Fat Busting: But at What Price?

November 12, 2010 By Tim Horn

Since the late 1990s, I've been working closely with a great group of activists--Matt Sharp, Jeff Taylor, Nelson Vergel, Jeff Berry, Jules Levin, Lynda Dee, the late Marty Delaney and a handful of others--on a huge advocacy initiative: the approval of a safe and effective treatment for the excessive buildup of abdominal fat being experienced by HIV-positive folks with lipodystrophy. Well, after failing to do this with one drug--EMD Serono's Serostim (recombinant human growth hormone)--we've finally succeeded with another: Theratechnologies' Egrifta (tesamorelin).

The drug, which acts on pituitary cells in the brain to stimulate growth hormone production, works relatively well. According to Phase III studies, it reduces the amount of deep belly fat (visceral adipose tissue, or VAT) by 15 to 17 percent. While this won't magically translate into a return to trim physiques for many with lipodystrophy, it will certainly allow for a tightening of the belt by a notch or two. And, as we argued before an FDA review committee in May, the benefits or Egrifta treatment outweigh its risks--certainly much more so than with an earlier contender, Serostim, which presented a significant risk of glucose impairment and diabetes.

After several years of (sometimes heated) meetings, conference calls and letters with Theratechnologies. EMD Serono and the FDA, we have an approval: the drug was given the green light by the agency on Wednesday, November 10. It has taken more than 12 years of drug research, development and advocacy--it was first suggested that growth hormone might reduce VAT in people with lipodystrophy at the 12th International AIDS Conference in Geneva in 1998--but, yes, we finally have a treatment for this disabling condition.

Prescriptions for Egrifta will start being filled in January 2011, possibly sooner. And it's EMD Serono that will be marketing and selling the drug in the United States, not Theratechnologies, after both companies entered into licensing agreement in 2008.

To streamline the prescription process--and to prevent drug counterfeiting and misuse of the drug by those who don't have HIV-associated lipodystrophy--EMD Serono is requiring all prescriptions be processed by a contracted group (The Axis Center: 877-714-2947), which will do a lot of the wrangling with insurers companies, and fulfilled by select mail-order pharmacies. In fact, The Axis Center is already standing by to receive prescriptions and get the ball rolling for people living with HIV and lipodystrophy.

But a central question remains: Will the drug be priced so that it's accessible to everyone who needs it? I strongly suspect that Egrifta won't be cheap. However, will the final price tag be so high that insurers ultimately balk at paying for it, despite the best intentions of The Axis Center and pre-authorization letters written by health care providers?

True, HIV treatment has never been considered inexpensive--ARV regimens are in the ballpark of

$20,000 annually--but Egrifta has its own set of unique cost challenges. Whereas ARV therapy has clearly been shown to keep people alive longer and healthier, Egrifta has not. If I was an insurer, operating in this economy while also being instructed to keep my doors open to everyone in need of insurance, all the while facing pressure to keep my premiums as low as possible, I'd probably think twice about paying thousands of dollars for a drug that hasn't been proven to reduce the risk of serious health problems and improve survival.

There's a lot of hope surrounding Egrifta. Studies have demonstrated that excess VAT is an independent risk factor for cardiovascular disease--no stranger to people living with HIV--and can contribute greatly to things like respiratory problems, difficulty sleeping and a long list of nutritional challenges. The problem is, Egrifta, while we know it reduces VAT and can helps some people with their self-image, hasn't been shown to improve any of these more serious health problems.

When it came time to advocate for Egrifta's approval, one of things I asked for, in a letter written on behalf of the AIDS Treatment Activist Coalition's Drug Development Committee, was a post-approval clinical trial exploring the potential benefits of Egrifta on the risk of cardiovascular complications like heart attacks, strokes or atherosclerosis. The problem is, a massive study--in both size and length--would be needed to address this issue and it became clear that neither Theratechnologies nor EMD Serono had the capital or resources to fulfill this request, which not only would have justified an (anticipated) high price tag for the drug, but also better inform people living with HIV and their health care providers about the need to treat lipodystrophy.

My ultimate fear is that we will have an approved lipodystrophy drug sitting on pharmacy shelves, collecting dust, because its cost exceeds what the market will bear. While EMD Serono has mapped programs to help defray out-of-pocket costs and for those who don't have adequate insurance, the company is still going to need to sell Egrifta--and plenty of it--in order to keep itself in business.

I, for one, am glad Egrifta is finally here. Cardiovascular risk issue aside, lipodystrophy is no trivial matter for the thousands of people living with HIV in the U.S. who suffer from it. It is disfiguring. It is disabling. It is stigmatizing. It is physically uncomfortable and painful. This drug is needed and very much wanted by many people still dealing with the untoward effects of lipodystrophy, despite dieting, exercising, switching offending meds--pretty much every approach that's been suggested to work.

We need to make sure that insurers understand the seriousness of lipodystrophy and fully appreciate the need for treatment--health care providers, lipodystrophy experts and people dealing with this syndrome will ultimately need to make their voices heard in this regard. Well, the same goes for EMD Serono and Theratechnologies: fair pricing isn't just good for people living with HIV and lipodystrophy, it is good for business as well.

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