

**[Slide #1] Medicare – How It’s Changing to Help More People:
A Teleconference Series for Healthcare Professionals**

Coverage Determinations, Drug Utilization Management, and Medical Therapy Management

Tuesday, November 15, 2005
Noon, Eastern Time

Beth Witten: Hi. My name is Beth Witten and I'm the National Kidney Foundation's Medicare Modernization Programs Manager.

[Slide #2] The Kidney Medicare Drugs Awareness and Education Initiative was established to inform professionals and people with kidney disease about Medicare prescription drug coverage.

[Slide #3] Nearly 40 organizations representing patients, professionals of all disciplines, government and industry have participated in it.

We're glad you joined us today. And I'd like to welcome you to the fourth of six teleconferences that are part of this initiative. The series is entitled "Medicare: How It's Changing to Help More People."

[Slide #4] Our first teleconference as you probably remember described upcoming changes to Medicare and extra help for those with limited income and resources. Our second teleconference addressed how Medicare's new drug coverage will coordinate with other types of coverage that patients may already have. And our last teleconference discussed tips to help you help your patients choose a plan.

If you missed any of these teleconferences, you can find the transcripts, audio and the PowerPoint presentations on our Web site at www.kidneydrugcoverage.org. Look for the archived teleconferences and you'll find slides, transcripts, and if your computer has speakers, you can hear the presentation with synched sound and slides.

[Slide #5] Remember that starting today, anyone with Medicare can choose a Medicare drug plan, but please don't panic. Those with Medicare and Medicaid have until December 31st to choose a plan or stick with the one that Medicare has chosen for them. They're receiving yellow letters now telling them about Medicare's plan choice. Remember, they can keep that plan or they can change.

Everyone else has until May 15, 2006 to choose a plan if they need one. Those who spend a lot for drugs can start saving right away if they choose a plan by December 31st.

Our goal is to help people with kidney disease and kidney failure make the best decision about whether they need a Medicare Drug Plan. And if so, which plan will help them afford to take the drugs they need to live long, healthy, and enrich lives. We know that is what you want too. This teleconference series is one of the many ways that the Kidney Medicare Drugs Awareness and Education Initiative is working to meet that goal.

So let's get started. I'd like to introduce you to our moderator, Deborah Collinsworth. (Deborah) is a Social Worker with Dialysis Clinic, Inc. and a past Executive Committee member of the National Kidney Foundation's Council of Nephrology Social Workers. She's going to introduce our speakers. Deborah?

Deborah Collinsworth: Thanks, Beth, and welcome, everyone.

I'm excited to be here today to moderate this teleconference on exceptions and other coverage determinations.

[Slide #5] And with us today, we have Babette Edgar who is Director of the Division of Finance and Operations in the Medicare Drug Benefit Group for CMS; Aaron Eaton, pharmacist, also in the Division Finance and Operations for CMS; and Dr. Bryan Becker, a nephrologist and affiliate assistant professor, Division of Transplantation and associate professor of medicine at the University of Wisconsin.

So let's start by reviewing a little. Aaron, can you tell us what a formulary is and why we and our patients should care about plan formularies?

Aaron Eaton: Thank you, Deborah. I'm glad to be here today to talk about the Medicare prescription drug coverage. And formularies are a big part of that.

[Slide #7] A formulary is a list of drugs that a plan will cover. Plans do not have to cover all drugs however. Although the statute states that formularies must contain at least two drugs per category and class where two drugs exist, there were additional formulary requirements that CMS outlined to plans before they submitted formularies. If beneficiaries want to save money, they should look for their drugs on plan formularies.

Deborah Collinsworth: How did CMS review the plan formulary?

Aaron Eaton: **[Slide #8]** CMS looked at best practices in private plans, Medicaid, as well as the federal employees' health benefits program in developing a series of formulary checks. For example, we looked at the categories and classes that plan included on their formulary. We looked at the key drug types that were in the USP model guidelines.

We looked at tier placement of drugs within the formulary. We looked at drugs that were used in nationally accepted treatment guidelines, as well as utilization management pool such as quantity limits, prior authorization and step therapy.

[Slide #9] CMS gave plans the flexibility in developing their formularies, yet to make sure that the beneficiaries could get the necessary drugs they needed at an affordable price. The overriding goal was that the plan design could not discourage any groups of Medicare beneficiaries from enrolling in a specific plan.

Medicare Drug Plans can use any method of categorizing or classifying drugs on their formulary. However, plans that followed formulary classes and categories established by USP past CMS' first discrimination test if they included drugs per category and class.

CMS also reviewed tier placement of drugs on the formulary along with the benefit design. Again, we wanted to make sure that any particular individual was not discriminated against.

As far as formularies are concerned, plans can change the drugs on their formulary during the course of the year. However, if they choose to do this, they have to either give 60 days notice to affected beneficiaries or provide the beneficiaries with the 60 days supply of the drug when someone gets a refill. These changes must be approved by CMS before they can take effect.

Deborah Collinsworth: **[Slide #10]** Patients that have a chronic illness such as high blood pressure, asthma, diabetes, or kidney disease should make sure that the drugs they made to control their illness are on any plan's formulary before they would join that plan. If some drugs that they made are not on the plan's formulary, then what should we advise the patients to do?

Aaron Eaton: First, I'd like to say that Medicare Drug Plan formularies are very robust. Given the number of available plans we do expect that most drugs will be on formularies. If a beneficiary would encounter an instance where a prospective plan does not include a particular drug, the patient should use the plan's exceptions process to help get this drug to be considered a formulary drug.

Deborah Collinsworth: Can you review for us what drug categories must be covered and which ones can be excluded?

Aaron Eaton: **[Slide #11]** Sure. All or substantially all of certain categories of drugs must be covered on formularies. These would include antineoplastics, drugs that treat HIV, antidepressants, anti-psychotics, anticonvulsants, and immunosuppressives to prevent rejection of transplanted organs. However,

Medicare Drug Plans are not required to cover every brand name or all dosage forms of these drugs.

[Slide #12] Drugs excluded from the standard Medicare drug plan—this is a very long list and I’ll go through them quickly—would include drugs when used to treat anorexia, weight loss or weight gain, fertility drugs, drugs when used for cosmetic purposes such as hair growth, drugs when used to - cough or cold, non-prescription or over-the-counter drugs, barbiturates and benzodiazepines, and any vitamins or minerals except for pre-natal vitamins, fluoride preparations or vitamin D analogs.

Enhanced plans may cover these excluded drugs. Enhanced plans are Medicare Drug Plans that offer more benefits or pay more of the cost share than the standard Medicare Drug Plan usually at a higher premium for beneficiaries.

[Slide #13] The Medicare Prescription Drug Improvement Modernization Act of 2003 gives Medicare Drug Plans lead way to decide which specific drugs to include in their formularies, the strength and dosage forms of covered drugs, and the types and levels of co-payments or co-insurance which will be required.

Deborah Collinsworth: Well, with so many drugs on the market today, Babette, how the plans choose which drugs to include on their formulary?

Babette Edgar: **[Slide #14]** Well, the MMA requires that plans have a Pharmacy and Therapeutics Committee or commonly known as P&T Committee which is made up mostly of physicians and/or pharmacists who make these decisions.

The committee must have at least one physician experienced in caring for the elderly or disabled and at least one pharmacist and a physician member who must be free of conflict with respect to the plan and pharmaceutical manufacturers.

[Slide #15] Plans may require other things besides co-payments for a beneficiary to get his or her usual drugs. Other requirements or limits on coverage may include things such as prior authorization, step therapy, quantity limits, mandatory generic substitution and/or therapeutic interchange. Another method of encouraging people to choose less expensive drugs is tiered cost sharing.

Deborah Collinsworth: We’ve heard that term “prior authorization.” What does that mean and how and when should someone request prior authorization?

Babette Edgar: [Slide #16] Well, if a plan requires prior authorization, it means that the patient or the beneficiary must obtain approval from the plan before the plan will pay for the drug.

PA or prior authorization is used for drugs that are on the formulary. The PA processes can be different for each plan. They are usually initiated at the pharmacy when a patient gets their prescriptions filled. The pharmacist or physician will be asked for additional patient information in order to determine whether that patient or whether that drug is appropriate for the patient.

Prior authorization is good for the whole contract year so that this process does not need to occur again until January of the next benefit year.

Deborah Collinsworth: Dr. Becker, what will the doctors need to do if a plan requires prior authorization?

Bryan Becker: [Slide #17] Everyone should know that a physician must complete the necessary paperwork or make the necessary phone call to provide medical justification for use of a medication. If the plan agrees, the patient can receive medications through that plan.

However, sometimes the first time the physician note that a drug requires PA or prior authorization is when the pharmacist notifies him or her that the prescribed drug requires pre-authorization or prior authorization. In this case, the physician can call or sometimes write the plan so the patient can get the drug that he or she needs.

Deborah Collinsworth: I think step therapy required for some drugs on the Formulary Finder on the Medicare Web site. Babette, what is step therapy?

Babette Edgar: [Slide #18] When a plan requires step therapy, it means that the patient needs to try other drugs before the prescribed drug can be approved.

Deborah Collinsworth: Well, Dr. Becker, what should patients and staff think about if the plan requires step therapy?

Bryan Becker: [Slide #19] Step therapy may be acceptable in many cases especially if a new CKD patient or even an established dialysis or transplant patient has never been on a drug before.

Step therapy makes sense from a therapeutic and cost standpoint. But there are situations when this is not the most economical or effective means of treating the patient. This is especially true if step therapy requires the patient to switch from a therapy that has been effective. The patient should tell the physicians if the plan requires step therapy for a specific drug.

Deborah Collinsworth: Babette, what process can help new plan members who are already taking drugs that may not be on the formularies?

Babette Edgar: [Slide #20] Well, Deborah, all plans has to have a transition process. And CMS put guidance out to plans in March and subsequently all plans were required to submit their transition processes to CMS for approval.

What this transition processes look like for example would be that plans might provide a 30-day supply to those patients needing refills who didn't know that their drug was not on formulary. This would allow the patient time to either find out what other drug might work for them in conjunction with their physician and ask for a prescription for that drug or ask the physician to write medical justification to request an exception so that the patient can then get that drug.

Deborah Collinsworth: At last month's teleconference, we talked a little about tier cost sharing. Aaron, can you explain to us what this is?

Aaron Eaton: [Slide #21] When a plan has tiered cost sharing, it relates to the co-payments or co-insurances that someone would pay for drugs on a plan's formulary. And plans can have any number of tiers. For example, a three-tiered formulary would have approved generics at one tier, preferred brands on the second tier, and non-preferred brands or specific drugs on the third tier.

If a plan uses two or more tiers, the beneficiary should compare plans for the drugs they need to tier the drug they needed on and the co-payment required for each of those drugs. There may also be higher tiers for new or more expensive drugs. It's important to look not only at the tier level for a drug but the co-payment or co-insurance as well. For example, a co-payment for a Tier 3 drug on one plan maybe less than a co-payment for a Tier 2 drug on a different plan.

Tiered cost sharing and tiered co-payment plans are designed to encourage beneficiaries to use less expensive drugs. The beneficiary needs to know that the plans may move medications from one tier to another during the year. But again, like I said earlier, if a drug is moved to a higher tier, a plan must notify all affected beneficiaries and parties at least 60 days in advance. Additionally, CMS must review and approve this tier change at least 60 days before the effective date.

Deborah Collinsworth: Can you remind our listeners how the standard plan was established by law?

Aaron Eaton: [Slide #22] Sure. And the example I'll go over is one of the defined standards that's written into law. Certainly there are other types of benefit design options for plans to choose.

The beneficiary would pay \$250 deductible. Of the next \$2,000 in drug cost, the plan would pay 75% or \$1,500 and the beneficiary would pay \$500. Then there is a gap until the beneficiary pays \$3,600 plus their premiums. Above this amount, Medicare then pays 95% of their medication cost for the rest of the calendar year. Plans can vary from the structure as long as their plan was determined to be actuarially equivalent.

[Slide #23] I would also add the *Medicare & You 2006* booklet and the Prescription Drug Plan Finder and Formulary Finder available at www.medicare.gov show co-payments and co-insurance ranges for plans across the country. The range shows what costs are for drugs on different tiers including both generics and brands.

Deborah Collinsworth: Dr. Becker, what can a patient do if a drug is on the higher tier making it unaffordable to them?

Bryan Becker: [Slide #24] When patients join a plan, they should get a list of covered drugs from that plan. The drug list should include drugs both by class and by drug name alphabetically.

Patients should know the - should re-show the formulary to their physician and ask if there are more affordable lower tier drugs that they can take instead. If there are no acceptable lower cost alternatives, the patient or physician can request a tiering exception.

Deborah Collinsworth: Babette, can you explain to us what a tiering exception is? And also, what if a patient's drug is not on the formulary at all?

Babette Edgar: [Slide #25] Medicare drug plans—both the stand-alone Medicare Prescription Drug Plans called PDPs and Medicare Advantage Prescription Drug Plans called MA-PDs—must have an exceptions process for enrollees to request that a formulary drug be provided at a lower tier for cost sharing. And this is especially if their MD feels that the drugs at the lower cost share are not appropriate for this patient. Now this would reduce the co-payment that the patient would have to pay. The plans must also have a process for a non-formulary drug to be covered by the plan. There are rules for exception request.

Deborah Collinsworth: In a situation where the patient has worked closely with their physician to find the correct drug and dosage, it can be quite upsetting to have a Medicare Drug Plan object to providing that drug. Dr. Becker, what should a

patient do if the plan or pharmacist won't accept to do a different less expensive drug?

Bryan Becker: [Slide #26] This is an important question. Although some substitution may be very safe, certain conditions require the use of specific drugs to obtain the desired therapeutic benefit or result.

[Slide #27] Physicians should know that state law in 40 states allows a pharmacist to substitute a generic medication unless a physician checks no generic substitution on the prescription. Physicians also need to know if their state allows this. In some cases, drug substitution may not present any problem whatsoever. In other cases, generics or preferred brand name drugs that could be substituted may harm a patient. People with kidney disease need to pay attention to what their physicians prescribe and what the pharmacist fills and ask questions if these are different. Physicians and nurses should expect to provide medical justification when a medication the physician prescribes is not available on a patient plan formulary.

Deborah Collinsworth: So it's important that patients should know their rights and use them when they need to. The patients should ask their physician to provide information to the Medicare Drug Plan that will explain why they need that specific medicine. So how does the physician justify an exception?

Bryan Becker: [Slide #28] Patients need to be reminded once again that if the medication the physician prescribes is not on the formulary, they have the right to file a formulary exception with the plan to ask it to pay for that drug anyway. I have heard that some patients are reluctant to burden their physicians with this. However, physicians want patients to take the drugs they need and prescribe. The physician must provide medical justification for the non-formulary drug and state why other formulary drugs would not be as effective or would cause adverse consequences. But this is in the benefit...the best benefit of the patient if this is necessary.

In some cases, the patient may have previously tried other drugs but didn't control their condition or the patient may have had side effects from less expensive drugs. It is widely known that people with kidney disease do not do well on certain drugs and they should always avoid certain medications. The Network 8 Prescription Drug Demonstration project told CMS this very thing.

Deborah Collinsworth: [Slide #29] If the Medicare drug plan refuses the exception request, the patient does have the right to several other steps in an appeals process. Plans must tell the members these steps when they deny the exception request. We'll be discussing grievances and appeals in more detail during our next teleconference, *Medicare: How It's Changing to Help More People: Grievances and Appeals*, which will be held on December 20th. So put December 20th on your calendar right now.

Getting back to our panel, Babette, how long could patient have to wait to get the drug that he or she needs under this plan's coverage determination process?

Babette Edgar: [Slide #30] If the beneficiary has a serious health condition, the plan must make a coverage determination within 24 hours. Under standard coverage determination rules, a plan can make a decision within 72 hours. If the plan doesn't meet these deadlines, an independent review entity must review the request and decide.

Deborah Collinsworth: I would suspect that people with kidney disease and transplants would be considered to have serious health conditions and should know their decision in 24 hours. Aaron, what happens if the organization changes the plan's tiered structure during the year?

Aaron Eaton: [Slide #31] First, CMS must approve all changes in the plans formulary. Patients on noted drugs must have 60 days notice of the change. A plan's exception process must address their tiering exceptions process. Beneficiaries and their advocates need to know that if a plan has a tier structure that includes generic drugs, the plan does not have the covered non-preferred drugs at the generic drug co-payment level.

Further, if the plan maintains a fourth or higher tier, it went to places very high cost and unique items such as genomic and biotech products, beneficiaries cannot request an exception for drugs on this tier, often called the Specialty Tier.

The law leaves to a plan's discretion, whether it will require a patient to request exception every year or continue coverage after an exception has been granted into subsequent plan years.

Deborah Collinsworth: Aaron, can you remind our listeners why a patient should care what pharmacy that they get their drugs?

Aaron Eaton: [Slide #32] Sure. A preferred network retail pharmacy may offer some financial incentives through lower cost sharing than non-preferred pharmacies would. Non-preferred pharmacies can be used but this will result in a higher cost share for the same medication.

The way the plan is structured, it is likely the beneficiaries will be able to save money by using mail-order pharmacies. There are preferred and non-preferred pharmacies, as well as preferred and non-preferred mail-order pharmacies.

Deborah Collinsworth: We've had a lot of questions about transplant patients who have the Medicare Part B that pays for their immunosuppressant medication. These

patients, as well as those who don't have Medicare Part B for immunosuppressants may choose to get Part D drugs through specialty pharmacies that are used to work with kidney transplant patients. Babette, how will Part D plans work with specialty pharmacies that provide drugs for transplant patients?

Babette Edgar: Well, any pharmacy, including specialty ones like those serving people with specific health conditions such as organ transplants must contract with plans to participate with Medicare prescription drug coverage. CMS would advise anyone using a specialty pharmacy to check with the pharmacy or with the plan to see if that pharmacy is in the plan's network.

Deborah Collinsworth: Can you describe medication therapy management programs and who qualifies?

Babette Edgar: **[Slide #33]** Well, the MAA requires Medicare drug plans to have a Medication Therapy Management Program or what some people call MTM or MTMP. The law left the design up to each plan.

The MTM programs are targeted to beneficiaries with certain conditions that are expected to incur high drug cost, specifically those who have multiple chronic disease such as, but not limited to, diabetes, asthma, hypertension, hyperlipidemia and congestive heart failure; taking into account that plans can choose how many of those diseases and what diseases would be required for MTM programs.

The second criteria is that the patients must be taking multiple Part D covered drugs, and again, the plan can define what multiple means.

And then the third criteria is that the patients have to be identified as to that are likely to incur annual costs for covered Medicare Part D drugs. For this year, it would exceed—meet or exceed—the level of \$4,000 and that level could change as specified by the Secretary of Health and Human Services in the future.

Deborah Collinsworth: Well, I've heard that beneficiaries whose drugs costs are expect to exceed \$4,000 would qualify. If this is so, then this would probably include many of our dialysis and transplant patients. What services could they receive?

Babette Edgar: **[Slide #34]** Well, CMS found that best practices of MTM programs in private plans included education and counseling by pharmacists, developing a drug plan, and monitoring the effectiveness of drug therapy.

One example might be a brown-bag appointment where a pharmacist consults with a patient who brings in a bag of all their drugs for the pharmacist to

review and would offer tips on ways to remember to take them and track their use.

The MTM program would be offered at new cost to qualify beneficiaries as part of the plan's administrative cost. Medicare hopes to coordinate MTM programs and Medicare Drug Plans with other Medicare disease management programs.

Deborah Collinsworth: Thank you. In the time that we have left, let's take up some questions that people have sent us about Medicare Part D and the upcoming changes. These and other questions will be posted with answers on the Web site, www.kidneydrugcoverage.org.

Social workers have asked if prescribed renal vitamins can be covered. What should we tell them, Aaron?

Aaron Eaton: **[Slide #34]** Well, standard plans cannot cover prescribed or non-prescription vitamins. An enhanced plan, however, may cover them. Social workers can check with the plan to determine whether the vitamins would be covered under particular plans or not.

Since vitamins are excluded from Part D, the Medicare beneficiary cannot ask for an exception for a vitamin. However, if the patient has Medicaid, the state may pay for the vitamin; if not, the patient will need to pay for the vitamin out of his or her pocket so that he or she should ask the doctor what low-cost vitamin would be best. What the patient pays for vitamins won't count towards the patient's true out of pocket or true cost.

Deborah Collinsworth: A transplant patient doesn't have Part B coverage for her anti-rejection medication. She's taking CellCept, Neoral, and prednisone, plus other drugs that are not anti-rejection medicines. One of the drugs is a tier 1 drug, another is a tier 2, but a third is a tier 3. What could she do to get the tier 3 drug at a lower tier price?

Aaron Eaton: **[Slide #35]** She may want to check several plans to learn if any has CellCept or the tier 3 drug at a lower tier. She should check co-payments to see what she pay on all plans that cover her drugs.

Also, if she hasn't done so already, she should apply for extra help available to some beneficiaries. Social Security is accepting applications at www.socialsecurity.gov or 1800-772-1213.

Finally, she could ask her physician to write a medical justification for an exception to this tiering structure to get that drug at a lower cost.

Deborah Collinsworth: Well, that's about all the time we have for questions. As we wrap up, I'd like to ask Beth Witten to say a few words.

Beth Witten: **[Slide #36]** Well, I'd like to thank Dr. Bryan Becker, Deborah Collinsworth, Aaron Eaton, and Babette Edgar for sharing their time and expertise with us today.

[Slide #37] As we've said before, many times, although Medicare prescription drug coverage will help some people afford drugs they need, others may not need this coverage.

Most of what you read is for the average person with Medicare. The Kidney Medicare Drugs Awareness and Education Initiative and its participating organizations have kidney-specific information to help patients make and form decisions about whether to join a Medicare Drug Plan.

Those who now have or choose kidney-friendly plans will fair better than those who don't.

One way social workers can help their patients is to ask them to bring in notices they get from government agencies, employers, health plans, or even Medicare Drug Plan. You're going to explain these notices, see if any current coverage is creditable, help review options and keep a copy in case your patients need them later.

We want to thank you for joining us and helping us to inform patients who have Medicare about the new drug benefit. We hope this teleconference helped you understand more about coverage determination, drugs utilization management and medication therapy management program.

[Slide #38] We're planning more teleconferences ahead. Be patient. Our motto is the right at the right time.

[Slide #39] Our next teleconference will be on Tuesday, December 20th, and we'll discuss grievances and appeals. You can participate live at noon Eastern Time or access our teleconference later at www.kidneydrugcoverage.org

Under the November 15th teleconference date, you'll find a link to today's live, in a couple of weeks you'll find the transcript and audio presentation in the same place on the Web site. We'll be adding more to the Web site so check back regularly or register to get updates from us.

For attendance certificate, go to www.kidneydrugcoverage.org, look under today's conference date and complete the online evaluation. Check with your licensing agency to learn if you can get continuing education credit using the certificate.

Also, feel free to submit questions on this and future teleconference topics by email to info@kidneydrugcoverage.org. We'll be responding to those promptly.

Thank you for listening. We look forward to your evaluations and hope you will listen in on December 20th.

Goodbye and have a great day.