End product prizes

James Love

Current “pull” incentive

Grant a temporary monopoly

Monopolist charges high prices

Access is limited and unfair

Senator Sanders proposal for delinkage of R&D costs from product prices for HIV ARV market

Prize Fund for HIV/AIDS

Context:

Worldwide, 36.7 million person living with HIV. Global sales of ARV drugs were $24.23 billion in 2015.

In the US. In 2013, CDC estimates 1.242 million people living with HIV. 39,513 new cases diagnosed in 2015*. Total sales of antiretroviral drugs were $13.43 billion in 2015, an increase of 13.9 percent from 2014.

The NIH spends about $3 billion per year on research for HIV/AIDs.

US GNI: 7.835 Trillion in 2015, 22.1% of world share, 35.2% of OECD share.

**CDC estimates that 1 in 8 persons living with HIV in the United States are not diagnosed.*

Prize Fund for HIV/AIDS

More context

- In the past 29 years, the FDA has approved 29 new molecular entity (NME) ARV drugs to treat HIV.
- The US government can acquire generic versions of the patented drugs from FDA approved suppliers for less than 1 percent of the AWP in the United States.

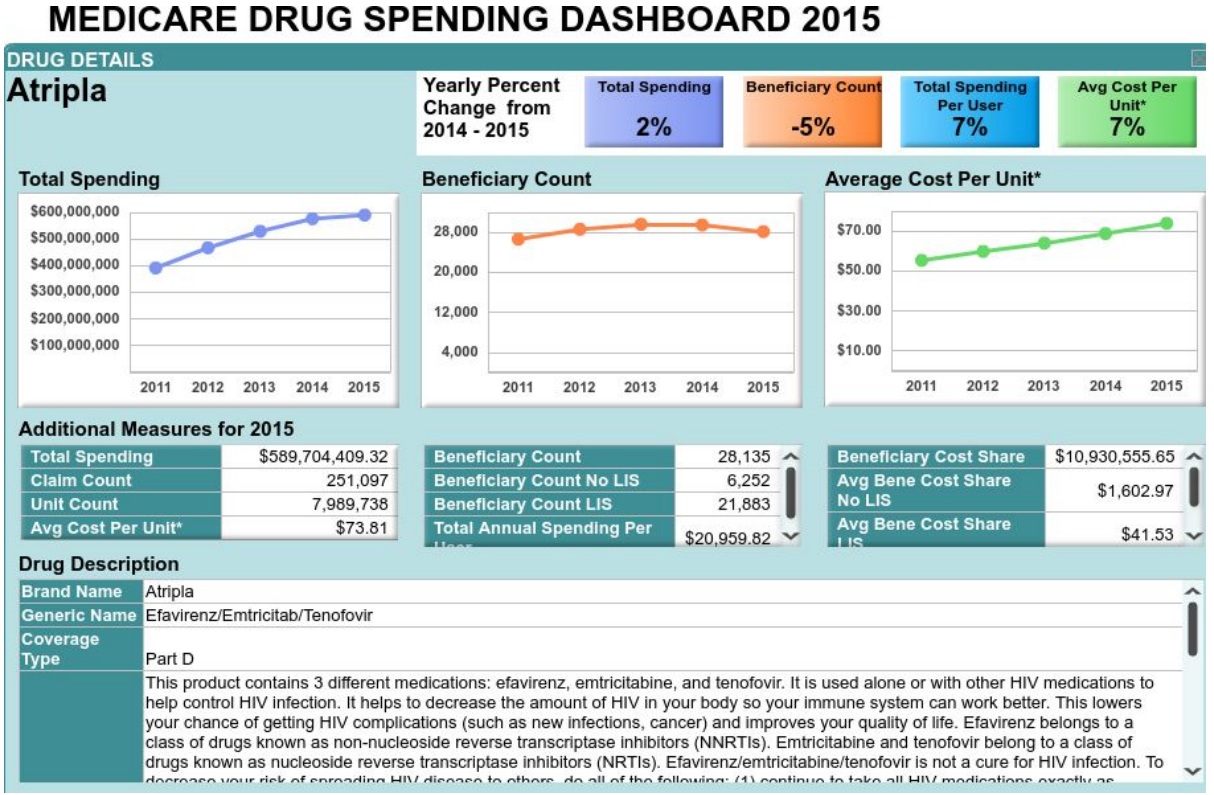
Atripla

2015 Medicare outlays were $590 million.

Spending be user was $20,960

Current GoodRx prices roughly $30,000 per year.

Best generic price outside of the United States: $100.



Motivation for end product prizes

Improve efficacy of incentives

Expand access

Save money

The Secret of Change Is to Focus All of Your Energy, Not on Fighting the Old, But on Building the New

S.626/113th Congress: Prize Fund for HIV/AIDS Act

A BILL

To de-link research and development incentives from drug prices for new medicines to treat HIV/AIDS and to stimulate greater sharing of scientific knowledge.

SEC. 2. FINDINGS.

(8) The United States Federal Government is the largest funder of treatments for HIV/AIDS in the developing world.

(9) The development of new medicines and vaccines for HIV/AIDS is a national priority.

(10) Market exclusivity for new products is an expensive, inefficient, and unfair mechanism to reward investments in new products, and has created hardships for persons with HIV/AIDS and businesses that employ persons with HIV/AIDS.

(11) By de-linking research and development incentives from product prices, and by eliminating legal monopolies to sell new medicines for the treatment of HIV/AIDS, it is possible to induce investments that are medically more important, procure products at low prices from competitive suppliers, and introduce more efficient incentives for research and development.

S.626, 113th Congress

SEC. 3. PURPOSE.

It is the purpose of this Act to provide sustainable financing of incentives to encourage investments in research and development of new medicines for HIV/AIDS and to share knowledge, data, materials, and technology, through the establishment of a Prize Fund for HIV/AIDS, while enhancing access to such medicines by eliminating legal monopolies on the manufacture, distribution, and sale of such medicines.

Funding of the HIV/Prize Fund

How much?

> Funding equal to 2 percent of US GDP. In 2015, US GDP was $18,036.6 billion, and the prize fund would have received 3.6 billion.

Where does the money come from?

> The Federal government and ““Each covered entity engaged in the business of providing health insurance” contributes to the fund.

Allocations of funding among covered entities

Collectively, non-federal covered entities shall be responsible for their share of the persons receiving treatments for HIV/AIDS.

The individual contributions from covered entities based upon the ratio of the covered entity's net premiums compared to all other covered entities, subject to this graduated scale:

(1) With respect to a covered entity’s net premiums written during the calendar year that are not more than $25,000,000, the percentage of net premiums written that are taken into account is 0 percent.

(2) With respect to a covered entity’s net premiums written during the calendar year that are more than $25,000,000 but less than $50,000,000, the percentage of net premiums written that are taken into account is 50 percent.

(3) With respect to a covered entity’s net premiums written during the calendar year that are $50,000,000 or more, the percentage of net premiums written that are taken into account is 100 percent.

Getting money out of the prize fund

Each developer of a new drug for HIV/AIDS qualifies for annual payouts from the prize fund, for ten years.

Criteria for awarding prize fund rewards

(c) Criteria.—The Prize Fund Director shall, by regulation, establish criteria for the selection of recipients, and for determining the amount, of prize payments under this section. Such criteria shall include consideration of the following:

(1) The number of patients who benefit from the qualifying treatment for HIV/AIDS or manufacturing process involved.

(2) **The incremental therapeutic benefit** of the qualifying treatment for HIV/AIDS or manufacturing process involved as **compared to existing** drugs, biological products, and manufacturing processes available to treat the same disease or condition, except that the Prize Fund Director shall provide for cases where drugs, biological products, or manufacturing processes are developed at roughly the same time, so that the comparison is to products that were not recently developed.

(3) **Improved efficiency** of manufacturing processes for drugs or biological processes.

(4) The extent to which knowledge, data, materials, and technology that are **openly shared have contributed** to the successful development of new products or improved processes for manufacturing products.

Additional requirements

Follow-on products don’t erode benefits for first in class:

In cases where a new qualifying treatment or manufacturing process for HIV/AIDS offers an improvement over an existing qualifying treatment or manufacturing process, or competes with or replaces the existing qualifying treatment or manufacturing process, the Prize Fund Director shall continue to make prize payments for the existing qualifying treatment or manufacturing process to the degree that the new qualifying treatment or manufacturing process was based on or benefitted from the development of the existing qualifying treatment or manufacturing process.

50 percent rule:

For any fiscal year, the Prize Fund Director may not award a prize payment for any single qualifying treatment for HIV/AIDS or manufacturing process for a qualifying treatment in an amount that exceeds 50 percent of the total amount appropriated to the Fund for that year.

Additional features

Open source dividend

Competitive intermediaries

Donor prize fund

Other end product prize fund proposals

- S.627, 113th, the S.627 - Medical Innovation Prize Fund Act
- The Cancer Prize Fund
- Chagas prize fund
- Various antibiotics proposals
- Lots of diagnostic prize proposals
- Etc, etc.

Progressive delinkage

Set a goal

Take steps toward that goal, that move progressively to full delinkage

While prices are lowered, offset negative impact on R&D by increasing a combination of direct funding, R&D subsidies and cash rewards.

More information

http://Delinkage.Org

james.love@keionline.org