

**NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES  
MEDICAID PREFERRED DRUG LIST REVIEW PANEL MEETING**

**Tuesday, June 29, 2010, 10:00am – 12:00pm  
MINUTES**

Jane S. McKimmon Center  
NC State University  
1101 Gorman Street  
Raleigh, NC 27606

**I. WELCOME**

Dr. Lisa Weeks welcomed panel members and meeting attendees to the first N.C. Medicaid Preferred Drug List review panel meeting. Before introductions by the panel members and before the review of the procedures for the meeting, Dr. Weeks introduced the Department of Health and Human Services Secretary Lanier Cansler to address the meeting.

**II. SECRETARY CANSLER'S COMMENTS**

Secretary Cansler began by thanking the panel members for agreeing to participate. He explained that this is a very important organization as we begin to implement and manage the Preferred Drug List for the State of North Carolina. He expressed appreciation for the willingness of the panel members to serve from the different organizations from which they have been selected. Secretary Cansler took a few minutes to lay the groundwork for the current efforts related to the Preferred Drug List. He explained that for many years the State of North Carolina and the Legislature has avoided the implementation of a mandatory Preferred Drug List in North Carolina but because of the budgetary situation, there has to be a change in the way we do business. He pointed out two concerns that we have to deal with and the input, vision and experience of the panel members will be extremely important. We are in a tough budget situation and we are looking for ways to be more cost effective. In addition, there is a concern about unintended consequences. As we make decisions, we need to make sure we do not make decisions that may save us money in pharmacy but results in increased costs somewhere else. For example, we do not want to limit access that saves \$100 but results in \$5000 in ED costs. The panel was chosen because the members have the understanding to make the best decisions so that we make the right decisions on how we deal with the issues related to Medicaid.

Secretary Cansler explained that Governor Perdue is very focused on having transparency in government. This is the reason the panel was formed so that we can have open meetings and have input with respect to the issues and with what is going on in state government. The legislative language says the panel makes the recommendations to the Secretary on how we need to proceed so that we have cost effectiveness but do not have unintended consequences. Secretary Cansler expressed appreciation for the panel's efforts. The panel will be very busy over the next few months, because until the Preferred Drug List changes are implemented, the impact on the supplemental rebates by financial estimates is about \$3-4 million each month. We will be working to get some of the initial changes in rapidly with the panel's help. The panel will be involved over time with adjustments that may be needed. Secretary Cansler ended his comments by thanking everyone again.

### III. INTRODUCTIONS

Following Secretary Cansler's comments, Dr. Weeks provided information on the Preferred Drug List both historical and current. In March of this year, North Carolina joined the First Health Services National Medicaid Pooling Initiative allowing the state to begin collecting supplemental rebates in addition to the federal rebates provided under the Medicaid program. During the first phase of the PDL, all drugs were listed as preferred in order to collect additional rebates. During the next phase in developing the PDL, the State has to determine which drugs are preferred and non-preferred. The non-preferred drugs will eventually require prior authorization in order to shift use to the drugs that are most cost effective to the state. Even though a drug may be listed as non-preferred, Medicaid recipients must continue to have access to the non-preferred drugs but only through a prior authorization process. The Division of Medical Assistance received recommendations for the proposed PDL from the Pharmacy and Therapeutics committee of the N.C. Physicians Advisory Group following three separate meetings. The meetings occurred during the month of April: a shorter meeting was held on April 8 followed by longer meetings on April 22 and April 29. The committee used the expertise of the committee members as well as therapeutic class reviews provided by First Health Services, Oregon Health Science University's Drug Effectiveness Review Project final documents and clinical information submitted by the pharmaceutical companies that was provided during the open forums held by DMA. The proposed PDL reflects drug selections that are in the best interest of the state financially while at the same time deemed clinically appropriate. The purpose of this review is to conduct a public clinical review and provide recommendations back to the Department on the proposed PDL.

Dr. Weeks then asked the panel members to introduce themselves.

Note: Dr. Byron Hoffman, representative from the N.C. Chapter of the American College of Physicians and Dr. John Gilmore, representative from the North Carolina Psychiatric Association were unable to attend.

Dr. Mary Parker was present by telephone for Dr. Stefanie Ferreri, representative from the North Carolina Association of Pharmacists.

The members present at the meeting introduced themselves:

1. Dr. Robert Schotzinger, Representative from a Research-Based Pharmaceutical Company
2. Dr. Theresa Flynn, Representative from North Carolina Pediatric Society
3. Larry Cutchin, Representative from Community Care of North Carolina
4. Dr. Beat Steiner, Representative from Physician Advisory Group Pharmacy and Therapeutics Committee
5. Dr. Paul Bush, Representative from Hospital-Based Pharmacy
6. Dr. Cedric Bright, Representative from Old North State Medical Society
7. Dr. Robert (Chuck) Rich, Representative from North Carolina Academy of Family Physicians

### IV. PROCEDURES

Dr. Weeks reviewed the procedures to be followed during the meeting. The procedures shared were as follows:

The panel will not be reviewing drug classes for which all drugs are considered preferred. The panel will only be reviewing those drug classes for which there are decisions to be made regarding preferred versus non-preferred status.

1. First, registered speakers will provide their comments. It was requested that speakers state their name, affiliation and disclose any conflicts of interest. Dr. Weeks asked speakers to be mindful of the time limitations of this meeting. Dr. Weeks reserved the right to intervene in order to ensure the meeting continues to move forward in a timely manner.
2. Next, discussion on comments that were provided through the DMA website during the 30-day comment period will occur. The panel members have been provided these comments ahead of time. A brief summary will be provided and then Dr. Weeks will ask if there is any discussion on the comments.
3. The drug class reviews will begin next. Dr. Weeks will:
  - a. provide a brief description of the proposed decisions within the drug class.
  - b. ask for panel discussion on the drug class.
  - c. ask for a motion to approve as is or with stated changes.
  - d. ask for a second to the motion.
  - e. ask for a vote by all in favor raising their hands; all opposed raising their hands. I would like to request that panel members with any conflicts of interests regarding any specific drug class recuse themselves from voting.

#### IV. DRUG CLASS REVIEWS

The panel started the clinical reviews of the standard request form and the individual drug classes present on the agenda as follows:

##### 1. STANDARD REQUEST FORM

- No speakers were registered to speak.
- No comments were received during the 30-day posting period.
- Dr. Weeks explained that the form is to be used when the prescriber decides that the patient needs a non-preferred drug. The form includes a requirement for failure of two preferred drugs or only one if that is all that is in the class. It allows prescribers to indicate reasons why non-preferred drugs may be required. This form is also supported in the Smart PA automated approval system North Carolina Medicaid has in place for its prior authorization system.
- The panel discussed the use of the form and how a failure is determined. The form was developed with the intent that the prescriber will make the judgement regarding treatment failure. The information collected on the form will be monitored and collected for use in future criteria development. Dr. Steiner provided additional comments regarding the use of the form and input from the physicians on the P&T committee. The form was intended to be a simple form from a clinical perspective and the committee wanted to give physicians an opportunity to check any of the boxes on the form and then have DMA collect the information. Any box checked on the form would allow the physician to get access to the non-preferred drug. The use of the form and how it will be used with electronic prescribing was discussed and it was noted that the form would be available online. The turnaround time for decisions is 24 hours and is a federal guideline. The panel members discussed that the form is very similar to what is currently used by private insurers and that it is actually less complicated than most forms being used.
- First and second motions were made to approve the drug class as presented.
- Vote: 9 in favor; 0 opposed

2. ACE INHIBITORS
  - No speakers for this drug class
  - No comments were received during the 30-day posting period.
  - 95% of market share is in generics. The PDL reflects generics as preferred and brands as non-preferred.
  - The panel discussed the possibility that for less complicated reviews with little differences in the products, if it would not make sense to just move on. Comments included that the drugs listed as preferred are tried and tested drugs and there was no hesitation with the delineation brand versus generic present on the list.
  - First and second motions were made to approve the drug class as presented.
  - Vote: 9 in favor; 0 opposed
  
3. ACE INHIBITORS DIURETIC COMBINATIONS
  - No speakers for this drug class
  - No comments were received during the 30-day posting period.
  - 95% of market share is in generics. The PDL reflects generics as preferred and brands as non-preferred.
  - There was no discussion by the panel on this drug class.
  - First and second motions were made to approve the drug class as presented.
  - Vote: 9 in favor; 0 opposed
  
4. ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs)
  - There were two speakers for this drug class
    - Dr. Paula Miller – Boehringer Ingelheim (not present)
    - Dr. Julie Cave - Novartis
  - No comments were received during the 30-day comment period.
  - More than 60% of market share is in the proposed preferred drugs. The proposal is to require a trial and failure with an ACE inhibitor before going to the ARBs unless contraindicated. It is important to note that brand Cozaar is preferred over generic losartan. This is one of a few cases where it is in the financial interest of the state to prefer the brand over the generic product.
  - The panel discussed the clinical criteria and clarified the requirement of trial and failure, adverse events and clinical indications specific to non-preferred drugs. It was clarified that the criteria for the ARB drug class would allow for trial and failure of only one ACE inhibitor as well as allow for use of non-preferred agents with unique clinical indications noted on the standard request form. The panel considered evidence from clinical trials during the discussion.
  - First and second motions were made to approve the drug class as presented.
  - Vote: 8 in favor; 1 opposed (Dr. Robert Schotzinger)
  
5. ANGIOTENSIN II RECEPTOR BLOCKERS DIURETIC COMBINATIONS
  - No additional speakers for this drug class.
  - No comments were received during the 30-day comment period.
  - More than 50% of market share is with proposed preferred agents. The same clinical criteria are proposed with this drug class as with the ARBS. It is proposed to require a trial and failure with an ACE inhibitor before going to the ARBs unless contraindicated in a patient. It is important to note here that brand Hyzaar is preferred over generic losartan/HCTZ.

- Discussion included clarification on prescriptions written for generic losartan/HCTZ and the ability for the pharmacist to substitute the brand medication. It was clarified that pharmacists can automatically substitute the brand for the generic in these situations. The panel discussed that often patients on these medications may take multiple drugs to get to goal. Dr. Weeks offered to provide utilization data for patients using these medications showing those that are on monotherapy versus multiple therapies. This reporting will be provided as part of the future drug class reviews.
- First and second motions were made to approve the drug class as presented with a recommendation to provide utilization data on patients using monotherapy versus multiple therapy options.
- Vote: 8 in favor; 1 opposed (Dr. Robert Schotzinger)

6. ANGIOTENSIN II RECEPTOR BLOCKER CALCIUM CHANNEL BLOCKER COMBINATIONS

- No additional speakers for this drug class.
- No comments were received during the 30-day comment period.
- All products are proposed to be preferred. The same clinical criteria are proposed as with previous ARB classes – a trial and failure of an ACE inhibitor before going to one of these products.
- There was no discussion by the panel on this drug class.
- First and second motions were made to approve the drug class as presented.
- Vote: 8 in favor; 1 opposed (Dr. Robert Schotzinger)

7. DIRECT RENIN INHIBITOR

- No additional speakers for this drug class.
- No comments were received.
- All products are proposed to be preferred. The same clinical criteria are proposed as with previous ARB classes – a trial and failure of an ACE inhibitor before going to one of these products.
- There was no discussion by the panel on this drug class.
- First and second motions were made to approve the drug class as presented.
- Vote: 8 in favor; 1 opposed (Dr. Robert Schotzinger)

8. BETA BLOCKERS

There was one speaker registered to speak on Bystolic:

- Dr. Charles Cook – Raleigh Associated Medical Specialists

- No comments were received.
- Around 87% of the market share is with the generic products. The PDL reflects generics as preferred and brands as non-preferred. In this drug class, it would have been financially more favorable for the state to propose generic Toprol XL as non-preferred but for clinical reasons, the P&T committee and the Division decided that this would not be in the best interest of Medicaid recipients. This generic drug has adherence implications.
- The panel discussed the information provided by Dr. Charles Cook. There was discussion regarding the differences between the tolerability and outcomes with diabetic patients. Dr. Cook provided a general reference, a review article in the Journal of the American College of Cardiology, October 2009. Oregon Health Science University’s drug reviews for this drug class concluded there is not much difference in outcomes related to death and mortality. It was pointed out during the discussion that the standard request form would allow for use in patients with unique indications supported by the

FDA and peer-reviewed literature. The panel addressed the need for regular updates regarding input from the standard request forms and changes to the clinical literature impacting this drug class including quicker updates for issues related to safety.

- A first and second motion was made to approve the drug class as presented with a recommendation for DMA to provide as needed and regular (bi-annual) updates from the standard request forms and updates to the clinical literature related to this drug class. The panel requested that information provided to the Pharmacy and Therapeutics committee and the Drug Utilization Review committee that changes clinical policy be brought back to the panel. The panel would like quicker updates (not wait 6 months) for issues related to safety. The panel would like the updates to include clinical data that reflect the diversity of the populations for which we are making decisions.
- Vote: 8 in favor; 0 opposed; No vote from Dr. Mary Parker

9. PLATELET INHIBITORS

- There are 2 speakers registered to speak on Effient.
  - Dr. Joseph Rossi – UNC Hospitals
  - Julie Kivor – Eli Lilly and Company
- Comments were received from one cardiologist regarding Effient. Concern was expressed about the exclusion of Effient from preferred status.
- More than 98% of market share is with the proposed preferred products. The PDL reflects all products as preferred except Effient and brand Persantine. Brand Persantine has no market share. Effient’s proposed non-preferred status is due to indications that are specific to certain patient populations in order to reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndrome who are to be managed with percutaneous coronary intervention.
- The panel discussed the comments made by Dr. Rossi and the restrictions of Effient in place at UNC. Dr. Rossi explained that failure of clopidogrel prior to the use of Effient would put some patients at a disadvantage because they are in a high-risk group. UNC advises that interventional cardiologists are the only ones prescribing this drug. There was concern expressed that if this medication was listed as preferred, family physicians may interpret this status to prescribe Plavix or Effient equally and this would be a concern. Clarification was provided that approvals for prior authorization are patient specific and would carry forward to other providers that may be treating the patients. Clarification was also provided that the use of Effient would not require a trial and failure of clopidogrel if the prescriber indicated on the standard request form that the medication has a special indication. Dr. Cook commented that the proposal is reasonable if acute coronary syndrome patients can receive Effient in a 24-hour turnaround time if no proven failure is required.
- First and second motions were made to approve the drug class as presented.
- Vote: 9 in favor; 0 opposed

10. CHOLESTEROL LOWERING AGENTS (STATINS)

- There are 4 speakers that have registered to provide comments:
  1. Dr. Paula Miller – UNC School of Medicine (not present)
  2. Dr. AnnMarie Mazzocchi – Stokes Medical Associates
  3. Dr. Charles Cook – Raleigh Associated Medical Specialists
  4. Dr. Vicki Star – Merck & Company
- Forty-four comments were received from 22 individuals. Some of the issues raised were:
  1. oppose removal of Lipitor from preferred status

2. adverse effects on vulnerable populations reductions in heart attacks and strokes
  3. more evidence on primary and secondary prevention for branded products
  4. superior effectiveness of Lipitor and Crestor over generics
- Market share is 40% with generic simvastatin, 18% with Crestor and 34% with Lipitor. The proposed PDL status supports generic use over brand use. This drug class has clinical criteria for use of a brand statin which requires a two-month trial on the maximum tolerated dose of generic simvastatin. There are exemptions in the criteria for patients with contraindication, allergy or intolerable side effect to the generics and for patients with coronary artery disease who are currently receiving Lipitor 80mg, Crestor 20mg and 40mg and for patients with familial hyperlipidemia. There is also a proposed override at point-of-sale built into the process to allow for override by the pharmacist if “Meets PA Criteria” is written on the prescription by a prescriber.
  - The panel discussed patients that are on a high dose statin and that patients stable on a high dose statin would not be required to switch to a preferred agent. The panel discussed the clinical data that compares atorvastatin 80mg to pravastatin 40mg and that atorvastatin 80mg is a more potent statin compared to pravastatin 40mg. The panel discussed the importance of conducting evidence-based reviews. Atorvastatin has not been compared in head-to-head trials with any of the generic drugs at equivalent doses.  
The panel discussed that it would be advisable to include a transition for individuals that are already on statin therapy. Patients on high dose brand statins can continue to remain on those medications. The panel members discussed adding metabolic syndrome to the list of exemptions. In addition, the panel members reviewed the mechanism for the point-of-sale override that can be used by the pharmacist to override the prior approval requirement if “Meetings PA Criteria” is written on the prescription by the prescriber. This phrase can also be indicated on the comment block on e-prescriptions.
  - First and second motions were made to approve the drug class as presented with the recommendation that DMA include a six-month transition period into the implementation for those patients on statin therapy and to add metabolic syndrome to the list of exemptions.
  - Vote: 9 in favor; 0 opposed

#### 11. SYSTEMIC QUINOLONES

- There are 2 speakers registered to speak on the quinolones drug class:
  1. Jessica Geisler – Merck & Company
  2. Dr. Melanie Crain – Johnson and Johnson
- Comments were received from one physician favoring preferred status of Levaquin.
- Market share is around 50% for generic Cipro, Levaquin’s market share is about 34% and Avelox around 10%. The proposed PDL provides antimicrobial coverage for upper and lower respiratory tract infections with the preferred products.
- The panel discussed the dosing schedules for community required pneumonia and sinusitis. Evidence from clinical trials was considered by the panel during the discussion. Avelox preference was based on cost since sufficient antimicrobial coverage was thought to be provided with the proposed preferred agents. The panel questioned the frequency of change of the preferred agents. The panel discussed no more than annual changes to the preferred agents in the drug class. Dr. Weeks explained that financial review by the state are annual and the rebate contracts are for 3 years so DMA does not anticipate frequent changes to statuses.

- First and second motions were made to approve the drug class as presented.
- Vote: 8 in favor; 1 opposed (Dr. Robert (Chuck) Rich)

12. 2<sup>nd</sup> GENERATION CEPHALOSPORINS

- No speakers
- No comments
- Around 90% market share with generic products. Low utilization of cefaclor products. The proposed status of making generic and brand cefaclor non-preferred is related to the clinical implications of the side effects such as serum sickness.
- The panel discussed the fact that not all of the medications available in a drug class are listed on the PDL. The list only includes drugs for which supplemental rebates are available. Drugs that are not listed have open coverage with no restrictions.
- First and second motions were made to approve the drug class as presented.
- Vote: 8 in favor; 0 opposed; No vote by Dr. Mary Parker

13. MACROLIDES

- No speakers
- No comments
- More than 90% of market share with generic products. Does not include extended release products – around 1% with clarithromycin ER. The proposed drug statuses support use of generics over brands.
- The panel members discussed the absence of some of the generic macrolides such as erythromycin from the list. The panel discussed the need for DMA to work harder to communicate these omissions and the reasons why. DMA will need to include generics that are not part of the rebate program in order to assist prescribers.
- First and second motions were made to approve the drug class as presented with a recommendation to list all of the generic drugs available on the market.
- Vote: 8 in favor; 0 opposed; No vote from Dr. Mary Parker

14. NITROMIDAZOLES

- No speakers
- No comments
- 95% market share with generic metronidazole. Proposed drug statuses support the use of generics over brands.
- There was no discussion by the panel on this drug class.
- First and second motions were made to approve the drug class as presented
- Vote: 9 in favor; 0 opposed

The meeting was adjourned at 12:00pm.