MedicalXpress

Expensive drug driving up Medicare expenditures without evidence of greater efficacy

September 11 2017

Medicare spent more than $1 billion over a five-year period on a high-priced drug that has not been proven more effective for a collection of inflammatory conditions than much less expensive corticosteroids, research by the OHSU/OSU College of Pharmacy shows.

The analysis also indicates that a comparatively small group of "frequent prescribers" combine to write prescriptions that lead to the bulk of Medicare's expenditures on the drug, repository adrenocorticotropin, or ACTH.

In 2015 alone, Medicare spending topped $500 million on the drug, the cost of which has soared to $36,000 per course of therapy.

Known by the trade name H.P. Acthar Gel, often shortened to just Acthar, the drug's primary use is to treat rare epileptic spasms in children under age 2.

"The drug has an interesting back story," said Dan Hartung, lead author on a research letter that was published today in *JAMA Internal Medicine*. "It's a fairly old drug, first approved in 1952, prior to many of the FDA rules about clinical efficacy. The bar for what constitutes approved indications was much different then, much lower; it has many indications that came before the current rules were set in stone in the 1960s."

The drug, classified as a "biologic," was initially approved for a broad range of corticosteroid-responsive inflammatory conditions.

"It's a hormone produced in the human body that signals the release of steroids," Hartung said. "It does the same job as low-cost corticosteroids. And it really wasn't much on anyone's radar until 2007."

Questcor Pharmaceuticals purchased the rights to the largely forgotten Acthar in 2001 for $100,000 and began steadily raising Acthar's price. In 2007 Questcor increased the price of the drug, which once sold for $40 for a vial, or course of therapy, from $1,650 to $23,000 overnight.

Questcor, acquired by Mallinckrodt Pharmaceuticals in 2017, markets the drug aggressively for relatively common conditions such as rheumatoid arthritis, multiple sclerosis and nephrotic syndrome, Hartung said. The Food and Drug Administration approved Acthar for those types of conditions decades ago when requirements were less strict; no clinical trials were required.

"There are a variety of FDA-approved indications that lack a lot of evidence that Acthar is even effective, let alone better than inexpensive corticosteroids," Hartung said. "And what allows for this kind of pricing is that it's a fairly complex molecule and no competitors can exactly duplicate it; they have a monopoly on this particular molecule."

In 2015, Acthar generated gross revenue of about $1 billion - more than half of which came from Medicare, and much of the rest coming from Medicaid, Hartung said, meaning public expenditures likely accounted for almost all of the sales.

Hartung and the other collaborators found Medicare spending on the drug increased tenfold and totaled $1.3 billion from 2011 to 2015.

In 2014, a total of 1,621 prescribers were responsible for $391.2 million in Acthar spending; among those, 203 frequent prescribers - 94 rheumatologists, 55 neurologists and 54 nephrologists, each with more than 10 prescriptions - accounted for $165 million of the total.

"And in general these physicians are prescribing about the same number of other drugs compared to their peer specialty groups, so we suspect they are not treating more severely ill patients," Hartung said. "Mallinckrodt is really aggressively marketing in ways that possibly subject prescribers to conflicts of interest. From the payer side, there's really little that little justifies this drug and its exorbitant cost over much cheaper alternatives. If Medicare were to take a firm stand on reimbursements, this wouldn't be happening."

More information: *JAMA Internal Medicine* (2017). DOI: 10.11001/jamainternmed.2017.3631

Provided by Oregon State University