

FDA OKs Glaxo's inhaler, first one to combine three medicines

September 19 2017, by Linda A. Johnson



This photo provided by GlaxoSmithKline PLC shows the company's Trelegy Ellipta inhaler. Late Monday, Sept. 18, 2017, the Food and Drug Administration approved the product, which is the first inhaler that combines three medicines to

ease breathing in patients with emphysema or chronic bronchitis.
(GlaxoSmithKline PLC via AP)

The Food and Drug Administration has approved the first inhaler combining three medicines to ease breathing in patients with emphysema or chronic bronchitis.

The FDA late Monday approved sales of Trelegy Ellipta, developed jointly by GlaxoSmithKline PLC and Innoviva Inc. It contains three widely used types of medicine to prevent—rather than treat—flare-ups of the life-threatening breathing disorders.

Once daily, patients inhale the medicines through their mouth to open breathing passages and reduce inflammation that can make breathing difficult in people with chronic obstructive pulmonary disease, which includes emphysema and bronchitis.

The disorder worsens over time, requiring patients to add more medicines to prevent flare-ups that can land them in the emergency department—or worse. Many patients use two inhaler types plus other medicines.

An estimated 384 million people worldwide have chronic obstructive pulmonary disease, or COPD, which can make everyday activities such as walking up stairs difficult. It's usually caused by cigarette smoking or exposure to secondhand smoke, chemical fumes or excess dust in the environment.

U.K.-based GlaxoSmithKline is launching Trelegy with a list price of \$530 per month. That's \$146 a month cheaper than the combined prices of two GlaxoSmithKline inhalers that together contain the same three

medicines: Incruse Ellipta and Breo Ellipta.

The medicines are an inflammation-reducing steroid called fluticasone furoate, and umeclidinium and vilanterol, drugs that widen narrowed airways and relax their muscles. Common side effects include headaches and other pain, diarrhea, nausea, stomach cramps and cough. Vilanterol and similar drugs carry an increased risk of asthma-related death. Trelegy also can worsen glaucoma and certain infections.

Insurers and prescription benefit managers likely will win significant discounts off the \$530 retail price in exchange for covering Trelegy. However, those payers may pass all or much of the savings on to employers and other clients, rather than reducing patients' out-of-pocket costs.

The product's approval, the fourth for a Glaxo inhaler since 2013, should help the company rebuild its flagship respiratory medicine business. It was long a leader in the category, thanks to its widely used allergy drug Flonase and its Flovent and Advair inhalers. Flonase has generic competition now, and the drugmaker now sells a nonprescription version.

Flovent, launched in 1994, has seen sales cut by newer inhalers, including Glaxo's products. Advair, which provided about one-third of Glaxo's revenue for many years, also has seen increasing competition in recent years. Advair sales are down by more than half since their peak of \$8.15 billion in 2011 and are expected to decline to just \$1.43 billion by 2020.

The Incruse and Breo inhalers, both launched since 2014, and the Anoro inhaler launched in 2013 have barely made up for one-sixth of that lost revenue.

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