

## Medicare Part D Specialty Tier April 7, 2015

### Background

Part D sponsors may choose to designate one formulary tier as their specialty tier that is exempt from tier cost-sharing exceptions. Sponsors may only place Part D drugs with sponsor negotiated prices that exceed the dollar-per-month threshold established by CMS in the annual Call Letter on the specialty tier. As part of our formulary review process, we limit the placement of drugs on specialty tiers to only those drugs for which the majority of prescription drug events (PDE) exceed the dollar threshold. These are referred to as *specialty tier-eligible drugs*.

Specialty tier drugs represent a limited number of Part D drugs that are used by a small proportion of beneficiaries. The current specialty tier threshold of \$600 per month was established in 2008 and has remained at that level based on Part D data analysis. We have consistently observed in PDE data that less than 1% of claims exceed \$600 per 30 days. In preparation for the draft CY 2016 Call Letter, we evaluated PDE data to investigate whether an increase in the current specialty tier threshold was warranted. We specifically examined trends over the past three plan years in the number of drugs that meet the threshold, the Part D utilization of these drugs, and the costs associated with these drugs.

### Data Sources and Methodology

This analysis utilizes CY 2012-2014 formulary and Plan Benefit Package (PBP) data, CY 2012-2014 Health Plan Management System (HPMS) Formulary Reference Data, and CY 2012-2014 PDE data (10% sample of beneficiaries with PDE utilization). The 10% sample, drawn based on a unique beneficiary identifier, has been shown to be unbiased. The CY 2014 PDE sample was based on data available as of November 12, 2014.

A PDE-reported covered drug was identified as being a specialty tier drug if that drug was on the specialty tier for the plan as designated in the PBP.

### Findings

#### *Proportion of Part D Claims Exceeding \$600 per Month*

In order to estimate the proportion of Part D claims that exceed the \$600 per month threshold, PDEs were first converted to 30-day equivalents. A 30-day equivalent fill was defined as the total days supply divided by 30 when the days supply was greater than 34. A days supply of less than or equal to 34 was defined as one 30-day equivalent. As per Table 1 below, while increasing, the percentage of 30-day equivalent PDEs that meet this threshold continues to be less than 1%.

**Table 1. Proportion of Part D PDE Exceeding \$600 per Month.**

CY 2012	CY 2013	CY 2014
0.78%	0.84%	0.95%

#### *Part D Plan Sponsors Utilizing a Specialty Tier*

As shown in Table 2, most Part D plans (at the PBP level) utilize a specialty tier in their plan design. This is true over time for both stand-alone prescription drug plans (PDPs) and Medicare Advantage Prescription Drug Plans (MA-PDs).

**Table 2. Percentage of PDPs and MA-PDs that Include a Specialty Tier**

	CY 2012	CY 2013	CY 2014
<b>PDP</b>	96.1%	93.0%	96.6%
<b>MA-PD</b>	97.7%	97.9%	98.5%

*Drugs Eligible for Specialty Tier Inclusion*

As part of our annual formulary review process, we evaluate the cost and Part D utilization of the drugs included on the CMS Formulary Reference File (FRF). The drugs (represented by RxNorm RXCUIs) that meet the annual cost criteria are permitted to be included on each sponsor's specialty tier. Table 3 includes the percentage of FRF drugs that met these criteria. The percentage of drugs that met the specialty tier criteria increased between CY 2012 and CY 2014.

**Table 3. Percentage of FRF Drugs Meeting Specialty Tier Criteria**

CY 2012	CY 2013	CY 2014
11.9%	12.9%	14.1%

*Percentage of Formulary Drugs Included on Plans' Specialty Tiers*

If a Part D drug meets the specialty tier threshold, Part D sponsors may opt to include the drug on their formulary, but not place it on the specialty tier. Table 4 shows the average percentage of drugs that were actually included on each plan's specialty tier. These percentages, though increasing in recent years, have remained consistently low and are lower than the percentage of drugs that are eligible to be included in the tier.

**Table 4. Percentage of Formulary Drugs Included on Sponsors' Specialty Tiers**

CY 2012	CY 2013	CY 2014
8.5%	8.9%	11.2%

*Utilization of Drugs on Specialty Tiers*

When examining utilization of specialty tier drugs, we again employed the 30-day equivalent fill methodology. A beneficiary was identified as a utilizer of a specialty tier drug if his/her plan included the drug on its specialty tier. The number of utilizers of specialty tier drugs was divided by the total number of beneficiaries with an event in the PDE data. Beneficiaries were further delineated based on low-income subsidy (LIS) status. Similar to other statistics, the proportion of beneficiaries who utilized specialty tier drugs has been increasing slightly, and LIS beneficiaries continue to utilize these drugs at a higher rate than non-LIS beneficiaries (Table 5).

**Table 5. Proportion of Beneficiaries Utilizing Drugs on their Plan's Specialty Tiers**

Category	CY 2012	CY 2013	CY 2014
LIS	3.02%	3.61%	4.11%
Non-LIS	0.85%	0.87%	1.00%
Total	1.63%	1.78%	1.99%

*Percent of Total Part D Fills For Drugs on Specialty Tiers*

The overall proportion of Part D claims that were comprised of drugs contained on plan sponsors' specialty tiers was also determined. Again, the percentage of claims is very low (less than 1%), though increasing during the past three plan years (Table 6).

**Table 6. Proportion of all CY 2012-2014 Part D 30-day Equivalent Fills of Drugs on Specialty Tiers**

CY 2012	CY 2013	CY 2014
0.24%	0.25%	0.32%

*Percent of Total Part D Expenditure for Drugs on Specialty Tiers*

The total expenditure for all Part D fills was calculated. The total expenditure for fills for drugs on plan sponsors' specialty tiers was also calculated. The total expenditure for specialty tier drugs was divided by the total Part D expenditure to determine the proportion of total costs attributed to drugs on specialty tiers. As shown in Table 7 below, we do observe an increasing proportion of expenditure related to specialty tier drugs.

**Table 7. Percent of Part D Total Expenditure Related to the Specialty Tier**

CY 2012	CY 2013	CY 2014
10.27%	11.04%	16.22%

Conclusion

Based on the previous three plan years, there appears to be some increases in statistical measures of specialty tier utilization. However, when examining the \$600 threshold itself, this value continues to identify outlier claims – 99% of 30 day equivalent PDEs are below this value. While the data does not support a shift in the specialty tier cost criteria at this time given that less than 1% of 30-day equivalent PDEs meet the current threshold, we will perform additional analyses to explore these increasing trends. We will consider the comments received in response to the CY 2016 Call Letter and will evaluate options for future guidance related to specialty products for CY 2017.