August 25, 2010

Mr. Lanier Cansler Secretary of Health and Human Services N.C. Department of Health and Human Services 101 Blair Drive Raleigh, N.C. 27603

Dear Secretary Cansler,

On behalf of the North Carolina Department of Health and Human Services Medicaid Preferred Drug List Review Panel, I am pleased to present our recommendations to you for the North Carolina Medicaid Preferred Drug List. The following recommendations are a result of clinical reviews completed during three separate meetings occurring on June 29, July 27 and August 20, 2010.

The panel reviewed drug classes on the proposed Preferred Drug List that were approved by the Pharmacy and Therapeutics committee and the North Carolina Physicians Advisory Group. The panel reviewed each drug class in which a decision was needed on preferred versus non-preferred status. Decisions were made with consideration given to the evidence-based data available for each drug class, the written comments received during the 30-day public comment period and the public comments received during each panel meeting. Financial analyses were not considered during the decision-making process.

RECOMMENDATIONS:

The panel recommends approval of the proposed N.C. Medicaid Preferred Drug List with associated prior authorization criteria as posted during the May 18, 2010 through June 17, 2010 thirty-day public comment period with the following changes:

1. STATINS

The panel approves the PDL proposal and the prior authorization criteria for the cholesterol lowering agents with the following changes:

- Build in a 6-month transition period for current users
- Add metabolic syndrome to the list of exemptions in the prior authorization criteria

2. MACROLIDES

The panel approves the PDL proposal for the macrolide antibiotics with the following changes:

List available generics under the preferred list of agents

3. INHALED CORTICOSTEROIDS AND COMBINATION PRODUCTS

The panel approves the PDL proposal and the prior authorization criteria for inhaled corticosteroids and corticosteroid combination products with the following changes:

- Build in a 6-month transition period for current users
- Add an exemption to the prior authorization criteria for patients whose condition is severe enough to warrant combination therapy
- Allow a failure of any monotherapy oral inhaled corticosteroid agent to qualify for a combination product

4. LEUKOTRIENE MODIFIERS AND LEUKOTRIENE FORMULATION INHIBITORS

The panel approves the PDL proposal and the prior authorization criteria for the leukotriene formulation inhibitors and leukotriene modifiers with the following changes:

- Build in a 6-month transition period for current users
- Allow interactive, real-time feedback from providers possibly through CCNC practitioners, list serves, and interaction at meetings and/or open forums

5. SMOKING CESSATION AGENTS

The panel approves the PDL proposal for the smoking cessation agents with the following changes:

- Change Chantix to preferred status
- Place a 6-month quantity limit on Chantix and require prior authorization for a longer duration of therapy

6. **PROTON PUMP INHIBITORS**

The panel approves the PDL proposal and the prior authorization criteria for the proton pump inhibitors with the following changes:

- Change the age exemption in children from less than 6 years old to less than 12 years old
- Revisit the exemptions for pregnancy and breastfeeding. These may not be needed with the addition of Nexium to the preferred list of agents. As follow up to this recommendation, it has been determined that the pregnancy and breastfeeding exemptions will not be needed due to the addition of Nexium to the preferred list of agents.

7. NEW CLASS LISTING FOR CII SHORT-ACTING NARCOTICS

The panel approves the PDL proposal for long-acting Schedule II narcotics and lozenges, tramadol products and Zamicet with the following changes:

- Consider having a new PDL drug class to include short-acting Schedule II narcotics to include Zamicet and Tylenol with Codeine products
- Consider adding tramadol agents to this list and delineate the risks of Tramadol products for their addictive properties
- Remove Nucynta from tramadol agents and add to the new short-acting Schedule II narcotics

8. SECOND GENERATION ANTICONVULSANTS

The panel approves the PDL proposal and the prior authorization criteria for the second generation anticonvulsants with the 6-month grandfathering of current users as proposed by the N.C. Physicians Advisory Group with the following changes:

- Patients with seizures are exempt from non-preferred prior authorization requirements and the prior authorization criteria
- Lyrica for neuropathic pain requires a failure of only one drug for 60 days instead of two drugs
- Prescribers can write meets PA criteria for seizures on prescriptions for these medications
- 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

9. INJECTABLE INSULINS

The panel approves the PDL proposal and prior authorization criteria for the injectable insulins with the following change:

 Move one convenience insulin product to preferred status within each insulin category after considering cost to the State (two if not cost prohibitive) and remove exemption for patients less than 21 years of age.

10. TZD, TZD/METFORMIN COMBINATIONS, TZD/SULFONYL UREA COMBINATIONS

The panel approves the PDL proposal for the thiazolidinediones, thiazolidinedionesmetformin combinations and thiazolidinediones-sulfonylurea combinations with the following changes:

Move Avandia, Avandamet and Avandaryl to preferred status

11. EMEND

The panel approves the PDL proposal and the prior authorization criteria for Emend with the following change:

Allow dosage limits by cycle instead of by month

Change length of prior authorization approval to 12 months

12. BIPHOSPHONATES

The panel approves the PDL proposal for the biphosphonates with the following change:

 Change the header of the drug class to another description other than biphosphonates

Sincerely,

Line Warks, Phanme, RPh

Lisa Weeks, PharmD, RPh Chair, Medicaid Preferred Drug List Review Panel

- Cc: Dr. Cedric Bright, Old North State Medical Society
 - Dr. Paul Bush, Hospital-Based Pharmacy
 - Dr. Larry Cutchin, Community Care of North Carolina
 - Dr. Stefanie Ferreri, N.C. Association of Pharmacists
 - Dr. Theresa Flynn, N.C. Pediatric Society
 - Dr. John Gilmore, N.C. Psychiatric Association
 - Dr. Byron J. Hoffman, N.C. Chapter of the American College of Physicians
 - Dr. Robert L. (Chuck) Rich, N.C. Academy of Family Physicians
 - Dr. Robert Schotzinger, Research-Based Pharmaceutical Company

Dr. Beat Steiner, N.C. Physicians Advisory Group Pharmacy & Therapeutics Committee

Dr. Craigan Gray, N.C. Division of Medical Assistance

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