 2007 through 2013, and this growth was driven primarily by new Part B drugs.

Five Highest Expenditure New Medicare Part B Drugs, 2013

Drug proprietary name	Approved use	Total expenditures (in millions)	Expenditures per beneficiary
Lucentis	Ophthalmologic	$1,369	$9,423
Eylea	Ophthalmologic	1,088	9,936
Prolia	Orthopedic	665	2,776
Treanda	Cancer	332	21,685
Lexiscan	Diagnostic Imaging	257	215

Source: GAO analysis of CMS and FDA data. I GAO-16-12

GAO received technical comments on a draft of this report from the Department of Health and Human Services, the agency that oversees FDA and the Centers for Medicare & Medicaid Services (CMS), and incorporated these comments as appropriate.