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

Friday, August 20, 2010, 1:00 p.m. – 5:00 p.m.

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

I. WELCOME AND INTRODUCTIONS

Dr. Lisa Weeks welcomed panel members and meeting attendees to the third N.C. Medicaid Preferred Drug List review panel meeting and thanked them for their interest in the North Carolina Medicaid PDL development process.

Panel members introduced themselves. Dr. Robert Rich joined by telephone.

1. Dr. John Gilmore, Representative from N.C. Psychiatric Association
2. Dr. Theresa Flynn, Representative from North Carolina Pediatric Society
3. Dr. Lisa Weeks, Representative from N.C. Division of Medical Assistance
4. Dr. Beat Steiner, Representative from Physician Advisory Group Pharmacy and Therapeutics Committee
5. Dr. Byron Hoffman, Representative from N.C. Chapter of the American College of Physicians
6. Dr. Paul Bush, Representative from Hospital-Based Pharmacy
7. Dr. Cedric Bright, Representative from Old North State Medical Society
8. Dr. Stefanie Ferreri, Representative from North Carolina Association of Pharmacists
9. Dr. Robert (Chuck) Rich, Representative from North Carolina Academy of Family Physicians

II. OVERVIEW OF PANEL ACTIVITIES AND PROCEDURES

Dr. Weeks provided an overview of the procedures for the meeting.

The panel will not review drug classes for which all drugs are considered preferred with the exception of the anticonvulsants. In order to provide a comprehensive review of the anticonvulsant drugs, the presentation will include two anticonvulsant drug classes in which all the drugs are preferred. The panel will make decisions based on preferred versus non-preferred status.

For each drug class review:

1. Registered speakers provided comments. Speakers provided their name, affiliation and disclosed any conflicts of interest before speaking. Speakers were to be mindful of the time limitations of this meeting. Dr. Weeks reserved the right to intervene in order to ensure the meeting continued to move forward in a timely manner.
2. Dr. Weeks provided a brief summary of the comments received through the DMA website during the 30-day comment period. The panel members received a copy of

the public comments prior to the meeting. Panel members had an opportunity to discuss the comments.

3. Dr. Weeks provided a brief description of the proposed decisions for each drug class. An opportunity for discussion by the panel members followed. Panel members made first and second motions to approve the proposal as is or with stated changes. Panel members voted on the proposal with recommended changes, if any. Panel members recused themselves if they had any conflicts of interests regarding specific drugs or drug classes.

III. DRUG CLASS REVIEWS

1. URINARY ANTISPASMODICS

- Four speakers registered to speak for this drug class:
  - Dr. Scott MacDiarmid, Alliance Urology, Greensboro (Requested to have Toviaz available as a preferred product)
  - Dr. Barry Bodie, Pisgah Urology (not present at meeting)
  - Dr. Bradley Chotiner, Family Physician, Rockwell, NC (Requested to have Toviaz available as a preferred product)
  - Dr. Robert Matthews, Urologist, WakeMed Faculty Physicians (Requested to have Ditropan XL or oxybutynin ER and Toviaz available as preferred products)
- Ten comments were received during the 30-day comment period.
- 39% of the market share is with the preferred products. Detrol LA market share is 34.6%; oxybutynin ER market share is 18.8%. Toviaz market share is 1.5%.
- Discussion
  - The literature supports the fact that most drugs in this drug class have similar efficacies, but there is variability among patients.
  - A non-preferred product can be obtained without completion of the Standard Drug Request Form if the patient had prescriptions for preferred products in the past two years and the claims are in the Medicaid history so the SmartPA program can detect them. If the claim is not in the Medicaid history, the pharmacists will get an alert at point-of-sale saying, "Non-preferred product". A patient does not need to be on a preferred product for any specific length of time before getting a non-preferred product.
  - Spinal cord patients or a small subgroup of patients may require higher doses of oxybutynin ER. Physicians can complete the Standard Drug Request form justifying the need for higher doses of oxybutynin ER.
  - A comment was made regarding 18% of the market share is with oxybutynin ER. A comment was made that a long-acting formulation may not necessarily work better, but compliance is better.
- First and second motions were made to approve the drug class as presented.
- Vote: 7 in favor; 2 opposed (Dr. Cedric Bright and Dr. Stefanie Ferreri)

2. CHOLINESTERASE INHIBITORS

- No registered speakers for this class.
- No comments were received during the 30-day comment period.
- 96% of the market share is with the preferred products.
- There was no discussion by the panel.
- First and second motions were made to approve the drug class as presented.

- Vote: 9 in favor; 0 opposed

3. SECOND GENERATION ANTICONVULSANTS

- Nine speakers registered to speak for this drug class.
    - Dr. Robert Tanenberg, Brody School of Medicine
      (Consider removing restrictions on Lyrica)
    - Dr. Paul Chang, Sulphur Springs Health Center
      (Consider removing restrictions on Lyrica)
    - Dr. David Meyer, Triad Neurological Associates
      (Consider removing restrictions on Lyrica)
    - Dr. John Winfield, Appalachian Regional Rheumatology (not present at meeting)
    - Ms. Patricia Gibson, Epilepsy Information Service
    - Dr. John Wooten, Pediatric Neurologist
      (Consider making all products available to seizure patients)
    - Mr. Jim Mitchell, Epilepsy Foundation (patient)
      (Consider making all products available to seizure patients)
    - Dr. Kevin Rathke, Raleigh Neurology
      (Consider making all products available to seizure patients)
    - Dr. Howard Peckman, N.C. Division of Mental Health/Developmental Disability/Substance Abuse Services
- Fifteen comments were received during the 30-day public comment period.
- The first-generation anticonvulsants and the carbamazepine derivatives were included in the anticonvulsant review list, although all products in these two classes are preferred. The anticonvulsants on the N.C. Board of Pharmacy Narrow Therapeutic Index list are included in these two drug classes. They are provided in order to give a complete view of the anticonvulsants. 72% of the second-generation anticonvulsants market share is with the preferred products. The proposed PDL statuses support primarily the use of generics. This drug class currently has prior authorization criteria for Lamictal, Lyrica, Topamax and Trileptal. Patients who have a diagnosis of seizures are exempt from the PA criteria for Lamictal, Lyrica and Topamax. The P&T Committee recommended a six-month transition or grandfathering period for patients who are currently on an anticonvulsant. Pediatric patients under the age of 21 qualify for second medical review for any drug prior authorization process under the federally required EPSDT Program. N.C. legislation mandates the use of generic products unless the net cost of a brand medication is cheaper to the State of N.C. than the generic, then the brand product is preferred.
- Discussion
    - A comment was made regarding a distrust of generic products for patients who have seizures as well as confusion with the prior authorization process.
    - Regarding the PDL and prior authorization process, there are preferred and non-preferred products. Mandated by N.C. law, generics must be used if a generic is available. Therefore, Medicaid would expect to see that a patient tried a generic before using a brand product. In addition to the PDL, there are clinical criteria for Lamictal, Lyrica, and Topamax. These three drugs have exclusions for patients with seizure disorders.
    - If a patient is currently on a brand name product, they will be allowed to continue on the brand product because of the grandfathering that is allowed for this drug class.
    - A comment was suggested for the advocate groups to notify the N.C. Board of Pharmacy about the differences in the generic anticonvulsant products.

- A suggestion was made to allow physicians to write on the prescriptions "Meets PA Criteria" if the patient has a seizure disorder.
- For chronic pain issues, change the requirement to failure of one required drug instead of two drugs.
- A suggestion was made to exempt sub-specialist from the criteria. In opposition to this suggestion is that family physicians also treat patients with fibromyalgia. It will be difficult to classify who can prescribe these drugs.
- A comment was made to cover these drugs for epilepsy. The key is have they tried a preferred drug first. The best way to capture that patients previously tried a preferred drug is by completion of the drug request form. Federal law mandates that the prior authorization request must be responded to within 24 hours. Currently the statistics show a 100% compliance with this mandate. If for some reason there is a delay in the 24-hour response, patients can get a 72-hour supply, which is also a federal mandate.

- First and second motions were made to approve the drug class with the following recommendations:
  - Patients with seizures are exempt from the criteria for non-preferred and clinical prior authorizations.
  - For the use of Lyrica in patients with a diagnosis of neuropathic pain, failure of only one of the suggested drugs for 60 days instead two drugs.
  - Prescribers can write "Meets PA Criteria" on the prescription for patients with seizures.
  - Increase patient education and look for strategies to make the PA process less burdensome for the prescriber community.
  - Recommend education for patients with seizures who are on generic anticonvulsants and their physicians to request the same formulation of anticonvulsant medication each time they have it filled
- Vote: 9 in favor; 0 opposed

4. <u>ANTINARCOLEPSY AGENTS (NUVIGIL/PROVIGIL)</u>
   - No registered speakers for this class.
   - No comments were received during the 30-day comment period.
   - The proposal indicates Nuvigil and Provigil as non-preferred. These medications also have prior authorization criteria for their use. The criteria have been in place since March 2002 and no changes are recommended.
   - There was no discussion by the panel.
   - First and second motions were made to approve the drug class as presented.
   - Vote: 9 in favor; 0 opposed

5. <u>SEDATIVE HYPNOTICS</u>
   - No registered speakers for this class.
   - One comment was received during the 30-day comment period.
   - More than 80% market share is with the preferred agents. This drug class currently has prior authorization quantity limits when more than 15 units each calendar month are needed. The criteria apply to both preferred and non-preferred products. DMA recommends removing Somnote and Chloral Hydrate from the PDL because it is not in the current prior authorization program.
   - Discussion
     - A concern was regarding the use of the preferred products in the older adult population due to falls and hangover drug effect. Generic Sonata or Lunesta

seem to work better in this patient population. The non-preferred products can be obtained by completing the PA request form.

- First and second motions were made to approve the drug class as presented.
- Vote: 8 in favor; 0 opposed (Dr. Gilmore temporary left the meeting.)

INJECTABLE HYPOGLYCEMICS

The next several drug classes are the injectable insulin products. Six comments were received for this class primarily regarding the insulin pens as non-preferred agents. It was proposed to place an exemption for use of the pens and cartridges in recipients who are less than 21 years of age. The N.C. Board of Pharmacy clarified through a written statement that in cases where the prescriber authorizes substitution, the pharmacist would not have to obtain a new prescription to dispense the vial-package insulin when a pen or cartridge-packed insulin prescription is written.

- Discussion regarding the public comments
  - A comment was made regarding a study that was done on the N.C. Medicaid population and a study that was done in a managed care organization. The cost savings around the use of the pens was impressive with the N.C. Medicaid patients in 2002, showing decrease in hypoglycemic episodes and an increase in adherence.
  - The initial criterion to give vials instead of pens was based on cost savings. Clinically the pens are just as effective as the vials. Most clinicians in clinical practice found that using the pens improves compliance, therefore improves the hemoglobin A1C.

6 - 11. RAPID ACTING INSULIN, SHORT ACTING INSULIN, INTERMEDIATE ACTING INSULIN, LONG ACTING INSULIN, PREMIXED COMBINATION INSULIN, PREMIXED 70/30 COMBINATION INSULIN

- One speaker that registered to speak for this drug class:
  - Dr. Mariola Ortiz, Sanofi-Aventis
    (Request to have Apidra available as a preferred product)
- 56% of the market share is with Humalog and Novolog vials.
- Discussion
  - The panel deliberated the clinical data provided in the public comments on healthcare costs and insulin pen use. The clinical references are provided:

    1. Lee WC, Balu S, Cobden D et al. Medication adherence and the associated health-economic impact among patients with type 2 diabetes mellitus converting to insulin pen therapy: an analysis of third-party managed care claims data. Clin Ther. 2006; 28(10):1712-25.
    2. Pawaskar MD, Camacho FT, Anderson RT et al. Health care costs and medication adherence associated with initiation of insulin pen therapy in Medicaid-enrolled patients with type 2 diabetes: a retrospective database analysis. Clin Ther. 2007; 29 Spec No:1294-305.

  - If there is not a huge difference in the cost of the pens, then the pens should be available as a preferred product.
  - A suggestion was to have one or two convenience products available as preferred products. In the event that one convenience product is considerably less expensive to the State than the other convenience products, then have only one convenience product available as the preferred product.
- First and second motions were made to approve the injectable insulin products with the following recommendation:

    - The panel recommends that one or two (if not cost prohibitive) options for pens in each subgroup of insulins be provided as preferred options. This includes the rapid-acting, short-acting, intermediate-acting, long-acting, and premixed combination products. (The exemption for patients less than 21 years of age will not be needed since pen/cartridge options will be available as preferred.)
- Vote: 9 in favor; 0 opposed

12. AMYLIN ANALOGS
- No registered speakers for this class.
- No comments were received during the 30-day comment period.
- Symlin and Symlin pen are proposed to have preferred status with prior authorization criteria in place. The proposed criteria require a trial and failure or insufficient response to metformin unless the patient has a contraindication or adverse event to metformin.
- Discussion
    - The SmartPA system can check for previous prescriptions of metformin.
- First and second motions were made to approve the drug class as presented.
- Vote: 9 in favor; 0 opposed

13. GLP-1 RECEPTOR AGONISTS
- No registered speakers for this class.
- One comment was received during the 30-day comment period.
- Byetta and Victoza are proposed to have preferred status with the same prior authorization criteria as the previous class.
- There was no discussion by the panel.
- First and second motions were made to approve the drug class as presented.
- Vote: 9 in favor; 0 opposed

ORAL HYPOGLYCEMICS

The next several drug classes are the oral hypoglycemic. Two comments were received during the 30-day comment period.

14. BIGUANIDES
- No registered speakers for this class.
- No comments were received during the 30-day comment period.
- 96% of the market share is with generic metformin.
- Discussion
    - A significant number of patients have gastrointestinal side effects with the generic formulation of metformin. If patients have intolerance to generic metformin, the brand product is available by completing the Standard Drug Request Form.
    - Another educational opportunity is that if a patient had GI side effects to generic metformin, it is recommended to try the brand metformin before moving on to other products.
- First and second motions were made to approve the drug class as presented.
- Vote: 9 in favor; 0 opposed

15. DPP-IV INHIBITORS
- One speaker registered to speak for this drug class:
    - Dr. Vicki Star, Merck and Co.

(In support of the proposed criteria)

- Januvia and Onglyza are proposed to have preferred status with prior authorization criteria. The proposed criteria require a trial and failure or insufficient response to metformin unless the patient has a contraindication or adverse event to metformin.
- Discussion
  - A suggestion was made to provide additional education regarding Brand Medically Necessary.
- First and second motions were made to approve the drug class as presented.
- Vote: 9 in favor; 0 opposed

16. DPP-IV INHIBITOR/BIGUANIDE COMBINATION

- One speaker registered to speak for this drug class.
  - Dr. Vicki Star, Merck and Co.
    (In support of the proposed criteria)
- Janumet is proposed to have preferred status with the same prior authorization criteria as with the previous class. The proposed criteria require a trial and failure or insufficient response to metformin unless the patient has a contraindication or adverse event to metformin.
- There was no discussion by the panel.
- First and second motions were made to approve the drug class as presented.
- Vote: 9 in favor; 0 opposed

17. THIAZOLIDINEDIONES

- One speaker registered to speak for this drug class:
  - Dr. Steven M. Simmons, GlaxoSmithKline
    (Request to have Avandia available as a preferred product)
- 87% of the market share is with Actos.
- Discussion
  - A suggestion was made to grandfather patients who are currently on Avandia.
  - The reason Avandia was non-preferred was a safety issue, not a financial issue. A recommendation was to wait until the FDA made a decision regarding the safety of Avandia.
  - If 13% of the patients are grandfathered and the product is non-preferred, the State will not collect rebates when this product is used.
  - A suggestion was made to move Avandia to the preferred side and let the physician decide which product to use. If there are significant safety issues, the FDA will pull the drug from the market.
- First and second motions were made to approve the drug class as recommended:
  - Move Avandia to the preferred side and monitor the FDA's recommendations.
- Vote: 8 in favor; 0 opposed (Dr. Ferreri temporarily left the meeting.)

18. THIAZOLIDINEDIONES/METFORMIN COMBINATIONS

- No registered speakers for this class.
- No comments were received during the 30-day comment period.
- 70% of the market share is with ActoPlus Met.
- There was no discussion by the panel.
- First and second motions were made to approve the drug class as recommended:
  - Move Avandamet to the preferred side and monitor the FDA's recommendations.
- Vote: 8 in favor; 0 opposed (Dr. Ferreri temporarily left the meeting.)

19. THIAZOLIDINEDIONES/SULFONYLUREA COMBINATIONS

- No registered speakers for this class.
- No comments were received during the 30-day comment period.
- 44% of the market share is with Duetact.
- There was no discussion by the panel.
- First and second motions were made to approve the drug class as recommended:
    - Move Avandaryl to the preferred side and monitor the FDA's recommendations.
- Vote: 8 in favor; 0 opposed (Dr. Ferreri temporarily left the meeting.)

20. 5-HT3 ORAL ANTIEMETICS

- No registered speakers for this class.
- No comments were received during the 30-day comment period.
- 98% of the market share is with generic ondansetron. The proposal for this drug class supports generic use.
- There was no discussion by the panel.
- First and second motions were made to approve the drug class as presented.
- Vote: 8 in favor; 0 opposed (Dr. Ferreri temporarily left the meeting.)

21. EMEND

- One speaker registered to speak f this drug class.
    - Dr. Michael E. Trigg, Merck and Co.
      (Consider removing or revising the clinical criteria on Emend)
- 21 comments were received during the 30-day comment period. Most of the comments were regarding allowing Emend for each cycle and not a monthly limit.
- Emend is proposed to have preferred status with prior authorization criteria in place.
- Discussion
    - A comment was made regarding the public comments that were received in reference to Emend. Many of the clinicians who submitted comments used identical wording, which created a sense of dishonesty.
    - The guidelines say that Emend is not a salvage therapy. Some people respond to ondansetron even when receiving highly emetogenic chemotherapies. It is conceivable to try ondansetron for the first cycle to see the response. Then add Emend for subsequent cycles if the response was not adequate.
    - If a chemotherapy cycle is every three weeks, it makes sense to have Emend available for each cycle.
    - Extend the prior authorization period for 12 months if needed. A suggestion was made to allow the prior authorization period be for life, but currently all the policies have a time associated with them and there is a need to be consistent.
- First and second motions were made to approve the drug class with the following recommendations to the policy:
    - Length of therapy would be approved for 12 months.
    - Allow dosage limits for each cycle instead of each month.
- Vote: 9 in favor; 0 opposed

22. OTIC QUINOLONES

- No registered speakers for this class.
- No comments were received during the 30-day comment period.
- 92% of the market share is with the proposed preferred agents.

- There was no discussion by the panel.
- First and second motions were made to approve the drug class as presented.
- Vote: 9 in favor; 0 opposed

23. ALPHA BLOCKERS FOR BENIGN PROSTATIC HYPERPLASIA
- No registered speakers for this class.
- No comments were received during the 30-day comment period.
- There was no discussion by the panel.
- First and second motions were made to approve the drug class as presented.
- Vote: 9 in favor; 0 opposed

24. GOUT PRODUCTS
- No registered speakers for this class.
- No comments were received during the 30-day comment period.
- 97% of the market share is with the preferred products. Proposal supports generic use. DMA is monitoring colchicine availability at the request of the NC PAG following the approval of Colcrys.
- There was no discussion by the panel.
- First and second motions were made to approve the drug class as presented.
- Vote: 9 in favor; 0 opposed

25. XANTHINE OXIDASE INHIBITORS
- One speaker registered to speak for this drug class:
    - Dr. Keith Szymanski, Takeda Pharmaceuticals America
      (Request to have Uloric available as a preferred product)
- One comment was received during the 30-day comment period.
- 90% of the market share is with generic allopurinol. The proposal supports generic use.
- There was no discussion by the panel.
- First and second motions were made to approve the drug class as presented.
- Vote: 9 in favor; 0 opposed

26. BIPHOSPHONATES
- One speaker registered to speak for this drug class:
    - Rose Mullen, Eli Lilly & Company
      (Request to have Forteo available as a preferred product)
- One comment was received during the 30-day comment period.
- 45% of the market share is with generic alendronate. The proposal supports generic use.
- Discussion
    - Forteo has a black box warning. The review material supports generic utilization primarily because of the black box warning.
    - The head-to-head trials showed similar efficacy to the generic. One subcategory of people treated with glucocorticoids had a very small increase in improved results, but the improved results were mostly with toe fractures, not primary fractures such as hip fractures.
    - A suggestion was made to change the header of the drug class to Bisphosphonates and other Osteoporosis Agents.
- First and second motions were made to approve the drug class as presented.
- Vote: 9 in favor; 0 opposed

27. TOPICAL RETINOIDS

- No registered speakers for this class.
- One comment was received during the 30-day comment period.
- 77% of the market share is with the preferred products.
- There was no discussion by the panel.
- First and second motions were made to approve the drug class as presented.
- Vote: 9 in favor; 0 opposed

28. TOPICAL ANESTHETICS

- One speaker registered to speak for this drug class.
    - Dr. Sonia Pasi, Advanced Pain Consultants
      (Consider removing the clinical criteria on Lidoderm)
- One comment was received during the 30-day comment period.
- The proposed criteria for Lidoderm are in accordance with the FDA's label, which requires that patients have a diagnosis of post-herpetic neuralgia, and the maximum dosage is three patches a day.
- There was no discussion by the panel.
- First and second motions were made to approve the drug class as presented.
- Vote: 9 in favor; 0 opposed

29. TOPICAL ANDROGENIC AGENTS

- No registered speakers for this class.
- No comments were received during the 30-day comment period.
- 80% of the market share is with the preferred products.
- There was no discussion by the panel.
- First and second motions were made to approve the drug class as presented.
- Vote: 9 in favor; 0 opposed

30. TOPICAL ANTIBIOTICS

- No registered speakers for this class.
- One comment was received during the 30-day comment period.
- 80% of the market share is with the preferred products.
- There was no discussion by the panel.
- First and second motions were made to approve the drug class as presented.
- Vote: 9 in favor; 0 opposed

31. TOPICAL ANTIVIRALS

- No registered speakers for this class.
- No comments were received during the 30-day comment period.
- 50% of the market share is with Zovirax ointment.
- There was no discussion by the panel.
- First and second motions were made to approve the drug class as presented.
- Vote: 9 in favor; 0 opposed

32. BENZOYL PEROXIDE, CLINDAMYCIN & ACZONE PRODUCTS

- No registered speakers for this class.
- One comment was received during the 30-day comment period.
- 38% of the market share is with the Benzaclin products. This is one of the few cases where we propose making the brand preferred and the generic non-preferred.

- Discussion
  - This is one of the classes where the pharmacist can substitute the brand product if the physician writes clindamycin-benzoyl peroxide-aczone gel.
  - A generic Benzaclin recently became available. It is unlikely that the status of the brand Benzaclin will change.
  - It is important to educate pharmacists and prescribers about allowing brand products to be dispensed since N.C. has a mandatory generic substitution law. Pharmacists will receive a point-of-sale message that says, "Brand preferred" when they dispense the generic, if the brand product is preferred over the generic. The State MAC price will also be removed from this drug. The recent bulletin articles include information about the preferred brand products when generics are available. The CCNC Network pharmacists are also helping with this educational effort.
- First and second motions were made to approve the drug class as presented.
- Vote: 9 in favor; 0 opposed

The meeting was adjourned at 4:12 p.m.