New York State Medicaid
Drug Utilization Review (DUR) Board
Meeting Summary for May 16, 2019

The Medicaid DUR Board met on Thursday, May 16, 2019 from 9:00am to 4:00pm
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 0:03:11 to 0:03:48

Department of Health

Douglas Fish, MD - Chairperson
Robert Correia, PharmD
Anthony Merola, RPh, MBA
Robert Sheehan, RPh
Monica Toohey, RPh
Janet Zachary-Elkind

DUR Board Members

Donna Chiefari, PharmD
Lisa Anzisi, PharmD
Peter Deane, MD
James Hopsicker, RPh, MBA
Renate Ignacio, MD
Jacqueline Jacobi, RPh
Peter Lopatka, FSA
Christopher Murphy, MD
Jadwiga Najib, PharmD
John Powell
Casey Quinn, PhD
Asa Radix, MD
Tara Thomas, RPh, MBA, MPA

Magellan Medicaid Administration

Eileen Zimmer, PharmD, MBA

B. Public Comment Period

Audio Cast Time 0:05:53 to 0:57:36

The following speakers provided public comment to the Board:

1.	Kelly Wright	Paratek Pharm	Tetracyclines
2.	Derek Ems	UCB	Anticonvulsants – other
3.	Jessica Roland	Greenwich Bio	Anticonvulsants – other
4.	Elizabeth Lubelczyk	Eli Lilly	Anti-Migraine
5.	Daniel Flores	Amgen Global	Anti-Migraine

6.	Paul J. Isikwe	Teva	Anti-Migraine
7.	Paul J. Isikwe	Teva	Movement Disorder Agents
8.	Bijal Sheth	Neurocrine Bio	Movement Disorder Agents
9.	Biran Patel	Biogen	MS
10.	Zil Patel	Novo Nordisk Inc.	Growth Hormone
11.	Paul J. Isikwe	Teva	Colony Stimulating Factors
12.	Robert A. Mead	Pfizer	Colony Stimulating Factors
13.	Robert A. Mead	Pfizer	Erythropoiesis Stimulating Agents
14.	Carmelina S. Tyler	Veloxis Pharm	Immunosuppressives – oral
15.	Natalie Venon	Sunovion Pharma	Anticholinergics/COPD Agents
16.	Dana Canning	GSK	Anticholinergics/COPD Agents
17.	Jalpa Patel	AstraZeneca	Anticholinergics/COPD Agents

During the public comment period two questions were raised by DUR Board Members. The first concerned the issue of suicide ideation identified during the trial period of the drug Ingrezza presented by the speaker from Neurocrine Biosciences. The speaker responded that during the trial of valbenazine (Ingrezza) it was reported that there was one attempt at suicide by an individual that had previous attempts and suicide ideation prior to the trial enrollment period. It was determined that this specific incident reported during the trial was not related to the study drug.

The second question raised pertained to the interchangeability of the bioequivalent agents identified in the therapeutic class of the Erythropoiesis Stimulating Agents addressed by the speaker from Pfizer. The speaker responded that interchangeability amongst the bioequivalent agents is yet to be determined as the FDA guidance was recently released.

C. Preferred Drug Program (PDP) Clinical Review Audio Cast Time 0:57:47 to 1:54:59

Eileen Zimmer, PharmD, MBA
Robert Correia, PharmD

1. Tetracyclines
   - New product – Nuzyra (omadacycline) – indications, dosing, contraindications and adverse reactions. Product has two indications. If used for community acquired bacterial pneumonia, it must be started with an IV loading dose.
   - The most significant differences between products in this class are between the different types of tetracycline, rather than the individual products. There is no evidence of any overall superiority.

2. Anticonvulsants, Other
   - Financial review only.

3. Anti-Migraine Agents, Other
    - Agents used in migraine prevention.
    - Calcitonin gene related peptides (CGRP) – indications, dosing, contraindications and adverse reactions.
    - Position statement and recommendations of American Headache Society (AHS).
    - AHS Guidelines, updated January 2019, recommend a trial of at least 6 weeks with two different oral prophylactic agents identified as having A or B level of evidence rating supporting use by the American Academy of Neurology. Current fee-for-service (FFS) DUR edits for this class have already been implemented consistent with the AHS Guidelines.

4. Central Nervous System Stimulants
    - Financial review only.

5. Movement Disorder Agents
    - Overview of Huntington's Disease (HD) and Tardive Dyskinesia (TD).
    - Agents used in the treatment of Huntington's Disease – dosing, contraindications and adverse reactions, warnings.
    - Agents used in the treatment of Tardive Dyskinesia - dosing, contraindications and adverse reactions, warnings.
    - Place in therapy – Chorea associated with HD, Tardive Dyskinesia.
    - There is more long-term data on effectiveness and adverse effects, including post marketing experience, for tetrabenazine versus deutetrabenazine or valbenazine.
    - There remains a lack of good comparative evidence between the drugs in this class.
    - A point of clarification was addressed for which drugs in the class had the potential for prolonged QT interval.

6. Multiple Sclerosis Agents
    - Financial review only.

7. Growth Hormones
    - Financial review only.

8. Colony Stimulating Factors
    - Agents indications, dosing, contraindications/warnings, adverse effects.
    - Comparative Studies – Biosimilars compared to reference products, limited head to head trials evaluating efficacy.
    - The FDA classifies biosimilar drugs as having no clinically meaningful differences between them.
    - National Comprehensive Cancer Network recommendation for use of biosimilars in the same instances as their respective reference products.
    - Place in therapy – filgrastim products carry more indications, comparing filgrastim products with pegfilgrastim products shows the latter having a slightly

better rate of reducing febrile neutropenia and the potential for less frequent dosing per chemotherapy cycle.
- Considerations for both the short and long half-life versions of the drugs as being represented as preferred if feasible.

9. Erythropoiesis Stimulating Agents (ESA's)
   - Financial review only.

10. Immunosuppressives, Oral
    - Indications, dosing, contraindications and adverse reactions, specific populations focusing on pediatrics and the condition of pregnancy, mechanism of action.
    - Focus was on the utility of the class in patient/graft survival after transplant.
    - Use of multiple agents capitalizes on the different immune-mediated mechanisms of action which allows for lower doses to minimize toxicities.
    - Most of the drugs in this category are not new discoveries, although newer dosage forms have been developed to attempt to address various shortcomings or adverse events.
    - Comparative studies focus on different combinations of drugs to optimize efficacy versus adverse effects.
    - Guidelines referenced regarding place in therapy – 2009 Kidney Disease Improving Global Outcomes (KDIGO), the 2012 American Association for the Study of Liver Disease and the American Society of Transplantation (AASLD/AST) guidelines for long term management of successful adult liver transplant; the 2010 International Society of Heart and Lung Transplantation guidelines for care of the heart transplant recipients.
    - There are major subgroups of drugs based on mechanism and uses, and it would be important to have those groups represented as preferred products as widely as can be accommodated.

11. Antihyperuricemics
    - Products added to the class: colchicine (Colcrys, Mitigare) – indications, mechanisms of action, dosing, contraindications and adverse reactions.
    - Colchicine is an old drug which was temporarily unavailable due to being so old that the FDA withdrew its approval for lack of clinical studies of efficacy.
    - Practice Guidelines – updated clinical consensus statement for Gouty Arthritis of the Foot and Ankle by American College of Foot and Ankle Surgeons (ACFAS) and the American Association of Nurse Practitioners (November 2018).
    - FDA Communications – FDA safety communication February 2019, Uloric (febuxostat) increased warning for risk of cardiovascular and all-cause death compared with allopurinol.

12. Anticholinergics/COPD Agents
    - New Product -Yupelri (revefenacin) – indications, dosing, contraindications and adverse drug reactions. It is a second nebulized product in this drug class.
    - New Guidelines Updates – Global Initiative for COPD (GOLD) 2019.

- Comparative evidence limited to increasing effect by adding drugs to therapy.
- Different products may be more appropriate at different points of the disease progression but quality evidence to support overall clinical superiority is absent.

D. Executive Session Recess to Excessive Session Audio Cast Time 1:54:00

The Board recessed to executive session at 11:00am to review financial information relating to each of the 12 therapeutic classes under review. No official action was taken in the executive session. The Board reconvened to the public session at 2:15 PM.

E. DUR Board PDP Recommendations Audio Cast Time 1:56:21 to 2:11:22

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

Recommendations of the DUR Board	**Commissioner's Final Determination**
Tetracyclines Audio Cast Time 1:59:15 **Preferred**: demeclocycline, doxycycline hyclate, minocycline capsules, Morgidox, tetracycline **Non- Preferred**: Doryx, Doryx MPC, doxycycline hyclate DR, doxycycline monohydrate, doxycycline monohydrate IR-DR, minocycline tablet, minocycline ER, Nuzyra, Oracea, Solodyn, Vibramycin, Ximino ER Passed unanimously	Approved as Recommended

Recommendations of the DUR Board	Commissioner's Final Determination
Anticonvulsants, Other Audio Cast Time 2:00:49 **Preferred:** clobazam tablet, gabapentin (cap, tab, soln), lamotrigine (tab, chew), levetiracetam, levetiracetam ER, Lyrica capsule, tiagabine, topiramate, zonisamide **Non-Preferred:** Banzel, Briviact, clobazam suspension, Epidiolex, felbamate, Felbatol, Fycompa, Gabitril, Keppra, Keppra XR, Lamictal (tab, chew, dosepak), Lamictal ODT (tab, dosepak), Lamictal XR (tab,dosepak), lamotrigine ER, lamotrigine (ODT,ODT dosepak, tab dosepak), Lyrica solution, Lyrica CR tablet, Neurontin, Onfi, Qudexy XR, Roweepra, Roweepra XR, Sabril Powder packet, Spritam, Subvenite, Sympazan Film, Topamax, topiramate ER, Trokendi XR, vigabatrin, Vigadrone powder packet, Vimpat Passed unanimously	Approved as Recommended
Antimigraine Agents, Other (New Class) Audio Cast Time 2:02:05 **Preferred:** Emgality **Non-Preferred**: Aimovig, Ajovy Passed unanimously	Approved as Recommended

Recommendations of the DUR Board	Commissioner's Final Determination
CNS Stimulants Audio Cast Time 2:02:42 **Preferred:** amphetamine salt combo IR (generic Adderall), amphetamine salt combo ER (generic Adderall XR), Aptensio, Daytrana, Dyanavel XR, dextroamphetamine tablet, dexmethylphenidate (generic Focalin), Focalin XR, methylphenidate tablet (generic Ritalin), Quillichew ER, Quillivant XR, Vyvance (capsule,chew) **Non-Preferred:** Adderall XR, amphetamine (generic Evekeo), armodafinil, Concerta, Cotempla XR-ODT, Desoxyn, Dexedrine, dexmethylphenidate ER (generic Focalin XR), dextroamphetamine solution (generic ProCentra), dextroamphetamine ER (generic Dexedrine), Evekeo, Focalin, Metadate ER, methamphetamine (generic Desoxyn), Methylin solution, methylphenidate (chew, tab, soln)(generic Methylin), methylphenidate CD (generic Metadate CD), methylphenidate ER (generic Concerta, Ritalin LA, Metadate ER), Modafinil (generic Provigil), Mydayis, Nuvigil, ProCentra, Provigil, Ritalin, Ritalin LA, Zenzedi Passed unanimously	Approved as Recommended
Movement Disorder Agents (New Class) Audio Cast Time 2:03:36 **Preferred:** Austedo, tetrabenazine **Non-Preferred:** Ingrezza, Xenazine Passed unanimously	Approved as Recommended

Recommendations of the DUR Board	Commissioner's Final Determination
Multiple Sclerosis Agents Audio Cast Time 2:04:44 **Preferred:** Avonex, Betaseron, Copaxone 20 mg/ml, Gilenya*, Rebif, Tecfidera * **Non-Preferred**: Aubagio, Copaxone 40 mg/ml, Extavia, glatiramer, Glatopa, Plegridy * Requires a trial with a preferred injectable product Passed unanimously	Approved as Recommended
Growth Hormones Audio Cast Time 2:05:29 **Preferred:** Genotropin, Norditropin **Non-Preferred**: Humatrope, Nutropin AQ, Omnitrope, Saizen, Zomacton, Zorbtive Passed unanimously	Approved as Recommended
Colony Stimulating Factors (New Class) Audio Cast Time 2:05:60 **Preferred:** Fulphila, Neupogen, Udenyca **Non-Preferred:** Granix, Leukine, Neulasta, Nivestym, Zarxio Passed unanimously	Approved as Recommended
Erythropoiesis Stimulating Agents Audio Cast Time 2:06:41 **Preferred:** Epogen, Retacrit **Non-Preferred:** Aranesp, Mircera, Procrit Passed unanimously	Approved as Recommended

Recommendations of the DUR Board	Commissioner's Final Determination
Immunosuppressives, Oral Audio Cast Time 2:07:23 **Preferred:** azathioprine, Cellcept Suspension, cyclosporine (softgel, cap), cyclosporine modified (cap, soln), Gengraf, mycophenolic acid, mycophenolate mofetil (cap, tab), Rapamune solution, Sandimmune capsule, sirolimus tablet, tacrolimus **Non-Preferred ^:** Astagraf, Azasan, Cellcept (cap, tab), Envarsus XR, Imuran, mycophenolate mofetil (susp), Myfortic, Neoral, Prograf, Rapamune tablet, Sandimmune solution, sirolimus solution, Zortress ^ Prior authorization will not be required for patients stabilized on a non-preferred drug. Passed unanimously	Approved as Recommended
Anti-hyperuricemics Audio Cast Time 2:09:22 **Preferred:** allopurinol, probenecid, probenecid/colchicine, Mitigare **Non-preferred:** colchicine (tab,cap), Colcrys, Uloric, Zyloprim Passed unanimously	Approved as Recommended
Anticholinergics/COPD Agents Audio Cast Time 2:10:01 **Preferred:** Atrovent HFA, Bevespi Aerosphere, Combivent Respimat, ipratropium, ipratropium/albuterol, Spiriva, Stiolto Respimat, Tudorza Pressair **Non-preferred:** Anoro Ellipta, Daliresp, Incruse Ellipta, Lonhala Magnair, Spiriva Respimat, Trelegy Ellipta, Utibron Neohaler, Yupelri Passed unanimously	Approved as Recommended

F. Final Comments and Adjournment

Audio Cast Time 2:11:27 to 2:12:37

Janet Zachary-Elkind, Deputy Director
Douglas Fish, MD - Chairperson
Anthony Merola, RPh, MBA

Contact for post meeting questions: DUR@health.NY.gov or 518-486-3209

Meeting adjourned at 2:30pm

G. 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 the PDP therapeutic classes reviewed are estimated at $8.5M. The savings would be achieved through utilization changes and the receipt of supplemental rebates from pharmaceutical manufacturers.