HIV Lipo Drug Egrifta Now Available; Financial Assistance Programs Open

January 27, 2011

Egrifta (tesamorelin), the lipodystrophy treatment approved by the U.S. Food and Drug Administration (FDA) late last year, is now officially available to people living with HIV and their health care providers, according to announcements from EMD Serono. To expedite prescriptions and reimbursement, the company also described various services—including patient assistance and co-pay programs—now open to HIV-positive patients who need the drug.

Egrifta was approved by the U.S. Food and Drug Administration (FDA) on November 10, 2010. The drug, requiring once-daily injections, was approved to reduce visceral adipose tissue (VAT)— deep belly fat surrounding the liver, stomach and other abdominal organs—in people living with HIV and experiencing lipodystrophy, a side effect of antiretroviral (ARV) therapy.

Egrifta was developed by Theratechnologies, a company based in Montreal, but is to be sold in the U.S. by Rockland, Massachusetts-based EMD Serono. It is a synthetic growth hormone release factor that acts on pituitary cells in the brain to stimulate growth hormone production, which has been shown to reduce VAT in people with lipodystrophy.

The company tested the drug in two Phase III clinical trials involving 816 HIV-positive adult men and women with lipodystrophy and excess abdominal fat. Of these, 543 patients received Egrifta during a 26-week, placebo-controlled period. In both studies, patients treated with Egrifta experienced greater reductions in VAT—about 15 to 17 percent—as measured by CT scan, compared with patients receiving placebo. Some patients reported improvements in their self-image.

The wholesale acquisition cost (WAP) of Egrifta—the pre-retail price charged by EMD Serono—is $23,900 annually, or $1,964 for a 30-day supply.

Prescriptions for Egrifta will need to be processed through the AXIS Center, a centralized group of prescription specialists contracted by EMD Serono. In addition to prescription processing, the AXIS Center offers in-home or in-office injection training to every new patient through a national network of injection trainers, along with educational kits and 24-hour support. The AXIS Center will also facilitate important financial assistance options, including EMD Serono's patient assistance and co-pay assistance programs.

For commercially insured patients with a prescription drug benefit that covers Egrifta, the co-pay assistance program covers up to $2,400 of patients' out-of-pocket cost over a 12-month period.

This can offset up to $200 of their co-pay or coinsurance for up to 12 uses before December 31, 2012, but not more than once every 21 days.

Patients may not use the co-pay assistance program if they receive drug benefits from state or federal health care initiatives (including Medicare or Medicaid). This program is not valid in the Commonwealth of Massachusetts.

EMD Serono's patient assistance program (PAP) provides free Egrifta for eligible patients who are uninsured or underinsured. Patients must meet other eligibility requirements, including a household income that does not exceed 600 percent of the Federal Poverty Level (FPL), which for one person is currently $10,830. Patients must also have a diagnosis of lipodystrophy and be a resident of the United States.

The PAP, which is being coordinated by the AXIS Center, will provide free Egrifta for one year, and patients will need to reapply if they want to continue receiving the drug.

To start the process, licensed health care providers must fax a Statement of Medical Necessity (SMN)—a detailed prescription—and completed patient authorization form to the AXIS Center at 866-823-9554. SMNs will be provided by the EMD Serono sales team or can be requested by calling the AXIS Center at 877-714-AXIS (2947).

© 2026 Smart + Strong All Rights Reserved.

http://beta.docker.poz.com/article/hiv-egrifta-tesamorelin-lipodystrophy-19804-4221