Policy & Practice

Payment for Part B Drugs

The federal government spent about $10 billion last year on drugs covered under Medicare Part B, with one rheumatoid arthritis treatment accounting for about 5% of the spending, according to the Centers for Medicare and Medicaid Services. Dr. Herb B. Kuhn, director of the Center for Medicare Management at CMS, presented information from a preliminary estimate of allowed charges under Part B to the House Ways and Means subcommittee on health in July. Infliximab (Remicade) made up about 5% of the total allowed charges under Medicare Part B in 2005, while intravenous immune globulin accounted for about 1.6%. About half the money paid last year for Part B drugs went to oncologists, 5% to urologists, and 4% to rheumatologists, according to Mr. Kuhn's written testimony.

Latest Vioxx Ruling

Merck has collected another win in its defense of Vioxx. A jury last month rejected the charge that the company was liable for a New Jersey woman's heart attack after nearly 3 years of taking Vioxx. Elaine Doherty of Lawrenceville said she took Vioxx daily from June 2001 until her heart attack in January 2004 at age 65, and then continued on the medication until it was withdrawn from the market in September 2004. But Merck attorneys countered that she had multiple risk factors for heart disease, such as high cholesterol, diabetes, high blood pressure, and obesity. "The company acted responsibly, the science was on our side, and the jury agreed," Jim Fitzpatrick of Hughes Hubbard and Reed, a member of the Merck defense team in the case, said in a statement. "Mrs. Doherty would have suffered a heart attack whether she was taking Vioxx or not." This is Merck's third courtroom victory. The company lost two other cases and was handed a split verdict in the case of two New Jersey plaintiffs in April. Next up: another Vioxx case ongoing in Los Angeles.

Translating Research to Prevention

Officials at the Department of Health and Human Services are spending about $15 million in an effort to bring new evidence-based approaches for managing chronic illnesses and preventing injuries to seniors. "Simply put, this collaboration will put the results of our research investments into the hands of older people so they can use it to improve the quality of their lives," HHS Secretary Mike Leavitt said in a statement. The money will be used to fund community-level programs in 12 states over 3 years, focusing on conditions such as arthritis, diabetes, and heart disease, as well as injury prevention. Thirty or more of these programs are expected to be operational within a year, according to HHS.

Postmarketing Study Failure

The Food and Drug Administration is doing a poor job of ensuring that pharmaceutical companies live up to postmarketing study commitments, according to a new report released by the Department of Health and Human Services' Office of Inspector General. The IG reviewed new drug applications from 1990 to 2004; 48% of those applications had at least one postmarketing study commitment. Drug makers are required to submit annual status reports. The IG found that 35% of the reports that should have been submitted in fiscal 2004 were missing or had no information on the study commitments. The IG noted that the FDA has limited enforcement power in this area, but suggested that the agency require more, and more relevant, information from drug makers. In response, FDA said it could not do that without additional regulations, but agreed that it needed to do more to improve its monitoring and to ensure that commitments are honored and that annual status reports are thorough.

—Mary Ellen Schneider

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