Fact Sheet – LIS Formulary Drug Coverage

Background

CMS' formulary review standards ensure that Part D formularies are robust and include drugs to treat all disease states. In addition to the statutory requirement of including at least two drugs from each category and class, Part D sponsors' formularies are also reviewed for additional requirements, such as the inclusion of drug classes addressed in widely-accepted treatment guidelines and for drug classes most commonly utilized by the Medicare population. The CMS formulary review looks for the inclusion of drug entities, regardless of their brand/generic status.

Low Income Subsidy (LIS) beneficiaries who receive premium and cost-sharing help through the Part D LIS program have a subset of premium-free PDPs referred to as LIS benchmark PDPs available to them, but they can also choose to enroll in a non-benchmark plan and pay a premium. The findings described below are from an analysis comparing LIS and non-LIS formularies from CY 2013 through CY 2016 to identify whether access issues exist on LIS plan formularies, as measured by drug coverage, brand drug coverage and use of utilization management edits.

Highlights of Formulary Drug Coverage Analysis 2013-2016

A. Drug coverage for low-income subsidy (LIS) benchmark formularies.

While there has been a slight decline in the percentage of drugs covered on LIS benchmark PDP formularies since 2013, the small decline (from 79.6% in 2013 to 76.1% in 2016) is consistent with a similar decline in the percentage of drugs covered in non-benchmark PDP formularies between CY 2013 and CY 2016 (from 82.2% in 2013 to 77.7% in 2016).[1] This decline may be attributed to the changing marketplace and overall strategic actions taken by plan sponsors that are not specific to LIS benchmark PDP formularies. The decrease of 4.5 percentage points in drug coverage since CY 2013 for non-benchmark PDP formularies is actually slightly higher than the 3.5 percentage point decrease in drug coverage noted in LIS benchmark PDP formularies during the same timeframe. In fact, the difference in coverage between LIS and non-LIS PDP formularies in CY 2016 of 1.6 percentage points is the smallest difference noted since 2013.

B. Brand Drug coverage comparison.

There has been a similar decline in the percentage of brand drugs that are covered on Part D formularies but the decline is actually higher for the non-benchmark PDP formularies (42.2% in CY 2013 to 38.3% in CY 2016; a decrease of 3.9 percentage points) compared to the LIS benchmark PDP formularies (38.6% in CY 2013 to 36.8% in CY 2016; a decrease of 1.8 percentage points)[1]. Again, this decline may be attributed to the changing marketplace and is not specific to LIS benchmark PDP formularies.

C. Utilization Management edits by PDP formularies.

As can be seen in Table 1 below, the use of Prior Authorization, Step Therapy and Quantity Limit edits is fairly consistent between LIS benchmark PDP and other non-LIS PDP formularies.

[1] Reference Table 1 below.

Table 1

	CY 2013		CY 2014		CY 2015		CY 2016	
	LIS PDPs	Non-LIS PDPs	LIS PDPs	Non-LIS PDPs	LIS PDPs	Non-LIS PDPs	LIS PDPs	Non-LIS PDPs
Average % of Drugs Covered*	79.6%	82.2%	79.8%	83.0%	77.6%	79.8%	76.1%	77.7%
Average % of Drugs that are Brands**	38.6%	42.2%	37.5%	41.0%	36.0%	38.5%	36.8%	38.3%
Average % of Drugs with Prior Authorization***	16.0%	15.1%	16.3%	15.7%	19.4%	19.3%	21.4%	21.0%
Average % of Drugs with Step Therapy***	1.1%	1.6%	1.1%	1.5%	1.7%	1.6%	1.2%	1.6%
Average % of Drugs with Quantity Limits***	21.1%	20.9%	19.9%	20.8%	22.0%	23.4%	22.1%	21.8%

Source: CMS Data using Approved formularies (with exception of CY2013 which was based on As Submitted formularies) and As Submitted plan bids.

* Drug counts are based on the number of unique drug entities.

** Brand drugs defined by FDA-based Applicable/Non-Applicable definitions.

*** Drug counts are based on the number of RXCUIs.

Percentages are the number of drugs in plan formularies relative to all drugs in plan formularies. Formularies used for both LIS PDPs and Non-LIS PDPs are represented in averages for both LIS PDPs and Non-LIS PDPs.

Discussion

While currently there are slightly higher number of drugs and branded products on non-LIS formularies than those formularies used by LIS plans, this difference does not appear to be clinically meaningful. Further, as noted above, the difference between the two formulary groups appears to be shrinking with time.

We are not aware of Part D access problems that are unique to LIS beneficiaries. In fact, the Patient Protection and Affordable Care Act (PPACA) of 2010 requires that The Office of Inspector General, U.S. Department of Health & Human Services produce an annual report with recommendations as appropriate, on the extent that Part D drugs commonly used by the dual-eligible population are included on their formularies. In their 2015 report (https://oig.hhs.gov/oei/reports/oei-05-15-00120.pdf), the OIG determined that, on average, Part D formularies included 95 percent of the commonly used drugs. In addition, they found that 71 percent of all commonly used drugs are included on all Part D formularies.

CMS will continue to review formulary data, Part D complaints, and other pertinent information in order to continue to ensure that LIS beneficiaries have access to the drugs they need.