Gilead Plays Hardball With Hep C Patient Assistance

In its latest attempt to wring profits from its hepatitis C medications, **Gilead Sciences Inc.** recently began limiting enrollment in its patient assistance program, *Support Path*. The move came after some payors, despite receiving discounts earlier this year, continue to restrict patient access to *Sovaldi* and *Harvoni*, which have high cure rates, but helped fuel a national debate over drug costs.

As a result, Gilead has been picking up the tab for more people than it would like who are seeking patient assistance, according to a July 1 letter sent to patient groups and community health providers. Gilead has not said how many people are enrolled in its Support Path assistance program, how many patients may be affected by the change or provide actions taken by specific payors.

The move has added another level of controversy surrounding the Gilead drugs, which sparked the national debate about the cost of prescription medicines. Before taking into account any discounts or rebates, Sovaldi costs $84,000 for a 12-week regimen and Harvoni costs anywhere from $63,000 to $94,500, depending upon the duration of the regimen.

Clearly, Gilead sees this as a way of applying additional pressure on payors to expand their coverage criteria. And by limiting enrollment, Gilead is counting on patients to complain to payors about a lack of access, although whether patients will do so is unclear. But its move is likely to raise questions about the extent to which drugmakers manipulate their patient assistance programs.

This adds to the concern about the real value of assistance programs that emanate from pharma, Randy Vogenberg, a partner at Access Market Intelligence, a consulting firm that specializes in managed care, told the *Pharmalot* blog, which first reported the Gilead move.

Reaction among patient groups was harsh and swift. Gilead and its backers make an important point that its drugs offer a more affordable alternative – in the long run – than the cost of liver transplants and hospitalizations. But the price tags for its drugs have literally caused sticker shock among payors – public and private – that worry the medicines are quickly overwhelming their budgets.

"In essence, Gilead is holding hepatitis C patients hostage as a negotiating strategy with health insurers for drugs that they ridiculously overpriced in the first place," says Michael Weinstein, president of the AIDS Healthcare Foundation, which runs numerous clinics around the country. "So whatever discounts Gilead offered are most likely rendered moot."

What exactly prompted Gilead to take this step? Last winter, **AbbVie Inc.** won FDA approval to sell its own hepatitis C treatment *Viekira Pak* and quickly struck deals with several payors offering discounts. Until then, Gilead dominated the field with Sovaldi, but was forced to respond by offering discounts averaging 46% on both Sovaldi and the newer Harvoni that had only recently been approved.

But unlike AbbVie, Gilead did not require payors to provide coverage for Sovaldi and Harvoni on a widespread basis, according to Roger Longman, chief executive of RealEndpoints, an analytics firm that tracks reimbursement issues. This meant that payors are free to place restrictions on the Gilead drugs while simultaneously absorbing the discounts. In doing so, payors quickly lowered their costs.

"Through its patient assistance programs, Gilead has taken on the cost of at least some of the less acutely ill patients," says Longman. "Now, though, Gilead, which won in part with a deal that allowed restricted access, seems to be trying to reverse course and transfer some of its costs back onto the payors and pry open the access to Harvoni."

But Gilead is irritated. Until AbbVie began selling a rival medicine, the drugmaker was able to fend off payor criticism as well as requests for price breaks. Over the past few

months, some payors did provide coverage for its drugs without placing restrictions on patients. But other payors have continued to maintain restrictions anyway, according to the July 1 Gilead letter.

"Our [program] criteria enabled continued restrictions by some payors by providing a generous route for them to deny access and refer patients they have chosen not to cover," wrote Coy Stout, Gilead's VP of managed markets. "While we have approved many of these patients in the past, we feel it is necessary to establish more specific guidelines for patient eligibility. Our [program] was designed to help uninsured patients with the most need, and changes are necessary to remain true to that mission. We believe these changes also will help increase access among those payors who continue to restrict access."

So how exactly is the patient assistance program changing? Gilead is limiting enrollment in its program if payors restrict access for patients with less severe hepatitis C or if a plan prefers or offers exclusive coverage to another drug on its formulary, or list of preferred medicines. An obvious example would be the AbbVie's Viekira Pak.

Gilead will also limit enrollment if plans restrict access to the medicines for a specific length of time or deny subsequent treatment after a patient has failed therapy, or if plans require step therapy, which involves using one treatment before trying another. And enrollment will be limited if plans restrict access to the drugs based on alcohol testing, among other clinical criteria.

The big question going forward is how payors are likely to react. Will they really respond as Gilead hopes or is Gilead displaying wishful thinking? After all, the company may be making a big bet that patients will lash out at their insurer or pharmacy benefits manager instead of the drugmaker, even though Gilead is already seen – by some – in a negative light.

Managed care sources tell us the drugmaker may be reaching. They say that many payors are likely to keep restrictions in place for several reasons. One big one is that no managed care company wants to find itself in the position of offering the most attractive coverage and then attract patients who have been denied by Gilead.

These sources say a fair degree of bitterness toward the Gilead pricing policy remains. As far as some payors are concerned, the drugmaker brought this on itself by setting the pricing for Sovaldi at high levels and then refusing to offer any kind of price break.

"Placing the patient in the middle is a losing strategy and is more likely to generate congressional interest in this issue than to get payors to actually change policies," says one source.

Then again, AbbVie is not having an easy time of it, according to Sector & Soverign Research analyst Richard Evans. Its market share for its Viekira Pak treatment is "stagnating, volumes are easing and soon likely to decline and Merck, a major entrant who will presumably compete on price, is due by the first quarter of 2016," he wrote in an investor note.

Viekira Pak has only a 9% share of total prescriptions and an 11% share of new prescriptions – well below the 20% lower range of his original estimate. In other words, Gilead continues to dominate the market, suggesting a steady stream of patents will be given prescriptions. Whether they will encounter restrictions from payors – or Gilead – is the big question. IV

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