

Part D Protected Drug Class

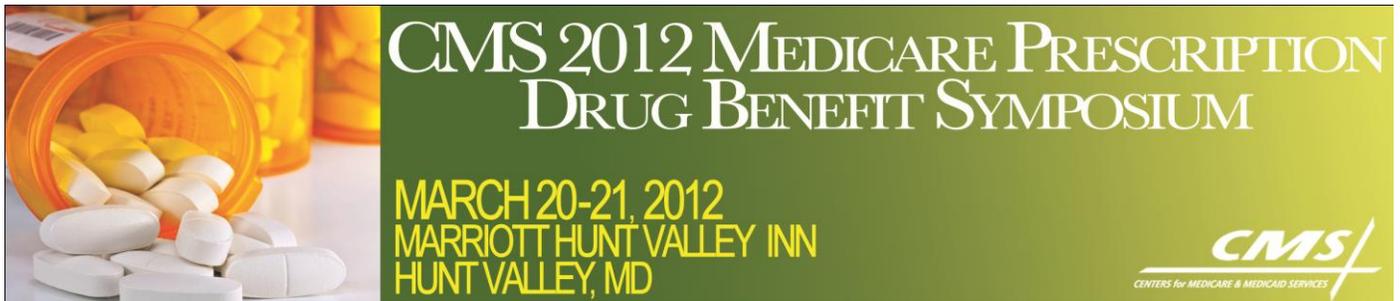
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My name is Monica Reed. I work in the Medicare drug benefit group in the division of formulary and benefit operations. My division is primarily responsible for formulary review process. We also do the formulary reference file and Part D plan benefit package review. Before I get started talking about the Part D protected class drugs, I'd like to acknowledge someone. Lu Ping Qu, his analytical work was really essential to this presentation, so I just wanted to take a moment and acknowledge him. So I do have two learning objectives, and the first is that by the end of the presentation, you be able to identify the percentage of Part D drug costs that were attributable to protected class drugs for 2010, and secondly, that you be able to identify the percentage of all fills of protected class drugs, represented by the top three most frequently prescribed protected drug classes for 2010.

So I'd first like to just do an overview of what I'll be talking about. I'm going to start with an overview of the protected class drug requirement, and talk about the policy, and then talk a little bit about how we address that policy in our formulary review process, and then we'll talk about the actual protected class drug utilization, starting out with more general utilization, and then moving into utilization of the top five protected class drugs and drug classes. And then we'll end with a discussion about some of the beneficiary characteristics such as race and gender.

So starting out talking about the protected class policy, the protected class policy has really been in place since the beginning of Part D. Originally its populations were moving from other programs into Part D. It was really essential to ensure that there was a continuity in care, and also that these beneficiaries continued to have access to medications that they were stabilized on. And so CMS was tasked and is tasked with the responsibility to ensure that beneficiaries reliant on these drugs continue to have access to them, and that they would not be substantially discouraged from enrolling in certain Part D plans. As a result, in 2005, CMS issued guidance requiring the inclusion of a vast majority of drugs in these six protected class formularies on sponsor formularies.

The selection of these classes was really based on a combination of things, and I'm going to discuss some of them. It's not exhaustive, there could be other reasons, but some of them included the concern that interruption of therapy in these--of drugs in these classes could really cause a significant negative outcome, especially short-term interruption of therapy. Also, the vulnerability of beneficiaries with the disease states associated with these drugs was concerning, and also at the time, a review of commonly used formularies for other programs actually show that there was pretty wide access to the drugs in these classes. In addition, at the time, ten of the top 15 are HCC diagnostic groups, and this is a diagnostic classification system that groups diagnosis codes into different condition categories. So at the time, ten of the top 15 were actually treated by drugs in these six protected classes, and so that really further supported the need to ensure access to these drugs.



So I'm now going to talk a little bit about chapter six, and I'll talk a little bit about it now, and then we'll come back to it. But for the benefit of those of you who don't know, the prescription drug benefit manual, the Part D manual as we call it, provides policy and operational guidance based on current Part D regulations, and chapter six specifically addresses Part D drugs and formulary requirements, and then section 30.2.5 in particular discusses protected class drug requirements. And as you can see here, the requirement is that formularies must include all or substantially all drugs in the six protected classes and those classes are anti-convulsants, anti-depressants, anti-neoplastics, anti-psychotics, anti-retrovirals and immunosuppressants for prophylaxis of organ transplant rejection.

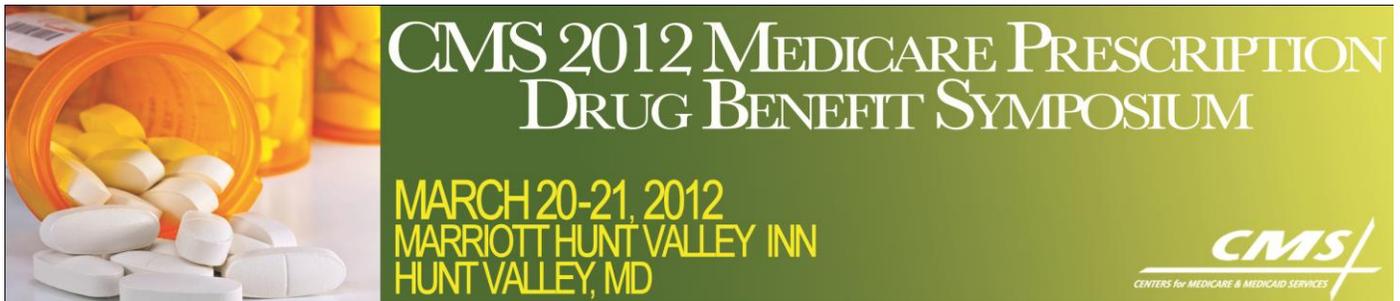
So I'd now like to discuss a little bit about the MMA and ACA and then we'll go back to chapter six. It was the Medicare Modernization Act that set forth the key requirements that relate to the approval of proposed plans, based on plan design. It essentially gave CMS the responsibility to assure that plans provide clinically appropriate medications and that they don't discriminate against particular types of beneficiaries - particular types of beneficiaries, such as those vulnerable populations taking medications in the six protected classes. Through the CMS formulary and benefits review process, and I'll talk in more detail about the formulary review piece of it, but through those processes, CMS has exercised its authority to ensure that Part D plan formularies and benefits are being administered consistent with CMS policy and that they don't discourage enrollment by certain Part D eligible individuals.

So now I'm going to talk a little bit about the Affordable Care Act. The Affordable Care Act further codified formulary requirements with respect to the inclusion of certain categories and classes of drugs. It states that generally, plans are required to cover Part D drugs in the six classes of clinical concern. However, there may be exceptions established by the secretary that would permit a sponsor to exclude a Part D drug in one or more classes from their formulary or to apply certain limitations to protected class drugs, and that would be such as prior authorization or other utilization management tools.

Until exceptions are established, the current classes that I previously mentioned are required. Exceptions would be established through a regulatory process, and that would include public notice and a comment period. So I'd now like to go back to chapter six, because chapter six provides guidance specifically related to protected class drugs and formulary submission requirements. There are requirements that are related to both upcoming contract years and then also new drugs or newly approved uses in the protected classes that occur during the contract year. And so I thought it would be helpful to go through examples of both of these situations.

For the upcoming contract year, formularies must include substantially all drugs in the six protected classes by the last CMS upload date for that upcoming contract year. So for example, for contract year 2013, we recently released the formulary reference file for 2013 on March 16, and contract year 2013 formularies are due on April 16. So even new protected class drugs that are included on that March 16 formulary reference file release will need to be added with that initial April 16 submission.

So for new drugs or newly approved uses for drugs in the protected classes, they are subject to an expedited review that must occur within the first 90 days of market release, and the drug must be added by the end of that 90 day period. And so an example of this, and this is an example that we provide plan



sponsors in a memo we release, would be if there were a protected class drug that was available on the market on May 12 of 2012, the P&T committee must review the drug, and they'd be reviewing it to determine tier and applicable utilization management, and they would add it to the formulary by August 10 of 2012. If the P&T does take the full 90 days, the drug must be covered at the pharmacy starting on August 10, and then it would be added to the HPMS formulary file at the next monthly submission, which in this case would be September 4 through the 6th. So hopefully that gives you kind of an idea of how it works when we're working on a future contract year versus the current contract year.

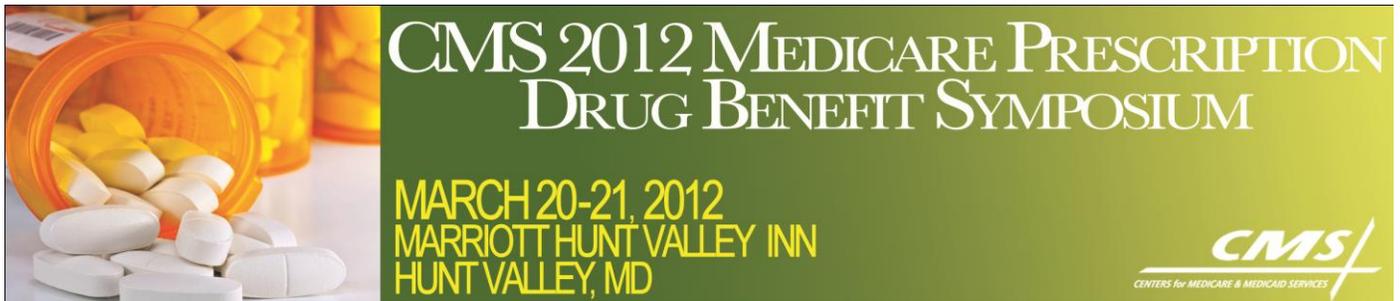
Unfortunately, in spite of these timeframes, we do continue to see plan sponsors not add these drugs to their formularies, and that does result in suppression of the Medicare plan finder. So I'd like to continue with chapter six. It also provides information about utilization management for protected class drugs, and this is important because there is a difference between what kind of utilization management can be applied to protected class versus non-protected class drugs. Plan sponsors cannot implement utilization management that attempts to steer beneficiaries to use formulary alternatives, and specifically beneficiaries that are currently taking the medication are actually grandfathered from any prior authorization or step therapy requirements.

In addition, HIV and AIDS medications, no utilization management can be implemented on those. That being said, Part D sponsors can still apply, B versus D where applicable, if they're trying to determine appropriate payment. However, the B versus D determination shouldn't cause a significant interruption in therapy.

And lastly, protected class drugs are still subject to concurrent drug utilization requirements, as these requirements really ensure safe and appropriate use of these medications. So I'd now like to talk about the formulary review process, so that I can discuss how we actually address this protected class policy in that process. So to ensure that Part D formularies meet the requirements that I've discussed, we've established this review process, and every formulary undergoes this process, prior to the effective date of that formulary.

Formulary inclusion of protected class drugs occurs with the initial formulary review, which is prior to the start of the contract year. So we do the review then, and then we do subsequent reviews with each submission. The initial formulary review takes process in several stages. CMS initially reviews for protected class drugs starting in stage one, and then as I mentioned, subsequent reviews are completed each month, and we do those subsequent reviews to ensure that these drugs continue to be included on the formulary. And as I discussed earlier, after the start of the contract year there are open submission windows each month, and that would be to make formulary updates such as to add new drugs, or to make approved changes, and it's also during this time that protected class drugs that meet that 90-day requirement must be added to formularies.

These checks are necessary, because as I previously mentioned, in spite of this guidance, we do continue to see formularies submitted without these required protected class drugs, and failure to add these drugs during the required timeframe does result in the drug not being viewable on Medicare plan finder, and therefore the formulary would be suppressed.

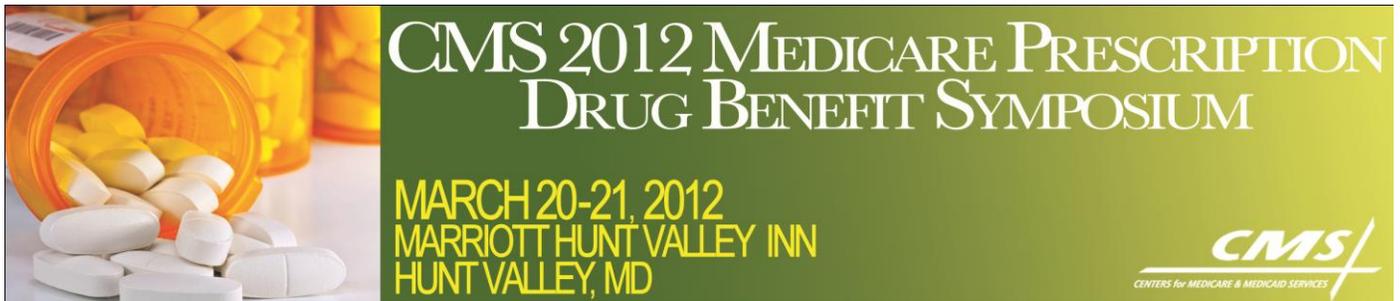


So now we can start talking about protected class drug utilization, and before I get into the more specific data, I thought it would be helpful to give you an overall idea of utilization of the six protected classes. Approximately 40 percent of all Part D enrollees used at least one drug in any of the six protected classes, and that was during 2010. When looking at the total number of fills for protected class drugs, they accounted for 13 percent, and there were three classes that actually accounted for 94 percent of that 13 percent, and I'll talk about this a little bit more later, but they were the antidepressants, the anticonvulsants, and the antipsychotics. Protected class drugs accounted for 18 percent of the total Part D drug costs, and later in the presentation I'll discuss that actually it was one specific drug class, the antipsychotics, that accounted for 40 percent of the protected class costs.

I'll also discuss a little bit later multi-drug use within each of the protected classes, but generally speaking, with the exception of antiretrovirals, most beneficiaries did use one drug within a specific protected drug class. So the next few slides provide some of the methodology. This is the data sources that we used. We used prescription drug event data, PDE data, and for the data that you'll see from 2009 and 2010, that PDE data was as of May 2011. We also did a trended analysis that I'll show you from 2006 through 2011, and that was PDE data current as of January 2012.

And then drug information and related drug identifiers we pulled from Metaspan and First Data Bank. So now I'd like to talk about how we compiled our universe of protected class drugs. We started the process of retrieving this data by identifying reference NDCs, national drug codes, from the drugs in our protected class formulary review check. So when I was talking about that stage one review, that check that occurs, that's where we actually started compiling the reference NDCs from. I should note that antineoplastics such as Elodea that are covered under Part B were actually excluded from the analysis. So by using the RXQE and the related NDC our formulary reference file and our protected class drug review, we were able to identify all NDCs representing those drugs. And then we went and identified the generic product identifiers, and I apologize, in your printed slides it may say indicators; it should say identifiers, GPIs. So we then took those reference NDCs and mapped them back to GPIs. And we did that at the GPI 10 level, and so I thought it might be helpful to talk a little bit about GPI, since the analysis was based on that. GPI is a classification system. It defines pharmaceutically equivalent products. The GPI has 14 digits, and products that have the same exact 14 digits are identical with respect to their active ingredients, their dosage form, route, and their strength or concentration.

And so the first two digits in the GPI 14 represent the drug group, so say, for example, antidepressants. And then the drug descriptors get more specific as you increase by two digits until you get to the GPI 14. And so as I mentioned, this analysis was done at the GPI 10 level, and so at that level we captured the drug group, the class, the subclass, the name and the salt. And so it did not capture dosage form or strength, and what that means is later on, when we're looking at the specific drugs, and you'll see Gabapentin, that means that at Gabapentin we included all the strengths and the dosage forms in that, when we accounted for the utilization.



And once those GPIs were identified, we then pulled all possible NDCs linked to those GPIs and we created the dataset of available protected class drug NDCs. So next, for the PDE, we used the PDE to determine the number of beneficiaries who utilize protected class drugs, the total gross drug cost, and the number of fills, which were adjusted for 30 day equivalents. And the 30 day equivalent adjustment is pretty standard. It's if the day's supply was less than or equal to 34 days, it was considered equal to one month, and if the day's supply was more than 34 days, then the days of supply were divided by 30. And then we used the common Medicare environment to pull beneficiary characteristics such as gender, age, and race.

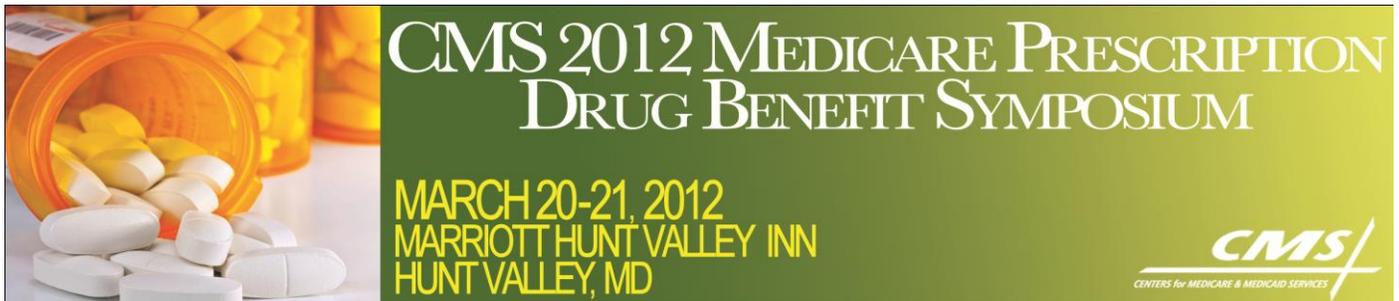
So now we can get started talking about utilization. This slide includes some of the information that I actually talked about in the overview slide for 2010, but in addition to the 2010 utilization it also includes information for 2009, and as you can see, the cost in the utilization varied slightly, but was fairly similar in 2009 and 2010. So now that we have a general idea of how much utilization is occurring, I'd like to take a look at the specific drug classes. And so this graph shows the percent of total fills by protected drug class. The percent of total fills here, out of total fills for protected class drugs; I'd like to mention not the total fills of Part D drugs.

And so as you can see, the antidepressants were the most highly utilized protected class for beneficiaries who utilize protected class drugs. Antidepressants were actually 50 times more likely to be utilized than immunosuppressants, which were the least utilized protected class, and about two times more likely to be utilized than the second highest utilized class which was anticonvulsants.

And again, there were three classes that accounted for 94 percent of all protected class drug utilization, and those were the antidepressants, the anticonvulsants, and antipsychotics, leaving antineoplastics, antiretrovirals, and immunosuppressants to account for only six percent of protected class drug utilization. In addition, you can see that there really is very little variance in the percentage of fills for protected class drugs or protected classes between 2009 and 2010.

And now that we have an idea of how much these drug classes are being utilized, we can take a look at cost. And so this is the percent of total drug costs by protected drug class, and as you can see, the drug class that made up the highest percent of fills does not necessarily equate to the drug class that accounts for the highest cost of protected classes. While antipsychotics have the third highest percentage of fills that was about 17 percent in 2010; it's the protected class with the highest percentage of total cost, about 43 percent in 2010. And antipsychotics, antineoplastics, and antiretrovirals all have a high share of percentage protected class drug costs as compared to their share percentage of fills. And conversely, antidepressants, which had a high percentage of total fills, was about 50 percent in 2010, actually only accounted for 13 percent of the total drug cost in 2010.

So now I'd like to actually go to a more granular level and look at specific drug utilization. This chart represents utilization ranked by total protected class drug fills, and it's for the top five protected class drugs. And again, this is out of total fills for protected class drugs. As illustrated in the slide, these top five are generally consistent with the classes that were in the top percent of fills that we discussed on slide 19, however, as you can see, Gabapentin was the most highly utilized drug, more than any single



antidepressant. I'll discuss this a little later but it's not unlikely that Gabapentin is so highly utilized because of its many off and on label indications.

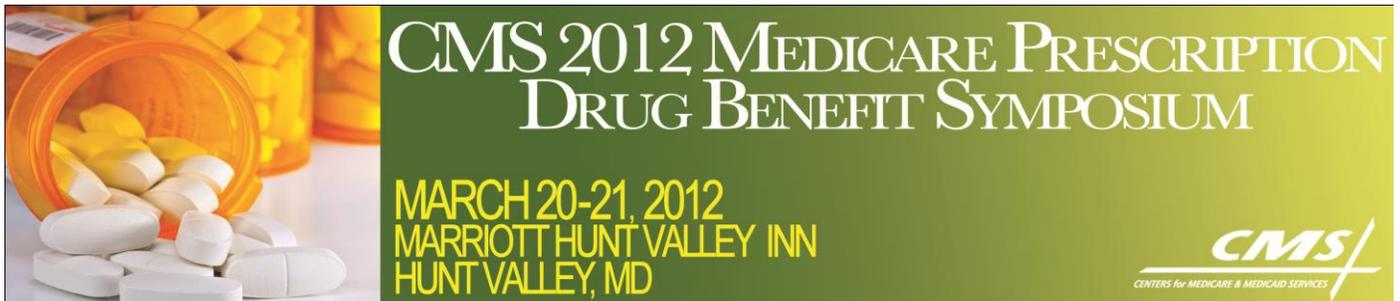
The next four most highly utilized protected class drugs are antidepressants, specifically selective serotonin reuptake inhibitors, SSRIs, making up almost 30 percent of the total fills for protected class drugs. So this is looking at utilization of the top five protected class drugs, ranked by cost, and once again, the drug with the highest percentage of fills does not necessarily equate to the drug that accounts for the highest cost in the protected class. As can be expected, based on antipsychotics leading the percentage of total drug costs, by protected drug class, antipsychotic drugs dominate the top five protected class drugs when ranked by cost.

From this data, it's pretty clear that the highest total drug cost is more greatly determined by the cost of the individual drug rather than the utilization of that drug. For example, again, Gabapentin, which is the most highly utilized drug, actually ranks fifth when ranked by cost, whereas the top three antipsychotics we have here, when ranked by cost, actually only account for 5.5 percent of the total fills for protected class drugs in 2010, and only the antidepressant drug Duloxetine and the anticonvulsant Gabapentin, once again the most highly utilized drug, manage to place fourth and fifth in protected class drugs when ranked by cost.

So now I'll take a look at some trended data. This is trended total gross cost and total number of fills, and it's from 2006 through 2011, and this slide also shows the total Part D enrollment by year at the bottom there. So to take a look at what was happening over the course of the years, I looked at the rate of change of cost of fills, and also the utilization per beneficiary. And so in the end, cost was actually relatively stable. The actual cost per fill increased slightly at times, but it was usually hovering around about \$115 per fill.

There has, however, been an increase in the number of fills per beneficiary. The number of fills per beneficiary progressed from an average of about three fills per beneficiary in 2006 and then increased to 4.6 fills per beneficiary in 2011. Now we don't have any additional data that can help explain why this is. This is really an area where further research is necessary. We can speculate that possibly beneficiaries are adhering better to their regimens, so the compliance is better, or possibly they're being diagnosed with additional disease states that's requiring the use of more drugs. At this point we really can't tell. So as I mentioned, it's really an area that's interesting for further exploration.

So I'd like to mention that these next few slides, I'm going to just speak to them at a high level. There is an appendix at the end of the presentation that has more details about gender and race and the age grouping, if you'd like to view those. But when looking at protected class drug utilization by gender and race, protected class drug utilization was consistent between 2009 and 2010. Females and white beneficiaries disproportionately count for a higher level of drug utilization; however their utilization is actually proportional to gender and race distribution of enrollment. And again, tables one and two in the appendix do provide additional information.



So we next looked at protected class drug utilization by age group, and we found that the highest percentage of total fills actually occurred in beneficiaries that were less than 65 years of age. This population accounted for 30 percent of the total number of beneficiaries who utilized protected class drugs, and they utilized 40 percent of the total fills for protected class drugs. And if you'd like additional information about how we grouped the ages, table three actually provides that in your appendix.

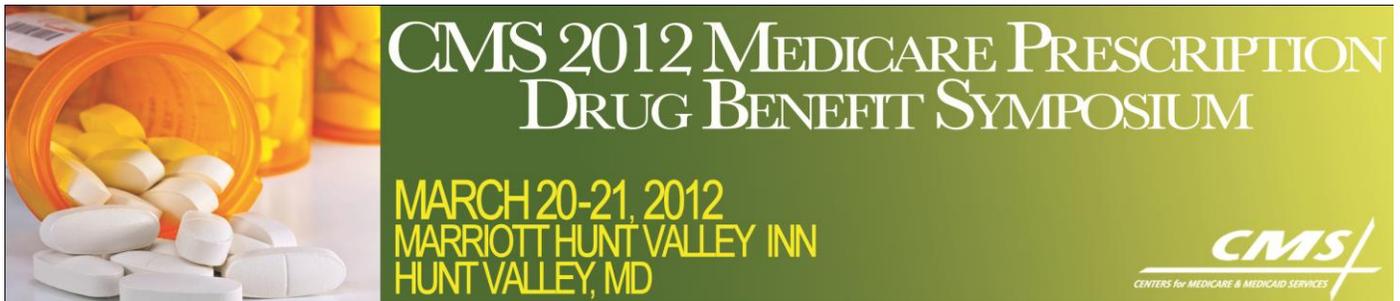
So this slide talks about average utilization per beneficiary, and I'd like to point out that previously when we looked at that trended chart, the trended data I talked about, it talked about overall number of fills, and this is actually number of fills per beneficiary. So this information pertains to the individual, to individuals that took protected class drugs.

And as you can see, the average utilization was consistent between 2009 and 2010, and when taking the total number of beneficiaries that utilized protected class drugs and in determining the average utilization--and this is again at the GPI ten level, beneficiaries utilized 1.7 and 1.8 distinct drugs and averaged 11.8 and 11.7 fills overall. So something else that we did was to take a look at the number of beneficiaries who utilized one or more protected class drugs within a specific class, and with the exception of antiretrovirals, as I mentioned earlier on in the discussion, in both 2009 and 2010, most beneficiaries only used one drug within a specific protected drug class. And as you can see here, all of the drug classes were well over 70 percent, with the exception of antiretrovirals, which I'm going to talk a little bit about when I discuss some of the considerations, and antiretrovirals was at 19 percent and 21 percent of beneficiaries using one drug within that protected class.

So before I highlight and summarize some of the more noteworthy aspects of the data, I wanted to talk about some things that really do need to be taken into consideration when looking at this data, the first of those being that we do need to recognize, as many of you are aware, that protected class drugs, many of these drugs, do have non-protected indications, and one example is Gabapentin, which is used for (inaudible) or other medically accepted neuropathic pain disorders.

We don't have the data to differentiate between fills based on those indications, therefore that utilization could include, does include, utilization of those indications, and we don't have a way to separate those out, so it is impacting the overall number. Secondly, the analysis to determine the number of beneficiaries who filled one or more protected class drugs was again completed at the GPI ten level, meaning all of the dosage forms and the strengths were wrapped into that.

And so as it was noted on the previous slide, that for 2010, 21 percent of beneficiaries that used antiretroviral drugs, actually used only one, and that is probably--this class, you would think it would be lower for antiretrovirals, based on treatment recommendations. And there are a couple of reasons for that, the first being that since this was completed at the GPI ten level, triple drug combinations, say like ATRIPLA, actually get counted as one drug. So instead of ATRIPLA being counted as that, three drugs, it's counted as one, and so that may be skewing that number a little bit.



And secondly, it may look like a claim for HIV when we look at the PDE data based on the drug, when it's actually possible that the beneficiary is being treated for something like Hepatitis B, which would explain that. And lastly, to determine the number of beneficiaries who utilized one or more protected class drugs, a multiple fill was actually considered a fill for a second agent that occurred at any point during that year, and so those numbers don't specifically represent overlap, or necessarily overlap; that second fill could have occurred at any point during 2009 or 2010.

So summary review, and many of this I covered in the overview slide also: there were over 130 million fills for protected class drugs, accounting for 13 percent of all Part D drug fills, and 18 percent of total Part D drug costs in 2010. In 2010, 40 percent of all Part D enrollees used at least one protected class drug. Antineoplastics, antiretrovirals, and immunosuppressants accounted for less than six percent of fills for protected class drugs, leaving antidepressants, anticonvulsants, and antipsychotics to actually make up 94 percent of fills for protected class drugs. The top five protected class drugs by fill account for over 40 percent of fills for protected class drugs in 2010, and the top five protected class drugs by cost actually account for over 30 percent of costs for protected class drugs in 2010.

And so it's now time to conduct the assessment, so if you can get out your ARS response cards, and again, as Dr. Tudor mentioned, we would encourage all of you to participate, and as a reminder, if you're seeking CPE credit, you must respond to all of the assessment questions. And again, after the questions and responses are read, you will have ten seconds to respond, and you'll see the timer on the screen.

And so the first question is--oh, and I'd like to actually make another note. This was actually updated from the slide that's in your printed slides, so if you could please read this question based on the screen, because it's slightly different. And the question is, what percentage of all fills of protected class drugs are represented by the top three most frequently prescribed protected drug classes for 2010. You can please vote now and you'll have ten seconds.

Okay, and I believe time is up. And I'm sure the answer was popping out at you because I mentioned it so many times, but it's 94 percent. And I will go to the second assessment question, and that question is, what percentage of the Part D drug costs were attributable to protected class drugs in 2010? And again, you can vote now, and you'll have ten seconds.

And time is up, and the answer to that is 18 percent, very good.

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