

New York State Medicaid Drug Utilization Review (DUR) Board Meeting Summary for April 22, 2015

The Medicaid DUR Board met on Thursday April 22, 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 00:07 - 02:28)

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

Nancy Balkon, PhD, NP

Leigh Briscoe-Dwyer, PharmD

Jeffrey Dubitsky, RPh

Marla Eglowstein, MD

Renante Ignacio, MD

Jadwiga Najib, PharmD

John McIntyre, MD

John Noviasky, PharmD

James Saperstone, MD

Magellan Medicaid Administration

Eileen Zimmer, PharmD, MBA

B. Public Comment Period

(Audio Cast Time 02:28 - 01:33:22)

The following speakers provided public comment to the Board:

- | | | | |
|----|----------------------|----------------------------------|-------------------------------------|
| 1. | Lee Marks | Orexo | Agents for Opioid Dependence |
| 2. | Charlotte Cavoores | BioDelivery Sciences Intl., Inc. | Agents for Opioid Dependence |
| 3. | Paul W. Wacnik, PhD | Pfizer Inc | Opioids - Long Acting |
| 4. | Trey Gardner, PharmD | Silvergate Pharm., Inc. | ACE Inhibitors |
| 5. | Paul W. Wacnik, PhD | Pfizer Inc | Anticonvulsants - Second Generation |
| 6. | Sonya A Lewis, PhD | Upsher-Smith Laboratories | Anticonvulsants - Second Generation |
| 7. | Tonya Taylor, PhD | Shire | CNS Stimulants |

8.	Heidi Belden, PharmD	Pfizer Inc	CNS Stimulants
9.	Robert Garris	Teva Pharmaceuticals	Multiple Sclerosis Agents
10.	Pallav Raval, PharmD	Novartis	Multiple Sclerosis Agents
11.	Aaron Ward	Nat'l. MS Society Upstate NY	Multiple Sclerosis Agents
12.	Julie M. Thompson, PhD	Genzyme	Multiple Sclerosis Agents
13.	Chris R Palmeiro, DO, MSc	Private Practice	GLP-1 agonist
14.	Anthony Wheeler, PhD	Eli Lilly and Company	GLP-1 agonist
15.	Rob Picone, RPh, PhD	Novo Nordisk Inc	GLP-1 agonist
16.	Domenic Paletta, PharmD	AstraZeneca, LP	GLP-1 agonist
17.	Barry H. Patel, PharmD	Glaxo Smith Kline	GLP-1 agonist
18.	Henry Tan, MD	Albany Medical Center	Anticoagulants - Oral
19.	Shaffee Bacchus, PharmD	Janssen	Anticoagulants - Oral
20.	Eric Wittbrodt, PharmD, MPH	Daiichi Sankyo, Inc	Anticoagulants - Oral
21.	Christina Baeta, PharmD	Boehringer-Ingelheim	Anticoagulants - Oral
22.	Shalini Hede, PharmD	Bristol-Myers Squibb	Anticoagulants - Oral
23.	Shalini Hede, PharmD	Bristol-Myers Squibb	Immunomodulator
24.	Pallav Raval, PharmD	Novartis	Immunomodulator
25.	Gary Brady, PharmD, MBA	Pfizer Inc.	Immunomodulator
26.	Marianne Pelletier	AstraZeneca Pharmaceuticals	Anticholinergics - COPD Agents
27.	Marianne Pelletier	AstraZeneca Pharmaceuticals	Anticholinergics - COPD Agents
28.	Christina Baeta, PharmD	Boehringer-Ingelheim	Anticholinergics - COPD Agents
29.	Barry H. Patel, PharmD	Glaxo Smith Kline	Anticholinergics - COPD Agents
30.	Christina Baeta, PharmD	Boehringer-Ingelheim	Beta-2 Adrenergic Agents LA Inhaled

C. Preferred Drug Program Clinical Reviews

(Audio Cast Time 1:33:22-3:47:20)

Eileen Zimmer, PharmD
Robert Correia, PharmD

1. Non-Steroidal Anti-Inflammatory Drugs – Prescription
 - No new clinical information

2. Agents for Opioid Dependence (Audio Cast Time 1:35:32)
 - New Product: Bunavail
 - New Formulation: Zubsolv new strengths
 - REMS Update

3. Opioids - Long Acting (Audio Cast Time 1:43:30)

- New Product: Hysingla
 - New Formulations: fentanyl transdermal patch, Zohydro
 - New Generics: hydromorphone extended release, oxycodone extended release
 - Additional Information: FDA Communications, Practice Guidelines, Controlled Substance Act Update, Label Revisions
4. Angiotensin Converting Enzyme Inhibitors (ACEIs) (Audio Cast Time 1:50:00)
 - New Product: Epaned
 - Practice guidelines update
 5. Niacin Derivatives
 - No new clinical information
 6. Triglyceride Lowering Agents
 - No new clinical information
 7. Anticonvulsants - Second Generation (Audio Cast Time 1:57:55)
 - New Product: Qudexy XR
 - New Generics: topiramate, lamotrigine ODT
 - New/Expanded Indications: Vimpat, Keppra XR, Banzel, Topamax
 - Additional Information: Label Revisions
 8. Central Nervous System (CNS) Stimulants (Audio Cast Time 2:07:30)
 - New Product: Evekeo
 - New Generics: methylphenidate chewable tablet, dexmethylphenidate
 - New Indications: Vyvanse
 - Label Revisions: Vyvanse
 9. Multiple Sclerosis Agents (Audio Cast Time 2:16:30)
 - New Product: Plegridy
 - Additional Information: FDA communication, manufacturer communication
 10. Sedative Hypnotics/Sleep Agents (Audio Cast Time 2:23:38)
 - New Product: Belsomra
 - New Generic: eszopiclone
 - Label Revisions
 11. Anti-Virals - Topical (Audio Cast Time 2:28:38)
 - New Product: Sitavig
 - New Indications: Xerese
 12. Psoriasis Agents – Topical (Audio Cast Time 2:33:10)

- New Product: Sorilux
 - New Generic: calcipotriene/betamethasone dipropionate ointment
 - Expanded Indications: Taclonex
13. Steroids, Topical - High Potency
- No new clinical information
14. Glucagon-like Peptide-1 (GLP-1) Agonists (Audio Cast Time 2:36:55)
- New Products: Tanzeum, Trulicity
 - New Formulation: Bydureon 2mg single dose prefilled pen
 - Additional Information: FDA assessment of pancreatic safety (NEJM), FDA communications, practice guidelines update
15. Anticoagulants – Oral (Audio Cast Time 2:49:25)
- New Product: Savaysa
 - Additional Information: practice guidelines, clinical trial, label revision
16. Erythropoiesis Stimulating Agents (ESAs) (Audio Cast Time 3:06:40)
- New Product: Mircera
17. Immunomodulators - Systemic (Audio Cast Time 3:11:00)
- New Products: Cosentyx, Otezla
 - New Indications: Humira
 - Label Revisions
18. Antibiotic/Steroid Combinations
- No new clinical information
19. Antihistamines – Ophthalmic (Audio Cast Time 3:28:18)
- New Product: Pazeo
20. Phosphate Binders/Regulators (Audio Cast Time 3:31:08)
- New Product: Auryxia
 - New Formulation: Fosrenol oral powder 750mg and 1000mg
 - New Generic: sevelamer carbonate tablet
21. Urinary Tract Antispasmodics
- No new clinical information
22. Anticholinergics - COPD Agents (Audio Cast Time 3:33:50)
- New Product: Incruse Ellipta

- New Formulation: Spiriva Respimat
- Additional Information: label revision, practice guideline

23. Beta-2 Adrenergic Agents Long Acting – Inhaled (Audio Cast Time 3:37:31)

- New Product: Striverdi
- Practice Guidelines Update

24. Corticosteroids – Inhaled (Audio Cast Time 3:40:35)

- New Product: Arnuity Ellipta
- New Formulations: QVAR device with dose counter, Asmanex with HFA propellant
- Practice Guidelines Update

E. Executive Session (Recess to Excessive Session Audio Cast Time 3:47:20)

The Board recessed the public session at 1:15 P.M. to go into executive session for review of financial information relating to each of the therapeutic classes under review. No official action was taken in the executive session. The Board reconvened to the public session at 3:15 pm.

F. DUR Board Recommendations (Audio Cast Time 3:47:22 – 4:09:34)

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
<p>Prescription Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) Audio Cast Time 3:48:19</p> <p>Preferred Ibuprofen, indomethacin, meloxicam tablet, naproxen, naproxen EC, naproxen sodium, piroxicam, sulindac, Voltaren Gel</p> <p>Non-preferred Anaprox, Anaprox DS, Arthrotec, Cambia, Celebrex, celecoxib, Daypro, diclofenac potassium, diclofenac sodium, diclofenac sodium XR, diclofenac topical solution, diclofenac/misoprostol, diflunisal, Duexis, etodolac, etodolac ER, Feldene, fenoprofen, Flector patch, flurbiprofen, Indocin, indomethacin SR, ketoprofen, ketoprofen SA, ketorolac, meclofenamate, mefenamic acid, meloxicam suspension, Mobic, nabumetone, Naprelan, Naprosyn, Naprosyn EC, oxaprozin, Pennsaid, Ponstel, Sprix, tolmetin, Vimovo, Voltaren XR, Zipsor, Zorvolex</p> <p>Passed Unanimously</p>	<p>Approved as Recommended</p>

<p>Agents for Opioid Dependence</p> <p>Preferred buprenorphine, Suboxone (film)</p> <p>Non-preferred Bunavail, buprenorphine/naloxone (tablet), Zubsolv</p>	<p>Audio Cast Time 3:51:54</p> <p>Passed Unanimously</p>	<p>Approved as Recommended</p>
<p>Opioids – Long Acting</p> <p>Preferred fentanyl transdermal 12, 25, 50, 75, 100 mcg., Kadian, morphine ER tablet</p> <p>Non-preferred Avinza, Butrans, Conzip, Duragesic, Embeda, Exalgo, fentanyl transdermal 37.5, 62.5, 87.5 mcg., hydromorphone ER, Hysingla ER, morphine ER capsule, MS Contin, Nucynta ER, Opana ER, oxycodone ER, Oxycontin, oxymorphone ER, tramadol ER, Ultram ER, Zohydro ER</p>	<p>Audio Cast Time 3:52:22</p> <p>Passed Unanimously</p>	<p>Approved as Recommended</p>
<p>ACE Inhibitors</p> <p>Preferred benazepril, captopril, enalapril, lisinopril, ramipril</p> <p>Non-preferred Accupril, Altace, Epaned, fosinopril, Lotensin, Mavik, moexipril perindopril, Prinivil, quinapril, trandolapril, Univasc, Vasotec, Zestril</p>	<p>Audio Cast Time 3:52:48</p> <p>Passed Unanimously</p>	<p>Approved as Recommended</p>
<p>Niacin Derivatives</p> <p>Preferred Niaspan</p> <p>Non-preferred niacin ER</p>	<p>Audio Cast Time 3:53:20</p> <p>Passed Unanimously</p>	<p>Approved as Recommended</p>

<p>Triglyceride Lowering Agents Audio Cast Time 3:53:52</p> <p>Preferred gemfibrozil, Tricor, Trilipix</p> <p>Non-preferred Antara, fenofibrate, fenofibric acid, Fenoglide, Fibracor, Lipofen, Lofibra, Lopid, Lovaza, omega-3 acid ethyl esters, Triglide, Vascepa</p> <p style="text-align: right;">Passed Unanimously</p>	<p style="text-align: center;">Approved as Recommended</p>
<p>Anticonvulsants – Second Generation Audio Cast Time 3:54:56</p> <p>Preferred felbamate, gabapentin capsule, gabapentin solution, Gabitril 2mg & 4mg, lamotrigine, levetiracetam, levetiracetam ER, Lyrica, Topiragen, topiramate, zonisamide</p> <p>Non-preferred Banzel, Felbatol, Fycompa, gabapentin tablet, Gabitril 12mg & 16mg, Keppra, Keppra XR, Lamictal, Lamictal ODT, Lamictal XR, lamotrigine XR, lamotrigine ODT, Neurontin, Onfi, Potiga, Qudexy XR, Sabril, tiagabine, Topamax, topiramate ER, Trokendi XR, Vimpat, Zonegran</p> <p style="text-align: right;">Passed Unanimously</p>	<p style="text-align: center;">Approved as Recommended</p>
<p>Central Nervous System Stimulants Audio Cast Time 3:55:22</p> <p>Preferred Adderall, Adderall XR, amphetamine salt combo IR, Daytrana, dexamethylphenidate, dextroamphetamine, Focalin XR, Metadate ER, Methylin, methylphenidate tablet, methylphenidate ER, methylphenidate SR tablet, Quillivant XR, Vyvanse</p> <p>Non-preferred amphetamine salt combo ER, Concerta, Desoxyn, Dexedrine, dexamethylphenidate XR, dextroamphetamine ER, dextroamphetamine solution, Evekeo, Focalin, Metadate CD, methamphetamine, methylphenidate CD, methylphenidate ER, methylphenidate chewable, methylphenidate solution, modafinil, Nuvigil, Procentra, Provigil, Ritalin, Ritalin LA, Ritalin SR, Zenedi</p> <p style="text-align: right;">Passed Unanimously</p>	<p style="text-align: center;">Approved as Recommended</p>

<p>Multiple Sclerosis Agents Audio Cast Time 3:55:53</p> <p>Preferred Avonex, Betaseron, Copaxone 20mg/ml, Gilenya*</p> <p>Non-preferred Aubagio**, Copaxone 40mg/ml, Extavia, Plegridy, Rebif, Tecfidera**</p> <p>*Gilenya as the preferred oral agent, requires a trial with a preferred injectable product.</p> <p>**Aubagio and Tecfidera require a trial with a preferred oral agent.</p> <p style="text-align: right;">10 in favor-1 opposed-no abstentions</p> <p>A DURB member voiced concerns with limitations associated with any MS drug.</p>	<p>Approved as Recommended</p>
<p>Sedative Hypnotic/Sleep Agents Audio Cast Time 3:58:48</p> <p>Preferred estazolam, flurazepam, temazepam (15mg, 30mg), zolpidem</p> <p>Non-preferred Ambien, Ambien CR, Belsomra, Edluar, eszopiclone, Halcion, Intermezzo, Lunesta, Restoril, Rozerem, Silenor, Sonata, temazepam (7.5mg, 22.5mg), triazolam, zaleplon, zolpidem ER</p> <p style="text-align: right;">Passed Unanimously</p>	<p>Approved as Recommended</p>
<p>Anti-virals – topical Audio Cast Time 3:59:12</p> <p>Preferred Abreva, Zovirax cream</p> <p>Non-preferred acyclovir ointment, Denavir, Sitavig, Xerese, Zovirax ointment</p> <p style="text-align: right;">Passed Unanimously</p>	<p>Approved as Recommended</p>

<p>Psoriasis Agents – Topical Audio Cast Time 3:59:46</p> <p>Preferred Drugs calcipotriene (cream, ointment, scalp solution)</p> <p>Non-preferred Drugs calcipotriene/ betamethasone, Calcitrene, calcitriol ointment, Dovonex, Sorilux, Taclonex, Vectical</p> <p style="text-align: right;">Passed Unanimously</p>	<p>Approved as Recommended</p>
<p>Topical Steroids – High Potency Audio Cast Time 4:00:12</p> <p>Preferred betamethasone dipropionate (cream, lotion), betamethasone valerate (cream, ointment), fluocinonide 0.05% (cream), fluocinonide emollient, fluocinonide-E, triamcinolone acetonide</p> <p>Non-preferred amcinonide, Apexicon-E, Beta-Val, betamethasone dipropionate augmented, betamethasone dipropionate (gel, ointment) betamethasone valerate (lotion), desoximetasone, diflorasone Diprolene, Diprolene AF, fluocinonide 0.1% (cream), fluocinonide (ointment), Halog, Kenalog, Topicort, Trianex, Vanos</p> <p style="text-align: right;">Passed Unanimously</p>	<p>Approved as Recommended</p>
<p>Glucagon-Like Peptide Agonists Audio Cast Time 4:00:49</p> <p>Preferred Byetta, Bydureon, Tanzeum</p> <p>Non-preferred Trulicity, Victoza</p> <p style="text-align: right;">Passed Unanimously</p>	<p>Approved as Recommended</p>
<p>Anticoagulants - Oral Audio Cast Time 4:01:19</p> <p>Preferred Coumadin, Jantoven, Pradaxa, warfarin, Xarelto</p> <p>Non-preferred Eliquis, Savaysa, Xarelto dose pack</p> <p>The DUR Board agreed during the voting process that there should be no change to patients' existing therapy.</p> <p style="text-align: right;">Passed Unanimously</p>	<p>Approved as Recommended</p>

<p>Erythropoiesis Stimulating Agents</p> <p>Preferred Aranesp, Procrit</p> <p>Non-preferred Epogen, Mircera</p>	<p>Audio Cast Time 4:02:02</p> <p>Passed Unanimously</p>	<p>Approved as Recommended</p>
<p>Immunomodulators - Systemic</p> <p>Preferred Enbrel, Humira</p> <p>Non-preferred Actemra SQ, Cimzia, Cosentyx, Kineret, Orencia SQ, Otezla, Simponi, Stelara, Xeljanz</p>	<p>Audio Cast Time 4:02:26</p> <p>Passed Unanimously</p>	<p>Approved as Recommended</p>
<p>Antibiotic/Steroid Combinations – Ophthalmic</p> <p>Preferred Blephamide, neomycin/polymyxin/dexamethasone, sulfacetamide/prednisolone, Tobradex (ointment), Tobradex (suspension)</p> <p>Non-preferred Maxitrol ointment, Maxitrol suspension, neomycin/bacitracin/polymyxin/HC, neomycin/polymyxin/HC, Pred-G, Tobradex ST, tobramycin/dexamethasone suspension, Zylet</p>	<p>Audio Cast Time 4:02:49</p> <p>Passed Unanimously</p>	<p>Approved as Recommended</p>
<p>Antihistamines - Ophthalmic</p> <p>Preferred Pataday</p> <p>Non-preferred azelastine, Bepreve, Elestat, Emadine, epinastine, Lastacaft, Optivar, Patanol, Pazeo</p>	<p>Audio Cast Time 4:03:30</p> <p>Passed Unanimously</p>	<p>Approved as Recommended</p>

<p>Phosphate Binders/Regulators</p> <p>Preferred calcium acetate, Eliphos, Fosrenol, Renagel</p> <p>Non-preferred Auryxia, Phoslo, Phoslyra, Renvela, Velphoro</p>	<p>Audio Cast Time 4:03:52</p> <p>Passed Unanimously</p>	<p>Approved as Recommended</p>
<p>Urinary Tract Antispasmodics</p> <p>Preferred oxybutynin, Toviaz, Vesicare</p> <p>Non-preferred Detrol, Detrol LA, Ditropan XL, Enablex, Gelnique, Myrbetriq, oxybutynin ER, Oxytrol, Sanctura, Sanctura XR, tolterodine, tolterodine ER, trospium, trospium ER</p> <p>A DUR Board member clarified that Oxytrol is a transdermal dosage form</p>	<p>Audio Cast Time 4:04:19</p> <p>Passed Unanimously</p>	<p>Approved as Recommended</p>
<p>Anticholinergics/COPD Agents - Inhaled</p> <p>Preferred Atrovent HFA, Combivent Respimat, ipratropium, ipratropium/albuterol, Spiriva</p> <p>Non-preferred Anoro Ellipta, Daliresp, Incruse Ellipta, Spiriva Respimat Tudorza Pressair</p>	<p>Audio Cast Time 4:05:49</p> <p>Passed Unanimously</p>	<p>Approved as Recommended</p>
<p>Long Acting Beta Agonists - Inhaled</p> <p>Preferred Brovana, Foradil, Serevent</p> <p>Non-preferred Arcapta, Perforomist, Striverdi Respimat</p>	<p>Audio Cast Time 4:06:19</p> <p>Passed Unanimously</p>	<p>Approved as Recommended</p>

<p>Corticosteroids - Inhaled Audio Cast Time 4:06:45</p> <p>Preferred Asmanex, Flovent Diskus, Flovent HFA, Pulmicort Flexhaler*, QVAR</p> <p>Non-preferred Aerospan, Alvesco, Arnuity Ellipta, Asmanex HFA</p> <p>*DOH recommendation modified by the DUR Board</p> <p style="text-align: center;">8 in favor, 2 opposed, 1 abstention</p>	<p>Approved as Recommended</p>
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G. Final Comments and Adjournment

Audio Cast Time (4:09:35 - 4:10:27)

Janet Zachary-Elkind
Anthony Merola, RPh, MBA

Meeting adjourned at 3:45 PM

H. Commissioner Final Determinations

The impact of this final determination is as follows:

1. 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.

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 modifications to the preferred drug list (PDL) are estimated at \$2.7M. The savings are achieved through changes in utilization to equally effective and less expensive products including the receipt of supplemental rebates from pharmaceutical manufacturers.