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 Sheehan, RPh
Robert Correia, PharmD                             Monica Toohey, RPh
Anthony Merola, RPh, MBA                          Janet Zachary-Elkind

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

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
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.
   - 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.
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:

<table>
<thead>
<tr>
<th>Recommendations of the DUR Board</th>
<th>Commissioner’s Final Determination</th>
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<tbody>
<tr>
<td>Tetracyclines</td>
<td></td>
</tr>
<tr>
<td><strong>Preferred</strong>: demeclocycline, doxycycline hyclate, minocycline capsules, Morgidox, tetracycline</td>
<td>Approved as Recommended</td>
</tr>
<tr>
<td><strong>Non-Preferred</strong>: Doryx, Doryx MPC, doxycycline hyclate DR, doxycycline monohydrate, doxycycline monohydrate IR-DR, minocycline tablet, minocycline ER, Nuzyra, Oracea, Solodyn, Vibramycin, Ximino ER</td>
<td>Passed unanimously</td>
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<tr>
<td>Recommendations of the DUR Board</td>
<td>Commissioner’s Final Determination</td>
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<tr>
<td><strong>Anticonvulsants, Other</strong></td>
<td>Audio Cast Time 2:00:49</td>
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<tr>
<td><strong>Preferred:</strong> clobazam tablet, gabapentin (cap, tab, soln), lamotrigine (tab, chew), levetiracetam, levetiracetam ER, Lyrica capsule, tiagabine, topiramate, zonisamide</td>
<td>Approved as Recommended</td>
</tr>
<tr>
<td><strong>Non-Preferred:</strong> 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</td>
<td>Passed unanimously</td>
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<tr>
<td><strong>Antimigraine Agents, Other</strong></td>
<td>Audio Cast Time 2:02:05</td>
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<tr>
<td><strong>(New Class)</strong></td>
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<tr>
<td><strong>Preferred:</strong> Emgality</td>
<td>Approved as Recommended</td>
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<tr>
<td><strong>Non-Preferred:</strong> Aimovig, Ajovy</td>
<td>Passed unanimously</td>
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</table>
## Recommendations of the DUR Board

### CNS Stimulants

**Preferred:** amphetamine salt combo IR (generic Adderall), amphetamine salt combo ER (generic Adderall XR), Aptensio, Daytrana, Dyanavel XR, dextroamphetamine tablet, dextmethylphenidate (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, dextmethylphenidate ER (generic Focalin XR), dextroamphetamine solution (generic ProCentra), dextroamphetamine ER (generic Dexedrine), Evekeo, Focalin, Metadate ER, methamphetamine (generic Desoxyn), Methylis 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

### Movement Disorder Agents

**Preferred:** Austedo, tetrabenazine

**Non-Preferred:** Ingrezza, Xenazine

Passed unanimously
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<thead>
<tr>
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</thead>
<tbody>
<tr>
<td><strong>Multiple Sclerosis Agents</strong></td>
<td><strong>Audio Cast Time 2:04:44</strong></td>
</tr>
<tr>
<td><strong>Preferred:</strong> Avonex, Betaseron, Copaxone 20 mg/ml, Gilenya*, Rebif, Tecfidera *</td>
<td><strong>Passed unanimously</strong></td>
</tr>
<tr>
<td><strong>Non-Preferred:</strong> Aubagio, Copaxone 40 mg/ml, Extavia, glatiramer, Glatopa, Plegridy</td>
<td><strong>Approved as Recommended</strong></td>
</tr>
<tr>
<td>* Requires a trial with a preferred injectable product</td>
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<tr>
<td><strong>Growth Hormones</strong></td>
<td><strong>Audio Cast Time 2:05:29</strong></td>
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<tr>
<td><strong>Preferred:</strong> Genotropin, Norditropin</td>
<td><strong>Approved as Recommended</strong></td>
</tr>
<tr>
<td><strong>Non-Preferred:</strong> Humatrope, Nutropin AQ, Omnitrope, Saizen, Zomacton, Zorbtive</td>
<td><strong>Passed unanimously</strong></td>
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<tr>
<td><strong>Colony Stimulating Factors</strong></td>
<td><strong>Audio Cast Time 2:05:60</strong></td>
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<tr>
<td>(New Class)</td>
<td><strong>Approved as Recommended</strong></td>
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<tr>
<td><strong>Preferred:</strong> Fulphila, Neupogen, Udenyca</td>
<td><strong>Passed unanimously</strong></td>
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<tr>
<td><strong>Non-Preferred:</strong> Granix, Leukine, Neulasta, Nivestym, Zarxio</td>
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<tr>
<td><strong>Erythropoiesis Stimulating Agents</strong></td>
<td><strong>Audio Cast Time 2:06:41</strong></td>
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<tr>
<td><strong>Preferred:</strong> Epogen, Retacrit</td>
<td><strong>Approved as Recommended</strong></td>
</tr>
<tr>
<td><strong>Non-Preferred:</strong> Aranesp, Mircera, Procrit</td>
<td><strong>Passed unanimously</strong></td>
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<tr>
<td><strong>Immunosuppressives, Oral</strong></td>
<td>Audio Cast Time 2:07:23</td>
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<tr>
<td><strong>Preferred:</strong> azathioprine, Cellcept Suspension, cyclosporine (softgel, cap), cyclosporine modified (cap, soln), Gengraf, mycophenolic acid, mycophenolate mofetil (cap, tab), Rapamune solution, Sandimmune capsule, sirolimus tablet, tacrolimus</td>
<td>Approved as Recommended</td>
</tr>
<tr>
<td><strong>Non-Preferred ^:</strong> Astagraf, Azasan, Cellcept (cap, tab), Envarsus XR, Imuran, mycophenolate mofetil (susp), Myfortic, Neoral, Prograf, Rapamune tablet, Sandimmune solution, sirolimus solution, Zortress</td>
<td>Passed unanimously</td>
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<tr>
<td>^ Prior authorization will not be required for patients stabilized on a non-preferred drug.</td>
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<tr>
<td><strong>Anti-hyperuricemics</strong></td>
<td>Audio Cast Time 2:09:22</td>
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<tr>
<td><strong>Preferred:</strong> allopurinol, probenecid, probenecid/colchicine, Mitigare</td>
<td>Approved as Recommended</td>
</tr>
<tr>
<td><strong>Non-preferred:</strong> colchicine (tab,cap), Colcrys, Uloric, Zyloprim</td>
<td>Passed unanimously</td>
</tr>
<tr>
<td><strong>Anticholinergics/COPD Agents</strong></td>
<td>Audio Cast Time 2:10:01</td>
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<tr>
<td><strong>Preferred:</strong> Atrovent HFA, Bevespi Aerosphere, Combivent Respimat, ipratropium, ipratropium/albuterol, Spiriva, Stiolto Respimat, Tudorza Pressair</td>
<td>Approved as Recommended</td>
</tr>
<tr>
<td><strong>Non-preferred:</strong> Anoro Ellipta, Daliresp, Incruse Ellipta, Lonhala Magnair, Spiriva Respimat, Trelegy Ellipta, Utibron Neohaler, Yupelri</td>
<td>Passed unanimously</td>
</tr>
</tbody>
</table>
F. Final Comments and Adjournment

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:
  o 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:
  o 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:
  o 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.