

Medicare Part D Specialty Tier April 7, 2014

Background

Part D sponsors may designate one tier as their specialty tier since this tier is exempt from tier cost-sharing exceptions, but they are not required to include a specialty tier on their formulary. Only Part D drugs with sponsor negotiated prices that exceed the dollar-per-month amount established by CMS in the annual Call Letter may be placed in 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 medications represent a limited number of 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. We have consistently observed in prescription drug event (PDE) data that less than 1% of claims exceed \$600 per 30 days. In preparation for the draft CY 2015 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 2011-2013 formulary and Plan Benefit Package (PBP) data, CY 2011-2013 Health Plan Management System (HPMS) Formulary Reference Data, and CY 2011-2013 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.

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, PDE 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 1 30-day equivalent. As per Table 1 below, less than 1% of 30-day equivalent PDEs continue to meet this dollar threshold. This percentage is consistent for all 3 contract years.

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

CY 2011	CY 2012	CY 2013
0.78%	0.78%	0.84%

Part D Plan Sponsors Utilizing a Specialty Tier

As shown in Table 2, the vast majority of Part D plans (at the PBP level) utilize a specialty tier in their plan design. This is true over time for both 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 2011	CY 2012	CY 2013
PDP	96.3%	96.1%	93.0%
MA-PD	98.3%	97.7%	97.9%

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 meeting the specialty tier criteria is stable between CY 2011 and CY 2013 and remains low.

Table 3. Percentage of FRF Drugs Meeting Specialty Tier Criteria

CY 2011	CY 2012	CY 2013
12.8%	11.9%	12.9%

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 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 2011	CY 2012	CY 2013
8.1%	8.5%	8.9%

Utilization of Drugs on Specialty Tiers

When examining utilization of specialty tier products, 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 remained stable, 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 2011	CY 2012	CY 2013
LIS	1.19%	1.09%	1.14%
Non-LIS	0.62%	0.54%	0.57%
Total	1.81%	1.63%	1.71%

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%) and has been stable during the past three plan years (Table 6).

Table 6. Proportion of all CY 2011-2013 Part D 30-day Equivalent Fills of Drugs on Specialty Tiers

CY 2011	CY 2012	CY 2013
0.24%	0.24%	0.25%

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 outlined 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 2011	CY 2012	CY 2013
8.51%	10.27%	11.04%

Conclusion

Based on the previous three plan years, there appears to be stability in several statistical aspects relating to the specialty tier. When examining the \$600 threshold itself, this value continues to identify outlier claims – 99% of 30 day equivalent PDEs are below this value.

Upwards of 90% of Part D plan benefit packages utilize a specialty tier in their benefit structure. CMS does not expect to see any reductions in this number in the future.

Similarly, the percentage of drugs meeting our review criteria for specialty tier inclusion also remains fairly constant (at around 13%). We also did not observe any significant increases in the percentage of plans' formularies that are comprised of specialty tier-eligible drugs. This number again has been fairly stable over the past three years and is still below 10%.

We also have not seen any significant increases in either the proportion of beneficiaries who utilize specialty tier drugs, or the proportion of Part D claims that are comprised of drugs on plans' specialty tiers. In contrast, we observed a slight increase in the proportion of total Part D expenditures attributable to products on plans' specialty tiers.

In summary, these data taken together may suggest that the costs of specialty tier-eligible drugs are increasing and we will perform additional analyses to investigate this. However, the current analyses do not currently support a shift in the specialty tier cost criteria of \$600 per month. In addition to performing the aforementioned analyses on cost stability of specialty tier-eligible products, we will repeat the analyses reported within this document prior to the draft CY 2016 Call Letter to assess whether an increase in the specialty tier cost threshold is warranted.