

Slowing Acthar sales are a warning about rising patient costs



[Jonathan Gardner](#)



Acthar's high price tag has led to slowing sales, but it is patients, not payers, who are leading the backlash.

Acthar, the old drug with the exploding pricetag, may have met its match not in stubborn payers but in patients who simply cannot afford it. Mallinckrodt reported a quarterly drop in the sales of its flagship drug thanks to an increasing number of unfilled prescriptions.

While executives were vague about the forces at work, the speciality pharma is facing increasing numbers of US patients with greater exposure to drug costs because of the growth of high-deductible health plans. That a well-established agent with good formulary access is having trouble ought to be a warning sign to biopharmas developing their pricing strategies for new agents.

Surprise!

With a pricetag of nearly \$4,000 per vial – the minimum recommended daily dose for treating multiple sclerosis exacerbations – H. P. Acthar Gel is one of the priciest drugs in biopharma and has been the subject of lawsuits and government scrutiny. Those factors have not proven to be a barrier to achieving sales that have grown above the blockbuster threshold – until the past three months.

In reporting third-quarter earnings, Mallinckrodt executives said Acthar sales fell to \$308.7m from \$319.4m in the three months ended June 30, and added that they expect continued shrinkage in the fourth quarter. The news caused Mallinckrodt shares to fall 36% on Tuesday and prompted analyst downgrades.

Without specifying the reasons, executives said the number of unfilled prescriptions for Acthar had risen, particularly among returning patients who had previously undergone a course of therapy. Elusive solutions – payer and patient “engagement” strategies were cited – cannot lend much confidence that there will be a quick return to sales growth.

“We do see prescriptions approved. And because of the time [it takes] for the patient to get access to it, sometimes those patients walk away from those prescriptions,” said Hugh O’Neill, president of the Acthar business. “And our challenge, really, is to ensure that that timeline is much more manageable.”

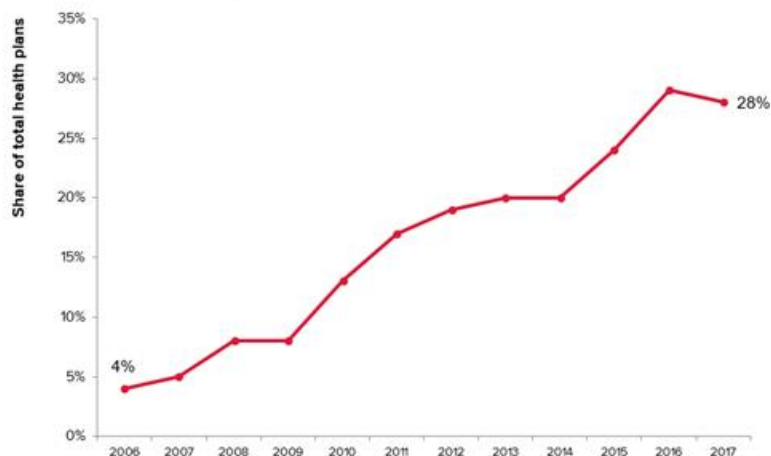
You pay more

Surely the potential for patients to be exposed to thousands of dollars of costs is also a factor. A course of

treatment in MS is at least one vial a day for two to three weeks – amounting to a minimum of around \$50,000 for the whole course – although Acthar can be tapered off.

Meanwhile, the number of Americans who are on high-deductible health care plans is growing quickly. The Kaiser Family Foundation/Health Research & Educational Trust annual survey of employer benefits has shown that such plans have grown from 4% of those receiving employer coverage in 2006 to 28% in 2017.

High-deductible US employee health plans



Source: Kaiser/HRET 2017 Employer Health Benefits Survey

The average annual deductible for a family in a high-deductible plan is \$4,527, and coinsurance for a tier-four drug, which Acthar is in many cases, averages 66%, according to the Kaiser/HRET survey.

In higher-deductible “bronze” plans purchased through the state marketplaces under the Affordable Care Act, total out of pocket costs top out at \$13,810 for family coverage – in 2016, 2.4 million of the 11.1 million people who gained coverage through the marketplaces chose bronze plans.

As further evidence of Acthar’s cost-sharing burden, the average Medicare beneficiary treated with the injection paid \$8,007 out of pocket in 2015, making it the eighth most expensive drug from the patient’s perspective. It had the highest total per-user spending in the programme for the elderly and disabled.

Mallinckrodt has a patient assistance programme that in some cases will cover copays of up to \$25,000, and also offers financial assistance to uninsured, underinsured and low-income patients. Some of these programmes have run out of money and have forced companies to give away drugs – this bedevilled Pfizer and Johnson & Johnson earlier this year in prostate cancer, and hit Jazz’s Xyrem just this quarter ([Vantage point – Are charities the best way to pay for costly drugs?](#), May 17, 2017).

If trends in healthcare benefit design are sustained, growing numbers of Acthar patients will be expected to pay a bigger share of the bill – in which case, Mallickrodt might need to shovel more money into the patient assistance programmes to sustain sales growth.

Mallickrodt will not be alone in facing this issue. Prompting reasonable people to wonder whether the problem is the high price in the first place, rather than any failure in the programmes designed to prop up sales growth.

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