

ViewPoints: Patients with cystic fibrosis not alone in grappling with payer copay adjustment programmes

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PUBLISHED: MARCH 26, 2023

Like so many others among the 40,000 Americans living with cystic fibrosis (CF), Molly and Emily Bonnell were waiting for a cure. While the advent of Vertex Pharmaceuticals' CF transmembrane conductance regulator (CFTR) modulators in 2012 represented a major breakthrough, Kalydeco (ivacaftor) and its successors — [Orkambi \(ivacaftor and lumacaftor\)](#) and [Symdeko \(tezacaftor/ivacaftor and ivacaftor\)](#), FDA approved in 2015 and 2018, respectively — offered relatively [modest efficacy](#) and were not applicable to as large a population as [Trikafta \(elexacaftor/tezacaftor/ivacaftor\)](#).

"When Trikafta came out, I literally was sobbing because I thought finally my girls are going to live," Molly and Emily's mother Laura Bonnell, founder and president of The Bonnell Foundation, said. "It meant everything."

With a price tag of over \$300,000 per year, however, it could cost everything to an average patient. Thankfully for those who desperately needed the triplet therapy, Vertex offered copay assistance through its Guidance & Patient Support (GPS) programme, which provided up to \$100,000 annually per eligible patient with commercial insurance.

Things changed in January, however, when Vertex did a major scale-back of its copay assistance programme, providing a maximum of \$20,000 per year.

"The main thing ... that impacted every person with cystic fibrosis in this decision is the anxiety and the stress of trying to understand this, understanding if and how they would be impacted, and then making a plan if they were impacted of what that meant," said Mary Dwight, Policy and Advocacy Officer for the Cystic Fibrosis Foundation (CFF).

At face value, the situation looks cut and dry — Vertex is the "bad guy," fitting neatly into the archetype of pharma company as greedy villain. But it's not that simple.

Vertex cut its copay assistance program in response to payer copay adjustment programmes, which include copay accumulator and maximiser programmes, Nina Devlin, Senior Vice President and Chief Communications Officer at Vertex, told *FirstWord*. Essentially, these programmes take assistance funds from drug manufacturers but do not apply them toward patients' annual deductibles or out-of-pocket maximums.

According to Dwight, people with CF often gravitate toward high-deductible insurance plans because they offer coverage for the specialized care needed in CF. These patients would leverage copay assistance funds to be able to afford such plans.

"These accumulators and maximisers are really upturning the apple cart on them and disrupting that very careful financial planning," she said.

Historically, health plans would count copay assistance monies from drugmakers toward patients' deductibles and out-of-pocket maximums, with the patient becoming responsible for any remaining costs when the assistance ran out. In 2018, however, things changed.

What is worse, Dwight said, is that the already difficult-to-understand accumulator and maximiser programmes are not readily disclosed by insurance companies, even when pointedly asked about them. They can also go by different names, such as out-of-pocket protection programmes or variable copay programmes. Therefore, the

timing of Vertex announcing the cutbacks in October, when many patients were already in the midst of their insurers' open enrollment periods, was less than ideal, Dwight said.

"[The CFF has] a programme called Compass, which has a team of case managers who are there to help people with cystic fibrosis navigate their health insurance needs, understand their plan options. They do this full-time professionally every day, and those case managers have a very difficult time often understanding and unearthing if a health insurance plan even has one of these accumulator or maximizer programmes," she said.

In her role at the CFF, Dwight has been privy to the ways in which patients have been affected by Vertex's cuts and payers' copay adjustment programmes. Through Compass, the organisation worked to help one parent of a child with CF who was down to a 10-day supply of Trikafta before they would have to pay \$750 for their January supply. With income too high to qualify for third-party assistance programmes, it was a challenge to secure help with the expense, she explained.

Another patient who had an insurance plan with an accumulator went without medication because of a \$13,000-per-month copay, among other factors, and suffered a decline in health as a result, according to Dwight.

Such situations are inarguably heart-wrenching, but according to Vertex, they are also unnecessary.

"... Vertex has been working individually with all patients enrolled in our copay assistance program since September of last year to create awareness of these predatory insurance practices, support patients in making any changes to their insurance programs ahead of open enrollment, and help ensure continued affordable access to our medicines," Devlin told *FirstWord*. "We already have confirmed plans for continued access to CFTR modulators for more than 99% of patients impacted by the program changes, and 96% of impacted patients have already scheduled and/or received their first refill of 2023."

Seeking to spread the word to the CF community, Laura Bonnell hosted representatives from Vertex on [The Bonnell Foundation's Podcast](#) in January. Explaining the rise in prevalence of copay adjustment programmes, Jenna Harrington, head of Vertex's GPS programme, said as of 2020, 68% and 58% of people with commercial insurance had accumulators and maximisers, respectively, as part of their health benefit design.

"The acceleration of these insurance trends have forced Vertex to make these changes for the 2023 calendar year," Harrington said, adding, "We're committed to ensuring that nobody discontinues their Vertex medicine due to these programme changes."

Both Harrington and Devlin pointed out that Vertex's new \$20,000 cap covers the maximum out-of-pocket costs for which an individual (\$9,100) or family (\$18,200) may be responsible in 2023 for essential health benefits under the Affordable Care Act.

The GPS programme does not stop at copay assistance, Harrington explained, saying that it also provides patients with other resources and aid to ensure that everyone prescribed their medications has access to them.

According to Bonnell, especially in light of the panic-inducing notices sent out by the CFF, she was vigilant following the changes to Vertex's programme to look out for patients who were falling through the cracks.

"I haven't heard of anyone," she said. "And believe me, in these moms' CF groups or on Facebook, if someone lost their Trikafta, it would've blown up everywhere. We would've known about it."

Dwight acknowledged that the CFF has been reaching out to Vertex about cases in which patients are going without their drugs and that the company is providing help.

“With that said, it shouldn’t take a large, national organisation to navigate an individual patient’s access,” she said. “That is not easy for somebody with CF.”

Although Bonnell agreed, she said it’s nothing new.

“I go through hoops every single day for drugs. Are you kidding me? My girls both have cystic fibrosis. Molly is 28 and Emily is 25. There has never been a time where there hasn’t been a situation with either prior authorisation or copay accumulator or step therapy, you name it.”

While Bonnell takes issue with the CFF’s approach to the problem, her organisation aligns with it and Vertex on one central point — that insurance copay adjustment programmes must go.

According to Vertex, 16 states and Puerto Rico have banned these types of programmes, with 15 other states considering such bans. In addition, a House bill called HR 5801, the HELP Copays Act, has been introduced at the federal level and would require insurance companies to apply drugmakers’ patient assistance monies to patient deductibles and out-of-pocket maximums, with the [All Copays Count Coalition](#) being a driving force behind it.

The CFF has played a central role in getting this legislation passed, and the Bonnell Foundation is working to get Michigan on board with states that have enacted bans. In addition, efforts are underway for a Rare Disease Advisory Council to amplify the voice of the CF community in the state.

As in many relationships, those among the three groups at play here could be described in two words: it’s complicated. Bonnell was quick to disclose that she has received a CF Impact grant from the CFF and that Vertex is a sponsor of her foundation’s Night of Hope Celebration. The CFF has contributed approximately \$200 million toward the development of Vertex’s CFTR modulators, for which it received \$3.3 billion when it sold its royalties to Royalty Pharma in 2014.

Inner workings of the community aside, it is generally united in its overall goals.

“These therapies are critical. They are remarkable treatments that are really changing the face of [CF] as we know it, and it’s wonderful to see the changes that they ... are bringing about for people with CF,” Dwight asserted. “That said, none of these drugs matter if somebody cannot ... have them. The financial ramifications are significant and it is particularly harmful to people with CF if they cannot access these therapies, so there has to be something that puts the patient need first.”

All parties agreed that the issue is larger than the CF community. Amit Sachdev, Executive Vice President and Chief Patient Officer at Vertex, said during The Bonnell Foundation Podcast that insurance companies often apply copay accumulators and maximisers to specialty medications for which manufacturers offer copay assistance, making those with serious and chronic illnesses the most often affected.

The American Society of Clinical Oncology and the Crohn’s & Colitis Foundation are among multiple organisations representing patient communities impacted by these payer programs.

“We are not the only ones that are also making these changes,” Sachdev said of Vertex during the podcast. “In fact, this is a trend. As we see the growth of these maximiser and accumulator programmes across the industry, we’re seeing [companies] have to make these changes to address what’s happening.”

Dwight described it as a game of “whack-a-mole” between pharmas and insurers, with the patient stuck in the middle.

“We need to shift the narrative here and think about how to ensure this high-quality, game-changing therapy for patients, and how do we make sure it is affordable for them instead of playing games and [creating] different programme designs that really harm people who are least able to make these decisions and are at the mercy of two large industries,” she said.

Bonnell contended that vilifying either party is not the answer.

“As I always say, no one's the bad guy,” she said. “We all need to work together. This pointing fingers thing is not my way, that's not how I work. We need to have a solution.”