New York State Medicaid
Drug Utilization Review (DUR) Board
Meeting Summary for September 17, 2015

The Medicaid DUR Board met on Thursday, September 17, 2015 from 9:00 AM to 4:00 PM Meeting Room 6, Concourse, Empire State Plaza, Albany, New York

An archived audio cast of the meeting proceedings is available on the Department of Health website: http://www.health.ny.gov/events/webcasts/

A. Welcome and Introductions

(Audio Cast Time 00:04 - 03:18)

Department of Health

Janet Zachary-Elkind
Robert Correia, PharmD
Anthony Merola, RPh, MBA
John Naioti, RPh
Alda Osinaga, MD
Robert Sheehan, RPh
Monica Toohey, RPh

DUR Board

Lisa Anzisi, PharmD
Leigh Briscoe-Dwyer, PharmD
Donna Chiefari, PharmD
Marla Eglowstein, MD
James Hopsicker, RPh, MBA
John McIntyre, MD
Jadwiga Najib, PharmD
Paula Panzer, MD
Asa Radix, MD
James Saperstone, MD
William Scheer, RPh
John Wikiera

SUNY – University at Buffalo

Holly Coe, PharmD
Irene Reilly, PharmD
Barbara Rogler, PharmD, MS

Magellan Medicaid Administration

Eileen Zimmer, PharmD, MBA

B. Public Comment Period

(Audio Cast Time 03:18 - 00:44:30)

The following speakers provided public comment to the board:

1.	Robert Kaslovsky, MD	Albany Medical College	Inhaled Antibiotics
2.	Jeffery Olson, PharmD	Gilead Sciences, Inc	Inhaled Antibiotics
3.	Laura Bartels Pharm.D.	Otsuka America Pharm.	Antipsychotics

4.	Wendy Burch	NAMI-NYS	Antipsychotics
5.	Edmond Amyot, M.D.	NYS Psychiatric Association	Antipsychotics
6.	Alan Chant, RPh	Sanofi US Medical Affairs	Insulin- Rapid Acting
7.	Rob Picone, RPh, PhD	Novo Nordisk Inc.	Insulin- Rapid Acting
8.	Jonathan Beach, MD	Private Practice	Insulin- Rapid Acting
9.	Anthony Wheeler, PhD	Eli Lilly and Company	Insulin- Rapid Acting
10.	Anthony Wheeler, PhD	Eli Lilly and Company	Platelet Inhibitors
11.	Marisa Winther, PharmD	AstraZeneca	Platelet Inhibitors
12.	Warren Wexelman, MD	Am. Heart Assn. of Brooklyn	Platelet Inhibitors
13.	Adam Bloomfield MD FAAP	AstraZeneca	palivizumab
14.	Paul Skodny, PharmD,MBA	Amgen	PCSK9 Inhibitors

C. Preferred Drug Program (PDP) Clinical Reviews (Audio Cast Time 0:44:30 - 2:04:50)

Eileen Zimmer, PharmD, MBA
Robert Correia, PharmD

1. Inhaled Antibiotics (Audio Cast Time 0:45:02)
    - Initial Review

2. Antipsychotics - Second Generation (Audio Cast Time 0:57:43)
    - New Product: Rexulti
    - New clinical information: new/expanded indications, FDA communications, label revisions.

3. Anabolic Steroids – Topical (Audio Cast Time 1:08:16)
    - New Products: Natesto, Vogelxo
    - New clinical information: FDA communications.

4. Insulin- Rapid Acting (Audio Cast Time 1:17:57)
    - New Product: Afrezza
    - New clinical information: FDA communications and practice guidelines.

5. Platelet Inhibitors (Audio Cast Time 1:30:36)
    - New Product: Zontivity
    - New clinical information: expanded indications, label revisions, FDA communications, and practice guidelines.

6. Agents for Actinic Keratosis (Audio Cast Time 1:48:31)
    - Initial Review

D. DUR Program Updates (Audio Cast Time 2:05:05)

Evaluation of Long-Acting Opioid (LAO) Editing

The board discussed Medicaid paid claims vs. cash payment, increased utilization with regard to influx of new patients, and details concerning patient plan transitioning. The board also discussed prior authorization associated with duplicative LAO therapy, the potential for multiple prescribers, and the potential decreasing burden on prescribers by combining two monitoring systems into one. The board questioned prior authorization denials and alternative medication prescribed, commented that managed care utilization for naïve LAO users seemed more appropriate than in fee-for-service, and inquired about the claim denial procedure for duplicative LAO claims.

E. Executive Session (Recess to Excessive Session Audio Cast Time 2:35:13)

The board recessed the public session at 12:00 PM to go into executive session for review of financial information relating to each of the PDP therapeutic classes under review. No official action was taken in the executive session. The board reconvened to the public session at 1:15 PM.

F. DUR Board Preferred Drug Program Recommendations

Based on the clinical and financial information, the board recommended the following to the Commissioner of Health for final determination:

Recommendations of DUR Board	**Commissioner's Final Determination**
Inhaled Antibiotics Audio Cast Time 2:36:15 **Preferred** Bethkis (tobramycin inhalation), Cayston (aztreonam), Kitabis Pak (tobramycin inhalation), **Non-preferred** TOBI Podhaler (tobramycin inhalation), tobramycin solution, TOBI solution (tobramycin inhalation) 12 in favor -1 opposed - no abstentions The Department recommended Cayston as non-preferred. The board modified the Department's recommendation and recommended that Cayston be preferred.	Approved as Recommended

Antipsychotics - Second Generation Audio Cast Time 2:41:12 **Preferred** Abilify (aripiprazole), clozapine, Fanapt (iloperidone), Latuda (lurasidone), olanzapine tab, quetiapine, risperidone, Saphris (asenapine), Seroquel XR (quetiapine), ziprasidone **Non-preferred** aripiprazole, clozapine ODT, Clozaril (clozapine), FazaClo (clozapine), Geodon (ziprasidone), Invega (paliperidone), olanzapine ODT, Rexulti (brexpiprazole), Risperdal (risperidone), Seroquel (quetiapine), Versacloz (clozapine), Zyprexa (olanzapine) 12 in favor -1 opposed - no abstentions The Department recommended Abilify remain non-preferred. The board modified the Department's recommendation and recommended that Abilify be preferred.	Approved as Recommended
Anabolic Steroids – Topical Audio Cast Time 2:43:36 **Preferred** Androgel (testosterone) **Non-preferred** Androderm (testosterone), Axiron (testosterone), Fortesta (testosterone), Natesto (testosterone), Testim (testosterone), testosterone gel, Vogelxo (testosterone) Passed Unanimously	Approved as Recommended
Insulin – Rapid Acting Audio Cast Time 2:44:14 **Preferred** Apidra, Humalog 100 U/ml, Novolog **Non-preferred** Afrezza, Humalog 200 U/ml Passed Unanimously	Approved as Recommended

Platelet Inhibitors Audio Cast Time 2:45:08 **Preferred** Aggrenox (aspirin/dipyridamole ER), Brilinta (ticagrelor), clopidogrel, dipyridamole, Effient (prasugrel) **Non-preferred** aspirin/dipyridamole ER, Persantine (dipyridamole), Plavix (clopidogrel), ticlopidine, Zontivity (vorapaxar) Passed Unanimously	Approved as Recommended
Agents for Actinic Keratosis Audio Cast Time 2:45:33 **Preferred** Aldara (imiquimod), diclofenac 3% gel, Efudex (fluorouracil), fluorouracil solution, fluorouracil cream 0.5% (generic Carac) **Non-preferred** Carac (fluorouracil), fluorouracil cream 5% (generic Efudex cream), imiquimod, Picato (ingenol mebutate), Solaraze (diclofenac sodium), Zyclara (imiquimod) Passed Unanimously	Approved as Recommended

G. Drug Utilization Reviews (DUR)

1. Topical Compounded Prescriptions (Audio Cast Time 2:46:25)

The board reviewed compounded topical drug products submitted for reimbursement in the Medicaid Program for the period January 1, 2014 through December 31, 2014. The presentation addressed the compliance of these compounds with State and Federal statutes as well as FDA or Compendia approval of drug products used in the compounding of the final product. The review found drugs in the classes of anticonvulsants, NSAIDS, and skeletal muscle relaxants, used in the compounding of topical preparations that did not have FDA approval or Compendia support for topical use. All appeared to be used in topical preparations for pain management. The review also noted the use of combined antifungal products in the compounding of topical preparations. Combinations of two or more antifungals do not have FDA approval resulting in the difficulty in determining the final topical products efficacy and safety. The report to the board recommended that a PA be considered for all compounded topical products as well as an educational mailing to practitioners notifying them of state and federal regulations regarding compounded drug products.

The DUR Board recommended the following: (Audio Cast Time 3:15:32 - 3:37:52)

1. Prior authorization required to ensure that topical compounded preparations are FDA approved or compendia supported. Passed Unanimously
2. Educational letter to practitioners notifying them of coverage requirements for topical compounded prescription - FDA approved or compendia supported for topical use. Passed Unanimously

Note: The DUR Board suggested that in addition to provider communications, there should also be public notification regarding concerns related to topical use of drugs in compounded prescriptions.

2. Palivizumab (Audio Cast Time 3:37:52)

The board reviewed the product palivizumab (Synagis). The purpose of the presentation was to evaluate the drugs utilization across the Medicaid population (fee-for-service (FFS) and Medicaid Managed Care) as well as to formulate standard recommendations to the Drug Utilization Board. A review of respiratory syncytial virus (RSV) infection was presented focusing on the virus, patient risk factors, and the pharmacologic management of the disease. Comparison charts were used to differentiate the 2009 American Academy of Pediatrics (AAP) guidance with the 2014 changes. A series of utilization charts were then presented to compare FFS use with Managed Care. Parameters identified in the charts included “in season” age use, claims per beneficiary by age as well as hospitalization data surrounding the use of palivizumab. Conclusions of the report described patient subgroups who should not receive palivizumab based upon risk factors as well as the changes between the 2009 and the new 2014 guidance recommendations. Recommendations were presented to the board which focused on dosing requirements during the RSV season as well as a summarized update of the clinical criteria for 2014.

The DUR Board recommended the following: (Audio Cast Time 4:12:08 - 4:13:05)

Align coverage criteria with the most recent American Academy of Pediatrics palivizumab guidelines. Passed Unanimously

3. Proprotein Convertase Subtilisin Kexin 9 (PCSK9) Inhibitors (Audio Cast Time 4:13:05)

The board reviewed proprotein convertase subtilisin kexin type 9 agents (PCSK9). The presentation characterized the place in therapy for these new agents and provided recommendations related to use. Background information was presented on hyperlipidemia and its management as well as compendia supported uses, pharmacology, safety and costs associated with this drug class. In discussing the place in therapy of this class the current American College of Cardiology and the American Heart Association (ACC/AHA) and National Lipid Association (NLA) guidelines were presented. Neither guidelines currently have recommendations on PCSK9 inhibitor use. Clinical trials for the two drugs in this class were presented to establish how both drugs were utilized prior to being marketed. Based upon the available literature, the report concluded the following: 1. Current ACC/AHA and NLA guidelines do not address this class, 2. The agents in this class are costly, 3. Beyond the trials, clinical experience with data outcomes are lacking, and 4. Peer reviewed guidelines advocate use of statins as first line therapy for the treatment of atherosclerotic cardiovascular disease (ASCVD).

The following recommendations were presented for consideration by the board: 1. Diagnosis requirement (familial hyperlipidemia, ASCVD) identified in a 2 year period preceding the drug claim, and 2. Concurrent use of a statin or ezetimibe.

The DUR Board recommended the following: (Audio Cast Time 5:02:58 - 5:23:42)

Diagnosis requirement: • Familial Hypercholesterolemia (heterozygous or homozygous) or • Atherosclerotic Cardiovascular Disease Passed Unanimously
Require trial of statin therapy at maximum tolerated dosage Passed Unanimously
Require concurrent statin therapy Passed Unanimously

H. Final Comments and Adjournment Audio Cast Time (5:23:52 - 5:25:00)

Janet Zachary-Elkind
Anthony Merola, RPh, MBA

Meeting adjourned at 4:15 PM

I. Commissioner Final Determinations

The impact of the final determinations on the PDP is as follows:

State Public Health Population:

- Minimal effect on Medicaid beneficiaries, as a large majority of beneficiaries currently utilize preferred products. Non-preferred products remain available with prior authorization.

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.

State Health Program:

- Annual gross savings associated with these therapeutic classes under the PDP are estimated at $833,000. The savings are achieved through changes in utilization including the receipt of supplemental rebates from pharmaceutical manufacturers.