COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF HUMAN SERVICES

OCT - 2 2015

The Honorable Ronald L. Wyden
The Honorable Charles E. Grassley
United States Senate
Senate Committee on Finance
Washington, D.C. 20510

Dear Senators Wyden and Grassley:

Thank you for the opportunity to describe Pennsylvania's experience with coverage of the newest Hepatitis C agents in the Pennsylvania (PA) Medicaid program. Sovaldi and Harvoni (manufactured by Gilead), Daklinza (manufactured by Bristol-Myers Squibb), and Viekira Pak and Technivie (manufactured by AbbVie) are all covered under the PA Medicaid program and available in both the fee-for-service (FFS) and the managed care delivery systems. All of the recently-approved drugs for the treatment of Hepatitis C are very costly. The high price of the newer Hepatitis C medications sparked national and international debate over fair pricing which, combined with several unknowns that made overall costs unpredictable, generated significant concern over potential cost of care and indirectly impacted policy decisions on coverage and access.

Cost Concerns and Potential Impact

The Department of Human Service's (Department's) clinical pharmacists routinely monitor the pipeline for new drugs coming to market. They were aware of the anticipated release of each of the new oral Hepatitis C drugs and their promise of higher cure rates with fewer side effects compared to previous treatment options. Like all new drugs, the pharmacists were not aware of costs until the drugs received final approval from the U.S. Food and Drug Administration (FDA) and became available in the market. When the prices were announced, PA Medicaid, like every other public and private third party payer in the nation, experienced "sticker shock."

Concerns about the cost of the new Hepatitis C drugs were exacerbated by a number of unknowns that made total cost unpredictable. The biggest unknown was the size of the target population due to the following:

- Pent-Up Demand – Many people diagnosed with Hepatitis C decided to delay treatment until the newer Hepatitis C drugs were available, as the new drug treatment regimens were entirely oral and were anticipated to increase effectiveness, decrease side effects, and shorten treatment time compared to previously-available regimens.

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- Centers for Disease Control (CDC) Recommendation for Testing – In 2012, the CDC recommended that everyone born between 1945 through 1965, also known as baby boomers, get tested for Hepatitis C. People with Hepatitis C often have no symptoms and can live for decades without feeling sick. The only way to know if a person has Hepatitis C is to get tested. The CDC recommended testing for early diagnosis and treatment to help prevent serious health problems, including liver damage, cirrhosis, liver cancer, liver transplants, and even death.

- Direct to Consumer Marketing – Manufacturers used television and magazine advertisements to promote their Hepatitis C drugs, targeting the baby boomer population.

Typically, the expenses associated with high-cost drugs, such as drugs to treat HIV/AIDS and hemophilia, are spread out over time and are predictable. In this case, pent-up demand, increased testing, and greater consumer awareness of the new drugs, combined with a shorter treatment time of 8 to 12 weeks for most patients, creates the potential for a one-time immediate spike in demand for the recently-approved high-cost treatments and challenges traditional fiscal projections and planning.

The PA Medicaid program prepared a rough estimate of the cost impact if every PA Medicaid beneficiary infected with Hepatitis C was treated. According to that estimate, the cost could range from $2.87 billion to $3.05 billion paid to the dispensing providers, or $1.58 billion to $1.73 billion after the federal drug rebates are collected. The ranges reflect the difference in paid amounts and net costs and are dependent upon which drug is designated as preferred on the FFS Preferred Drug List (PDL).

The PA Medicaid managed care organizations (MCOs) voiced their concern about the high cost of the drugs and the unpredictability of demand. The Department's actuary included Hepatitis C drug costs when they developed the calendar year 2015 MCO rates. However, the MCOs remain skeptical that the rates are sufficient given the high demand for access to treatment. The Department continues to monitor MCO expenditures in response to MCO demands for further financial adjustment.

PA Medicaid Efforts to Mitigate Cost

Both the PA Medicaid FFS program and the MCOs immediately implemented strategies to manage utilization and mitigate cost impact. Those strategies included prior authorization of the new Hepatitis C drugs and reinforced emphasis on its already robust collection of federal drug rebates on these drugs. The FFS program also worked with its state supplemental rebate contractor to negotiate supplemental rebates for these products. (NOTE: Drugs paid for by PA Medicaid MCOs do not qualify for state supplemental rebates. The MCOs negotiate and collect their own market share

rebates.) Initially, Gilead offered a very modest supplemental rebate for Sovaldi on the condition of a guarantee of unfettered access: no prior authorization, and no requirements for prescriptions to be written by, or in consultation with a medical specialist. When Gilead introduced Harvoni and AbbVie introduced Viekira Pak to the market, Gilead claimed willingness to negotiate supplemental rebates but negotiations were unproductive. Currently, Viekira Pak is designated as preferred on the FFS PDL; Harvoni, Sovaldi, Daklinza and Technivie are designated as non-preferred. They are covered and available when determined to be medically necessary. All of the drugs, including Viekira Pak, require prior authorization.

Current Utilization and Cost

The following chart reflects the current utilization and spend for Hepatitis C drugs in both FFS and managed care in PA Medicaid. The total spend does not account for rebates collected by PA Medicaid.

Hepatitis C Drug Utilization and Spend in PA Medicaid			
January 1, 2014 through August 8, 2015			
	Recipient Count	Claim Count	Spend
Total	2,041	11,969	$186,116,252

Policy Impact

PA Medicaid provides coverage of all FDA-approved drugs of manufacturers who participate in the Federal Drug Rebate Program. Consistent with federal Medicaid requirements, PA Medicaid's policy is to provide coverage for all medically-accepted indications. Both FFS and the Medicaid MCOs rely on package labeling, national and international treatment guidelines, and peer-reviewed medical literature to identify the guidelines to determine medical necessity.

In this case, expert consensus panels published treatment guidelines that shifted the emphasis on determining medical necessity from the clinical merits of these breakthrough treatments to an accommodation of the exorbitant costs. Instead of focusing their guidelines on the clinical merits of the drugs and their medically-accepted indications, treatment guidelines recommended prioritizing treatment for the "sickest" patients due to potential cost and access issues. And, unlike other communicable diseases such as HIV/AIDS, there was no emphasis on reduction in transmission to stem the spread of the disease through education and intervention at the point of transmission. One positive outcome of the concerns about high cost for Pennsylvania was the development and adoption of consistent guidelines to determine medical necessity of the newer Hepatitis C drugs among FFS and all of the PA Medicaid MCOs to ensure equal access across delivery systems.

I hope that this information is helpful. If you need additional information, please contact Mr. Abdoul Barry, Director, Office of Legislative Affairs, at (717) 783-2554.

Sincerely,

Theodore Dallas
Secretary

c: The Honorable Robert P. Casey, Jr.