



CMS 2012 Medicare Prescription Drug Benefit Symposium

Part D Protected Class Drugs

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(ARS Response Card: Channel 41)

Disclosure

“I, Monica Reed, declare no conflicts of interest or financial interests in any product or service mentioned in this presentation, including grants, employment, gifts, stock holdings, or honoraria.”

Learning Objectives

- Identify the percentage of the Part D drug costs that were attributable to protected class drugs for 2010
- Identify the percentage of all fills of protected class drugs represented by the top three most frequently prescribed protected drug classes for 2010

Discussion Topics

- Protected class drug requirement overview.
- Utilization rates
- Top classes and drugs by utilization and cost.
- Demographic data of Part D enrollees who utilized protected class drugs

Part D Protected Class Drug Requirement

Purpose of the Protected Class Policy

- Ensure beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans
- Ensure access to vital drugs for vulnerable patient populations
- Limit the risks and complications associated with interruptions in therapy
- Ensure continued access for beneficiaries stabilized on therapy

Chapter 6 of the Part D Manual- Section 30.2.5

- Part D sponsor formularies must include all or substantially all drugs in the following six classes:
 - Anticonvulsant
 - Antidepressant
 - Antineoplastic
 - Antipsychotic
 - Antiretroviral
 - Immunosuppressant (for prophylaxis of organ transplant rejection)

Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Section 1860D 11(e)(2)(D)(i):

- Set forth the requirements for the approval of proposed plans and plan designs
- Gave CMS the responsibility to ensure beneficiaries receive clinically appropriate medications so that formularies are not discriminatory
- As a result, CMS has exercised its authority to ensure that Part D plan formularies and benefits do not discourage enrollment by certain part D eligible individuals under the plan

Patient Protection and Affordable Care Act (ACA), Section 3307:

- Codified Part D formulary requirements with respect to certain categories or classes of drugs
- In general, a Part D sponsor is required to include all covered Part D drugs in the six clinical classes of concern.
- Exceptions may be established
- The Secretary shall establish the criteria for the identification of classes and categories of clinical concern and any exceptions through the promulgation of a regulation which includes a public notice and comment period

Chapter 6 of the Part D Manual- Section 30.2.5

- Protected class drug formulary requirements:
 - Formularies must include substantially all drugs in the six categories that are FDA approved by the last CMS upload date for the upcoming contract year
 - New drugs or newly approved uses for drugs in the six categories will be subject to an expedited P&T committee review
 - The expedited review must occur within 90 days of the drug entering the market
 - The drug must be added by the end of this 90 day period

Chapter 6 of the Part D Manual- Section 30.2.5

- Protected class drugs and utilization management:
 - Are designed to encourage adherence and access to drugs that are especially important for beneficiaries
 - Cannot be implemented to steer enrollees who are currently taking a protected class drug to preferred alternatives
 - For HIV/AIDS drugs, utilization management tools such as prior authorization and step therapy are not allowed
 - Part D sponsors may apply prior authorization to establish appropriate payment under Part B or Part D, even if the beneficiary is currently taking the drug
 - Protected class drugs are not exempt from concurrent drug utilization review requirements outlined in 42 CFR 423.153(c)(2)

Protected Classes Formulary Review

- Initial formulary review occurs during Stage 1 of the formulary review process:
 - Formularies are reviewed for drugs from the protected classes
- Monthly Submission Review:
 - Formularies are reviewed to ensure that new protected class drugs are added to the formulary within the 90 day expedited review timeframe
 - Consistent with the CY 2012 Formulary Information HPMS memo, failure to include a protected class drug during the required HPMS formulary submission window will result in the suppression of the formulary in Medicare Plan Finder (MPF)

Part D Protected Class Drug Utilization

Overview

- Approximately 40% of all Part D enrollees used at least one protected class drug in 2010
- Protected class drugs accounted for 13% of all Part D fills and 18% of the total Part D drug costs in 2010
- The top three protected classes (Antidepressants, Anticonvulsants, and Antipsychotics) accounted for 94% of fills for protected class drugs
- Most beneficiaries only used one drug within a specific protected class, with the exception of Antiretrovirals

Data Sources

- 2009 and 2010 Prescription Drug Event (PDE) data as of May 18, 2011
- 2006 – 2011 PDE data as of January 30, 2012 (for yearly utilization trends)
- Drug information derived from Medi-Span and First Databank

Formulary Review Data and Medi-Span

- Identified reference National Drug Codes (NDCs) for drugs included in the protected class drug formulary review check
- Identified Generic Product Identifier 10 (GPI 10) for protected class drug reference NDCs
- Created a protected class drug NDC dataset by using GPI 10s to identify all possible protected class product NDCs

Methodology (continued)

PDE Data

- Used to determine the following for protected class drugs:
 - Number of utilizing beneficiaries
 - Total gross drug cost
 - Number of fills (adjusted for 30 day equivalents)

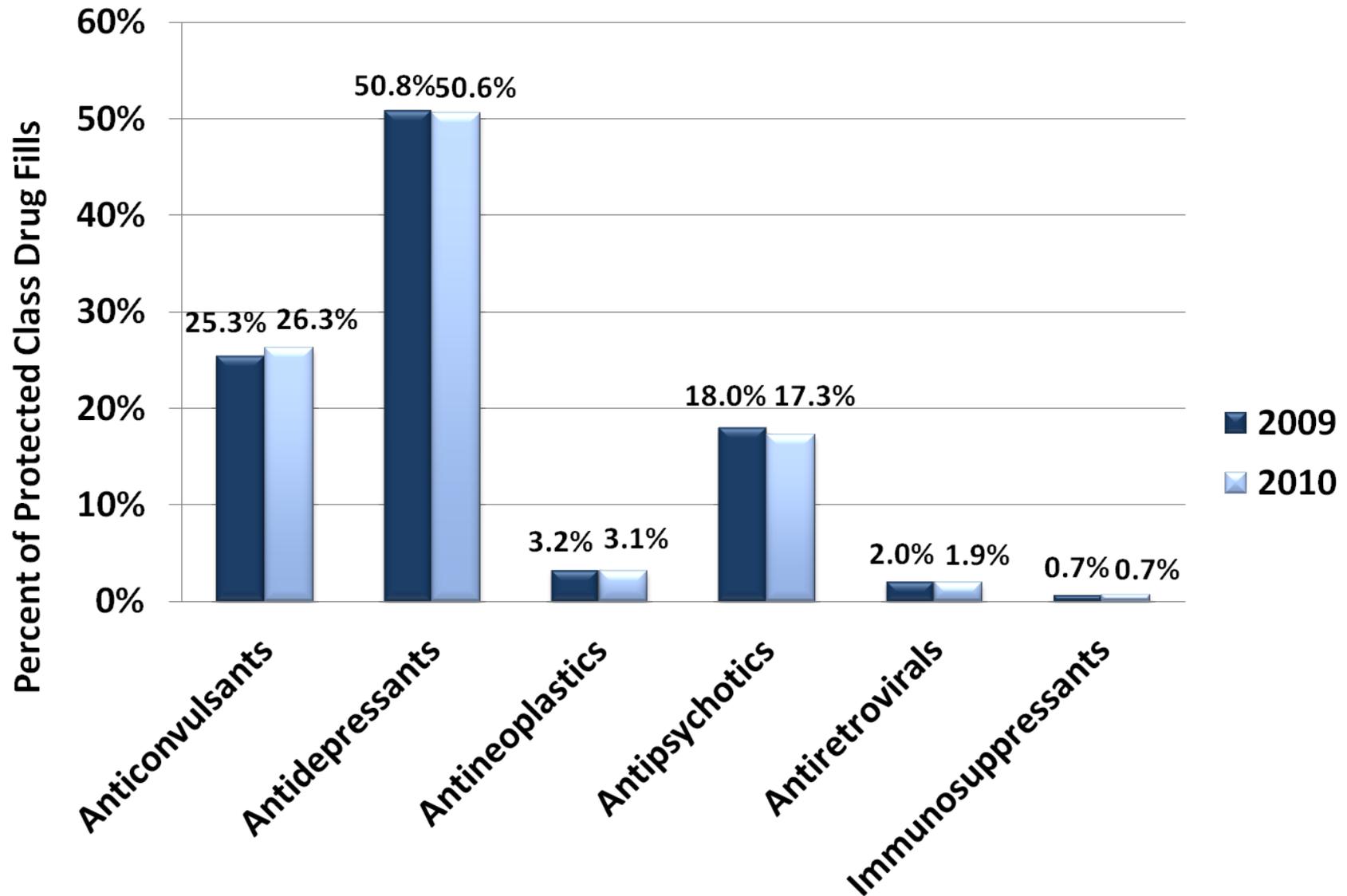
Common Medicare Environment (CME)

- Beneficiary characteristics (e.g. gender, age, and race)

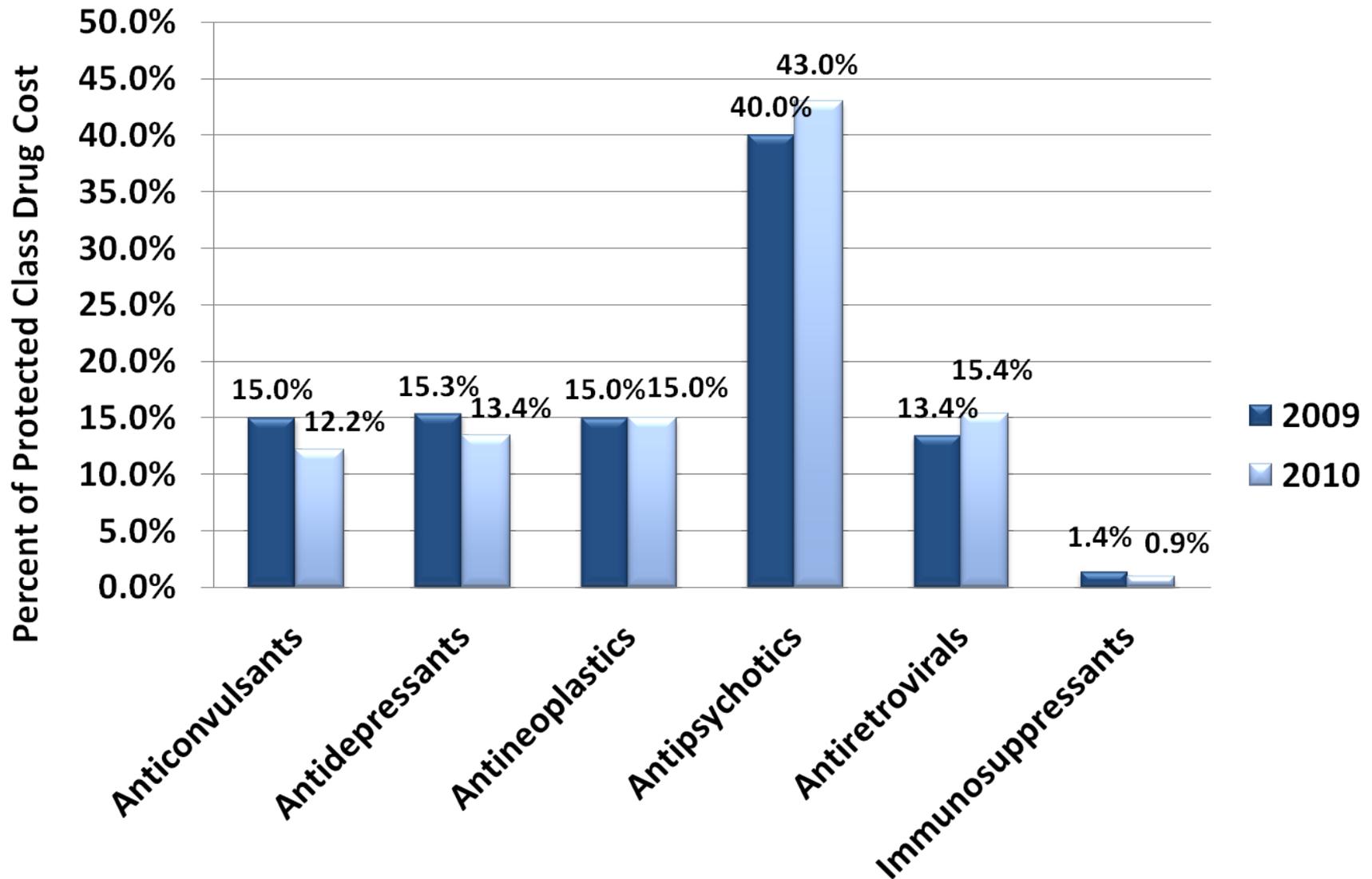
Protected Class Drug Utilization & Costs

- Protected class drug utilization and costs were similar in 2009 and 2010:
 - In 2009, 39% of all Part D enrollees used at least one protected class drug. These drugs accounted for 20% of all Part D drug costs and 12% of all Part D drug fills
 - In 2010, 40% of all Part D enrollees used at least one protected class drug. These drugs accounted for 18% of the total Part D drug costs and 13% of all Part D drug fills

Percent of Total Fills by Protected Drug Class



Percent of Total Gross Drug Cost by Protected Drug Class



Utilization of the Top Five Protected Class Drugs

Utilization Ranked by Total Protected Class Drug Fills for the Top Five Protected Class Drugs

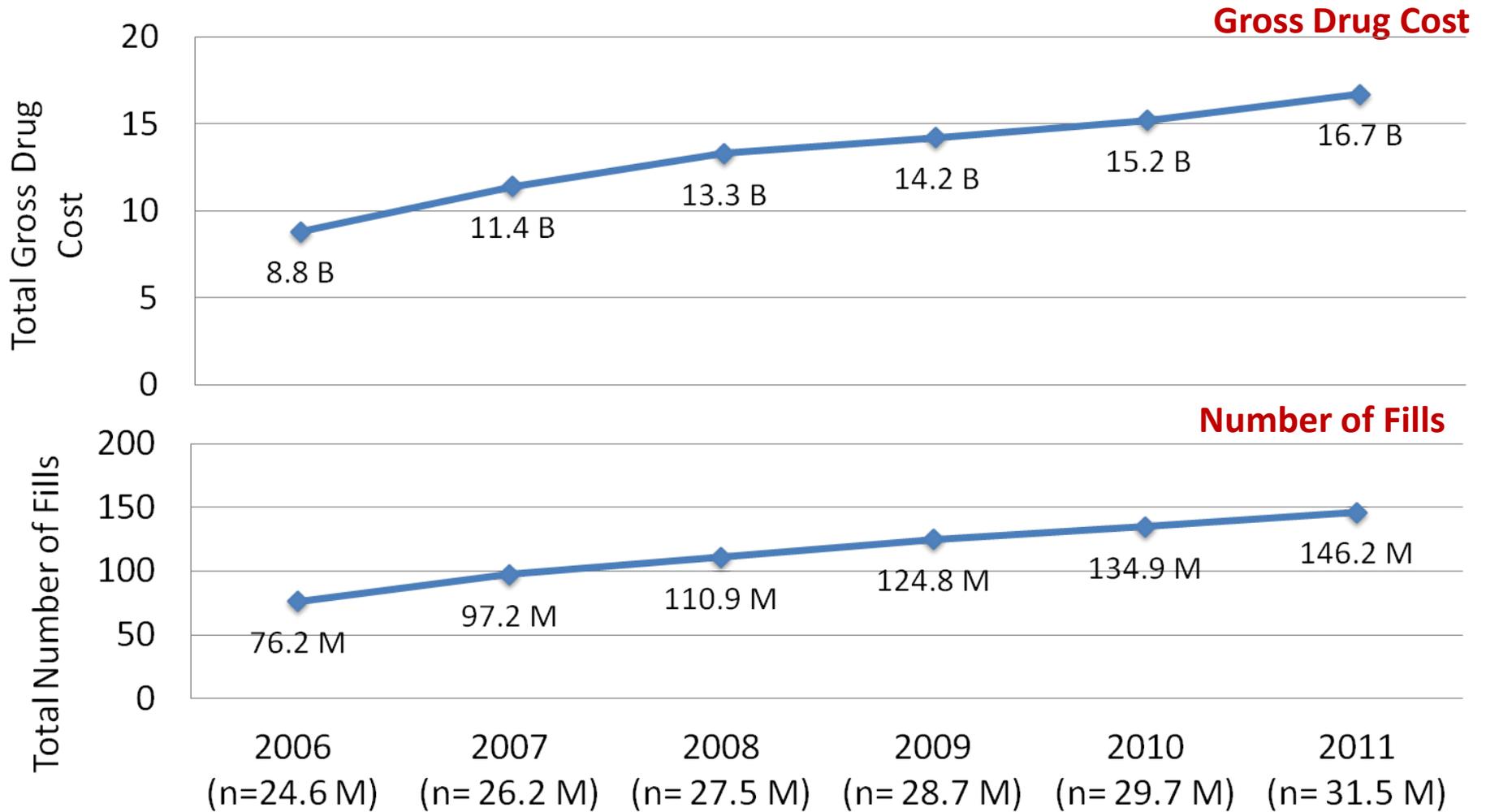
Protected Class	Drug Name	2010	
		Number of Fills	Percent of Total Protected Class Drug Fills
Anticonvulsants	Gabapentin	30,027,357	13.5%
Antidepressants	Citalopram Hydrobromide	22,399,490	10.1%
Antidepressants	Sertraline Hydrochloride	19,464,439	8.7%
Antidepressants	Fluoxetine Hydrochloride	12,078,551	5.4%
Antidepressants	Paroxetine Hydrochloride	11,944,208	5.4%

Utilization of the Top Five Protected Class Drugs

Utilization Ranked by Total Protected Class Drug Cost for the Top Five Protected Class Drugs

Protected Class	Drug Name	2010	
		Total Drug Cost	Percent of Total Protected Drug Cost
Antipsychotics	Quetiapine Fumarate	\$1,749,620,026	10.4%
Antipsychotics	Olanzapine	\$1,587,515,492	9.5%
Antipsychotics	Aripiprazole	\$1,184,940,152	7.1%
Antidepressants	Duloxetine Hydrochloride	\$685,563,514	4.1%
Anticonvulsants	Gabapentin	\$611,739,884	3.6%

2006-2011 Trend of Total Gross Protected Class Drug Cost and Utilization



Note: PDE data as of January 30, 2012
 n= Part D enrollment

Protected Class Drug Utilization by Gender & Race

- The distribution of protected class drug use by gender and race is consistent through time and proportional to gender and race distribution of enrollment:
 - In 2009 and 2010 females accounted for 66% of protected class drug utilization
 - In 2009 and 2010 white beneficiaries accounted for over 80% of protected class drug utilization

Please see Table 1 and Table 2 in Appendix A for additional information

Protected Class Drug Utilization by Age

- Beneficiaries less than 65 years of age were the highest utilizers of protected class drugs:
 - In 2009 and 2010 enrollees less than 65 accounted for approximately 40% of the total fills and over 30% of the total number of enrollees who utilized protected class drugs

Please see Table 3 in Appendix A for additional information

Average Utilization Per Beneficiary

- Average utilization was consistent across years:
 - Beneficiaries that used protected class drugs, on average used 1.7 distinct drugs (GPI 10) across all of the classes in 2009, and 1.8 in 2010
 - There were 11.8 fills (not unique drugs) for these drugs per beneficiary in 2009, and 11.7 fills in 2010

Number of Beneficiaries Who Used One or More Protected Class Drug

- With the exception of Antiretrovirals, in 2009 and 2010 most beneficiaries only used one drug within a specific protected class:
 - In 2009: Anticonvulsants 84%, Antidepressants 77%, Antineoplastics 96%, Antipsychotics 78%, Antiretrovirals 19%, Immunosuppressants 83%
 - In 2010: Anticonvulsants 84%, Antidepressants 77%, Antineoplastics 95%, Antipsychotics 79%, Antiretrovirals 21%, Immunosuppressants 84%

Please see Table 4 and Table 5 in Appendix A for additional information

Limitations

- Protected class drugs have non-protected indications
 - For example, gabapentin for post herpetic neuralgia
- The analysis to determine the number of beneficiaries who filled one or more protected class drug was completed at the GPI 10 level
 - For example, combination drugs such as Antiretrovirals were counted as one drug since they have a unique GPI 10
- The analysis to determine the number of beneficiaries who filled more than one protected class drug in a drug class is based on multiple fills at any point during the year

Summary Review

- There were over 130 million fills for protected class drugs accounting for 13% of all Part D drug fills and 18% of total Part D drug costs in 2010
- In 2010, 40% of all Part D enrollees used at least one protected class drug
- Antineoplastics, antiretrovirals, and immunosuppressants account for less than 6% of fills for protected class drugs
- The top 5 protected class drugs by fills account for over 40% of fills for protected class drugs in 2010
- The top 5 protected class drugs by cost account for over 30% of cost for protected class drugs in 2010



Assessments

Assessment Question 1

What percentage of all fills of protected class drugs are represented by the top 3 most frequently prescribed protected drug classes for 2010?

1/A 76%

2/B 64%

3/C 87%

4/D 94%

Assessment Question 2

What percentage of the Part D drug costs were attributable to protected class drugs In 2010?

1/A 11%

2/B 18%

3/C 24%

4/D 30%



Questions?

Contact Information

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Part D Formulary Questions

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Presentation Evaluation

Please get your ARS Response Card ready

APPENDIX A

Table 1

Number of Fills and Protected Class Drug Utilizing Beneficiaries by Gender				
Gender	Number of Fills	Percent of Total Fills	Number of Beneficiaries	Percent of Total Beneficiaries
2009				
Female	86,506,079	65.28%	6,774,056	65.75%
Male	45,983,967	34.70%	3,527,647	34.24%
Unknown	23,106	0.02%	1,793	0.02%
2010				
Female	91,039,928	65.26%	7,148,465	65.51%
Male	48,466,535	34.74%	3,764,061	34.49%
Unknown	2,641	0.00%	217	0.00%

Table 2

Percentage of Fills and Protected Class Drug Utilizing Beneficiaries by Race				
Race	2009		2010	
	Percent of Total Fills	Percent of Total Beneficiaries	Percent of Total Fills	Percent of Total Beneficiaries
White	83.42%	82.07%	83.11%	81.81%
Black	10.38%	10.91%	10.50%	11.00%
Asian	1.27%	1.59%	1.32%	1.64%
Hispanic	3.08%	3.50%	3.18%	3.57%
North American Native	0.53%	0.50%	0.54%	0.50%
Other/ Unknown	1.32%	1.44%	1.36%	1.49%

Table 3

Percentage of Fills and Protected Class Drug Utilizing Beneficiaries by Age Group				
Age Group	2009		2010	
	Percent of Total Fills	Percent of Total Beneficiaries	Percent of Total Fills	Percent of Total Beneficiaries
< 65	40.41%	30.70%	40.79%	30.98%
65 - 74	26.91%	31.25%	27.20%	31.64%
75 - 84	20.44%	24.04%	20.00%	23.60%
85 - 94	10.98%	12.49%	10.75%	12.28%
≥ 95	1.27%	1.51%	1.26%	1.50%

Table 4

Number of Beneficiaries Who Used One or More Protected Class Drug (GPI 10) by Protected Drug Class in 2009						
Protected Drug Class	% of Beneficiaries with 1 Drug	% of Beneficiaries with 2+ Drugs	% of Beneficiaries with 3+ Drugs	Beneficiaries with 1 Drug	Beneficiaries with 2 Drugs	Beneficiaries with 3 Drugs
Anticonvulsants	83.72%	16.28%	2.94%	3,226,445	514,204	91,976
Antidepressants	77.07%	22.93%	4.17%	5,435,503	1,322,846	242,660
Antineoplastics	95.54%	4.46%	0.22%	684,177	30,365	1,503
Antipsychotics	78.47%	21.53%	5.15%	1,891,539	394,986	89,632
Antiretrovirals	18.55%	81.45%	57.00%	21,371	28,172	36,118
Immunosuppressants	83.30%	16.70%	1.05%	75,326	14,143	902

Note: % of enrollees with 2+ and 3+ drugs are not mutually exclusive.

Table 5

**Number of Beneficiaries Who Used One or More Protected Class Drug
(GPI 10) by Protected Drug class in 2010**

Protected Drug Class	% of Beneficiaries with 1 Drug	% of Beneficiaries with 2+ Drugs	% of Beneficiaries with 3+ Drugs	Beneficiaries with 1 Drug	Beneficiaries with 2 Drugs	Beneficiaries with 3 Drugs
Anticonvulsants	83.85%	16.15%	2.93%	3,547,979	559,057	100,698
Antidepressants	76.80%	23.20%	4.23%	5,746,234	1,419,869	261,063
Antineoplastics	94.96%	5.04%	0.28%	701,100	35,198	1,945
Antipsychotics	78.72%	21.28%	5.14%	1,943,368	398,506	91,104
Antiretrovirals	20.69%	79.31%	56.33%	25,740	28,574	39,263
Immunosuppressants	84.24%	15.76%	0.90%	83,961	14,807	858

Note: % of enrollees with 2+ and 3+ drugs are not mutually exclusive.