New York State Medicaid Pharmacy and Therapeutics Committee
Meeting Summary
November 15, 2012

Agenda and Introduction

The Medicaid Pharmacy & Therapeutics Committee met on Thursday November 15, 2012 from 9:00 AM to 4:00 PM in Meeting Room 3, Concourse, Empire State Plaza, Albany, New York.

A. Background Materials Provided:

The Committee was provided copies of written materials submitted by interested parties in advance of the meeting.

B. Public Comment Period:

The following speakers provided public comment to the Committee:

1. Jess David Collins, MD, Director, Center of Disability Services – Neurology Clinic, Albany, NY
2. Barry Patel, PharmD, Scientific Account Liaison, GlaxoSmithKline, Malvern, PA
3. Maria Cannito, PharmD, MS, Director, Medical Outcomes Specialist, Pfizer Inc., New York, NY
4. Safiya Abouzaid, PharmD, Associate Director, Health Economics & Outcomes Research, Eisai Inc.
5. Dominic Iacobellis, PharmD, Global Heal Outcomes Liaison, Eli Lilly & Company, Indianapolis, IN
6. Pat Hunt, PharmD, Medical Science Liaison, Shire Pharmaceuticals, Wayne, PA
7. Donna King, Ph.D., Regional Medical and Research specialist, Endocrine, Pfizer Inc., Lawrenceville, NJ

C. Key issues raised by interested parties and Committee members during the public comment period:

Anticonvulsants

The Committee was asked to consider sharing the challenge of providing the best care for patients with seizure disorders. In addition, to provide access to all treatments that are available and maintain unrestricted, unmanaged status of anti-seizure medications for NYS Medicaid patients.

A Committee member asked for a point of clarification about the “prescriber prevails" provision within Preferred Drug Program (PDP). Another member commented on the metabolism and clearance of these drugs in the geriatric population.

Potiga

The Committee was asked to consider efficacy, safety, and indication for the use of Potiga. The Committee was asked to make the drug available for patients with uncontrolled partial-onset seizures in adults due to its pharmacology.

Lyrica

The Committee was asked to consider adding Lyrica as a preferred agent in the Preferred Drug List (PDL) due to its five approved indications, established treatment guidelines, and economic data.

A Committee member commended the company for going through the “proper route” and rigorous phase III trials to get FDA approval for an additional indication.

Banzel

The Committee was asked to consider Banzel for preferred status on the PDL for patients with Lennox Gastaut Syndrome due to its clinical and economic information.

Strattera

The Committee was asked to support Strattera as it has demonstrated experience, clinical value for patients with co-existing disorders and potential impact on diversion as it is not a controlled substance.

Intuniv

The Committee was asked to consider the efficacy and safety of Intuniv and to maintain the drug as preferred status on the PDL.

A Committee member had a question about its mechanism of action and commented on its effects on the cardiovascular system. The member also commented on the effect on the CNS as opposed to the periphery and asked speaker to comment on the pharmacology of the product and differentiate the effect between Intuniv and its prototypes.

Genotropin

A Committee member had a question about “DAW” and requested further information about substituting. The Committee discussed switching between brand name products within the class.

Studies on Genotropin were also discussed.

D. Clinical Presentation and Discussion

Linda Catanzaro, PharmD, Clinical Assistant Professor Director, Pharmacotherapy Information Center Chair, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo

Robert Correia, PharmD, New York State Department of Health, Office of Health Insurance Programs

Irene Hong, PharmD, Clinical Assistant Professor, School of Pharmacy & Pharmaceutical Sciences, State University of New York at Buffalo

Carole Kerzic, RPh, Magellan Medicaid Administration

Preferred Drug Program: Initial Review

1. Second Generation Anticonvulsants

Ms. Kerzic provided a general background about epilepsy and seizure disorder including the American Epilepsy Society (AES) and the American Academy of Neurology (AAN) guidelines. Regarding the products in the therapeutic class, information presented included indications, dosage and administration, warnings, adverse effects and drug interactions. Dr. Kerzic also noted that three of the anticonvulsants, Potiga, Vimpat, and Lyrica, were Schedule V controlled substances.

Dr. Correia stated that there was very little head to head comparative evidence between the drugs in the class. Dr. Correia found one new comparative study, which was an active comparator trial between lamotrigine and levetiracetam for efficacy and safety as initial monotherapy for Focal and Generalized Epilepsy. It was intended to demonstrate the superiority of levetiracetam over lamotrigine, however, in fact the conclusion was that there were no significant differences with regard to efficacy and tolerability of levetiracetam and lamotrigine. None of the drugs have demonstrated overall superiority within the class. It was recommended that there be product selection for the drug class to have as much representation as practical by mechanism of action, coverage of different FDA indication, inclusive of special populations, and with particular consideration of initial therapy for seizure disorders among preferred products. It was also recommended that in the event that some products are determined to be non-preferred, this would not require prior authorization for continued use of those products by patients that have already been established as stable on those therapies.

A Committee member questioned patient adherence to medications in this class as well as drug to drug interactions. Another member commented from professional experience on the relationship between non-adherence to medication and concerns for potential negative effects on fetal development.

The member also stated that access needs to be as open as possible and with ability to switch products.

2. Other Agents for ADHD

Ms. Kerzic provided a general background on ADHD. Regarding the products in the therapeutic class, information presented included FDA approved indications, dosage and administration, warnings, adverse effects and drug interactions. Dr. Kerzic mentioned clinical trials for clonidine ER and guanfacine ER. The American Academy of Pediatrics (AAP) practice guidelines were also presented.

Dr. Correia stated that there were basically two mechanisms of action between the three products in the class. The products in this class all have approval for pediatrics over the age of 6 years, adolescents, and also in some form for adults. There was no approval for any of these medications for children less than six years of age and there may have been additional safety and efficacy concerns for those younger children, especially related to blood pressure and heart rate. Head to head evidence between the drugs in the class was lacking. Current evidence identifies some concerns regarding additional adverse effects related to the included products; however there is no evidence of overall superiority between them.

A Committee member had a comment about the geriatric population specifically and the issue of cardiac/blood pressure effects. The Committee member discussed the pharmacology of the drug class. A Committee member asked if there were any identified guidelines as to how adults should be treated. A Committee member commented about the destigmatization of the use of the agents in adults. A Committee member commented on using these agents in patients for pyschosis.

Preferred Drug Program: Re-review

1. Carbamazepine Derivative

Ms. Kerzic provided the FDA approved indications for the products in the class. An overview of new information was provided. It was stated that there were no new products, generics, or formulations within the class. Dr. Kerzic provided information on label revisions for the products. In addition, new information included the elimination of the Risk Evaluation and Mitigation Strategies (REMS) requirement for the products.

Dr. Correia stated that there was no new information for these drugs. It was stated that there are only actually two drugs in this class, carbamazepine and oxcarbazepine, which are available in a variety of dosage forms. Oxcarbazepine is chemically related to carbamazepine and was developed with hopes of matching or improving response, while decreasing adverse effects. However, with continued use, the adverse effects have emerged for

oxcarbazepine as well. There was no comparative evidence to indicate that any of the products were better overall. It would be preferable to list as many product choices as preferred within the class as possible.

A Committee member had a comment about the pharmacology of oxcarbazepine and its structure that causes of certain side effects. The Committee member commented on the potent inducing of CYP3A4 enzymes and P-Glycoprotein. A Committee member had a comment about the dizziness side effect in his patients from the drug class. The Committee member also had a question about the percentage of geriatric patients that are being included in the studies.

2. Growth Hormone

Ms. Kerzic provided a summary of the FDA approved indications and an overview of new information about the class. It was stated that there were no new products, generics, or formulations within the class. Ms. Kerzic provided some new clinical information in terms of FDA safety communications for the drug (somatropin).

Dr. Correia stated that there was little new information in addition to safety information that was already presented. Since they are all the same drug, they produce identical clinical effects and comparative clinical information between the products in this class are lacking. There is also a variety in package sizes and delivery devices within the class. The Endocrine Society has stated there is no observable difference in the results obtained from the different preparations as long as the appropriate regimen is followed. Likewise, there was no evidence that clinical outcomes differed among the various injection systems. There were no clear comparative clinical issues as they are all the same drug. Dr. Correia stated that if there were any issues perceived due to a specific or rare labeled indication for a particular brand, it could be addressed in the prior authorization criteria if needed.

Clinical Drug Review Program (CDRP)

1. Truvada

Dr. Kerzic provided an overview of Truvada and its use for HIV Pre-Exposure Prophylaxis (PrEP) including indications, adverse effects, contraindications, and warnings. The iPrEx trial and PrEP study were discussed. The CDC interim guidance was also provided.

Dr. Correia stated that Truvada is the only pharmacological therapy FDA approved for PrEP of HIV in all adults at high risk due to sexual activity. It was also stated that in studies specifically of heterosexually active men and women as well as serodiscordant heterosexual couples, either the combination of tenofovir plus emtricitabine or tenofovir alone were effective protection against

HIV transmission with no statistical difference between the two. However, tenofovir monotherapy is neither FDA approved nor CDC recommended for PrEP at this time. The DOH recommendations are intended to initially address the areas most directly related to use of Truvada either in treatment of HIV infection, or the patient's initial as well as continued eligibility for PrEP. In the absence of any evidence that Truvada is being used for HIV treatment, prior authorization would be required to either confirm use is for HIV treatment or use is for PrEP. The prior authorization criteria recommended initially by the DOH are intended to primarily focus and emphasize the most critical issues relevant to preventing emergence of resistance to these antiretroviral drugs.

A Committee member asked a question about how a provider will be able to differentiate the use of Truvada in terms of actual treatment and prophylaxis. Another member had a question about how long prophylaxis would be provided for patients who have high risk behavior. Another Committee member asked for clarification of the relevance of a 30 day supply versus a 90 day supply.

2. Central Nervous System Stimulants

Dr. Hong provided an overview of past Drug Utilization Review (DUR) Board actions for this class. Dr. Hong provided FDA approved indications and additional compendia- supported uses for the drugs in the class. In addition, clinical consideration in terms of safety and misuse was presented. Utilization and its implications for the drug class were also discussed. The University at Buffalo (UB) recommendations to be considered included placing CNS stimulants in the CDRP for patients ≥ 18 years of age. Recommendations for PA criteria for this class were also provided.

Dr. Correia stated that that the findings presented by UB in the review and analysis of evidence from NY Medicaid outpatient pharmacy claims data and other clinical information were originally presented to the DUR Board. The Board then referred the issue to the P&T Committee for consideration for inclusion in the CDRP. The DOH concurs with the conclusions presented that multiple requirements have been met for inclusion of this drug class and age group (>18 years), but it also appears that there is significant evidence of appropriate use within the program. Dr. Correia also mentioned that claims processing system enhancements now allow more precision in how prior authorizations may be utilized. This applies to issues addressed by the CDRP, providing the ability to address areas of concern while having little or no impact on accepted utilization. The DOH recommendation is in consideration of the evidence which indicates that the best initial area of focus for intervention is related to utilization that is either for known non-covered uses or where the reason for use of the drug is not identifiable, while minimizing impact to prescribers and patients where evidence indicates utilization is likely consistent with pharmacy program policy and legislation.

A Committee member had a question about the use of drugs in the nursing

home population.

3. Anabolic Steroids

Dr. Catanzaro provided an overview of past DUR Board actions for this class. FDA approved indications and additional compendia- supported uses were presented. In addition, clinical considerations for this class including safety and misuse were presented. Utilization and its implications for the drug class were also discussed. The UB recommendations to be considered were placing anabolic steroids in the CDRP based on specific clinical parameters. Recommendations for PA criteria for the drug class were also provided.

Dr. Correia stated that these findings were also initially presented to the NYS DUR Board and referred by the Board to the P&T Committee for consideration for inclusion in the CDRP. The DOH concurs with the conclusions presented that multiple requirements have been met for inclusion of the drug class, but there is also significant evidence of appropriate use within the program. In consideration of the evidence, the best initial area of focus for intervention is related to utilization that is either for known non-covered uses or utilization where information presented indicates diagnosis or treatment should be supported by laboratory testing initially, and on an ongoing basis. In addition, interventions would also be needed in areas where testing would indicate an alternative therapy as first line or the reason for use of the drug is not identifiable. System enhancements will minimize impact to prescribers and patients where available evidence indicates utilization is likely consistent with pharmacy program policy and legislation.

E. Program Updates

Katie Counts, PharmD, Health Information Designs

Christine A. Rivera, Director, Uninsured Care Programs, New York State Department of Health

Charles John Gonzalez, MD, Associate Medical Director for Science and Policy/OMD, NYS Department of Health/AIDS Institute

1. Prior Authorization Processing Overview – Health Information Designs

Dr. Counts provided information about prior authorization processing, clinical editing, and system enhancements. PAXpress and RxPert systems and the overall systems process and benefits were discussed. Information about the automated PA process were reviewed and examples of the entire procedure were given.

A Committee member commented about how to obtain direct personal experience with the program, to see how it works. Another Committee member had a question about who calls the prescriber if there is no diagnosis for a certain claim on the system and if the prescriber will allow a diagnosis from a pharmacist.

2. The Challenges of Implementing Antiretroviral Intervention into AIDS Drug Assistance Program (ADAP)

   Ms. Rivera and Dr. Gonzalez provided an update on antiretroviral therapy and the challenges of implementing a clinical antiretroviral intervention model into ADAP. They discussed effective HIV therapy and associated drug interactions with the antiretrovirals. The New York ADAP system and its guiding principles were discussed. Retrospective Utilization Review and Prospective Utilization Review edits were described. They both emphasized the need for ongoing refinement to the process and the continuous monitoring of the guiding principle of “do no harm”.

   A Committee member commented and questioned if the scientific community had some thought in disseminating the information to clinicians about dangerous drug interactions.

F. Executive Session:

The Committee recessed the public session at 12:45 PM to go into executive session for review of financial information relating to the Committee's recommendations of preferred and non-preferred products within each of the therapeutic classes under review. No official action was taken in the executive session. The executive session was recessed at 2:00 PM.

G. Recommendations of the P&T Committee submitted to the Commissioner of Health for final determination.

Based on the submitted or presented clinical information and on the financial information provided during the executive session, the Committee unanimously (unless otherwise noted) recommended the following:

Recommendations of P&T Committee	Commissioner's Final Determination
Second Generation Anticonvulsants **Preferred** Felbatol, gabapentin, lamotrigine, levetiracetam, levetiracetam ER, Lyrica, topiramate, Vimpat, zonisamide **Non-preferred** Banzel, felbamate, Gabitril, Keppra, Keppra XR, Lamictal, Lamitcal ODT, Lamictal XR, Neurontin, Potiga, Sabril, Topamax, Zonegran Clinical editing to allow patients currently stabilized on a non-preferred agent to continue to receive that agent without PA.	Approved as Recommended
Carbamazepine Derivatives **Preferred** carbamazpeine tablet/chewable, Carbatrol, Equetro, oxcarbemazepine tablet/suspension, Tegretol XR, Tegretol suspension, Trileptal suspension **Non-preferred** carbamazepine ER, carbamazepine XR, carbamezapine suspension, Tegretol tablet/chewable, Trileptal tablet Clinical editing to allow patients currently stabilized on a non-preferred agent to continue to receive that agent without PA.	Approved as Recommended
Growth Hormone **Preferred** Gentropin, Norditropin, Nutropin/Nutropin AQ **Non-preferred** Humatrope, Omnitrope, Saizen, Tev-Tropin, Zorbtive	Approved as Recommended

Other agents for ADHD **Preferred** Intuniv, Strattera **Non-preferred** Kapvay	Approved as Recommended
Truvada Addition to CDRP for Pre-Exposure Prophylaxis (PrEP). Electronic bypass when used for HIV treatment. For Pre-Exposure Prophylaxis (PrEP): • HIV-1 testing immediately prior to initiation of therapy to confirm negative HIV-1 status. • HIV-1 testing every 3 months to verify negative HIV-1 status.	Approved as Recommended
Anabolic Steroids Addition to the CDRP. Confirm diagnosis for Medicaid coverage. Electronic bypass for covered diagnosis identified in the claims system. • For diagnosis of hypogonadotropic or primary hypogonadism: 1. Requires documented low testosterone concentration with two tests prior to initiation of therapy. 2. Require documented testosterone therapeutic concentration to confirm response after initiation of therapy. • For diagnosis of delayed puberty: 1. Require documentation that growth hormone deficiency has been ruled out prior to initiation of therapy.	Approved as Recommended
CNS Stimulants Addition to CDRP for patients age 18 years and older. Confirm diagnosis for Medicaid coverage. Electronic bypass for covered diagnosis identified in the claim system.	Approved as Recommended

Meeting adjourned at 3:30 PM

Meeting Summary posted 12/11/2012

H. Final Determinations

Preferred Drug Program (PDP)

The Commissioner has determined that the Medicaid program will require prior authorization under the PDP for non-preferred products in each of the drug classes as listed in Section G.

Preferred drugs will not require prior authorization within the PDP. PDP drugs may still be subject to utilization management programs as noted on the preferred drug list (PDL).

The impact of this final determination is as follows:

1. State Public Health Population:
   - Minimal effect on Medicaid enrollees, as a large majority of enrollees currently utilize preferred products. Non-preferred products remain available with prior authorization.

2. Program Providers:
   - No impact on prescribers when utilizing preferred products. Prescribers, or their agents, will need to initiate the prior authorization process when ordering non-preferred products.

3. State Health Program:
   - Annual gross savings associated with these therapeutic classes under the PDP are estimated at $7.2M. The savings are achieved through changes in utilization to equally effective and less expensive products including the receipt of supplemental rebates from pharmaceutical manufacturers.

Clinical Drug Review Program (CDRP)

The Commissioner has determined that the Medicaid program will require prior authorization under the CDRP for Truvada (emtricitabine/tenofovir), Anabolic Steroids and Central Nervous System Stimulants as detailed in Section G.

The impact of this final determination is as follows:

1. State Public Health Population:
   - Products requiring prior authorization under the CDRP will continue to be covered by the Medicaid program. The prior authorization requirement will have a minimal effect on Medicaid beneficiaries while ensuring that these products are used in a medically appropriate manner.

2. Program Providers:
   - Minimal impact on prescribers and pharmacies as they are familiar with the prior authorization process. The prior authorization process is simple to use

and available twenty-four hours a day, seven days a week. Prescribers will need to initiate the prior authorization process and will be asked for clinical information to support appropriate use of the product.

3. State Health Program:
   - Prior authorization through the CDRP will reinforce appropriate use and provide an additional means to detect and deter overuse, misuse or abuse. The fiscal impact will depend on changes in utilization associated with assuring the appropriate use of the product. Utilization is expected to decrease subsequent to the implementation of the prior authorization requirement.

Final Determinations Posted 1/18/2013