

**New York State Medicaid
Drug Utilization Review (DUR) Board
Meeting Summary for June 27, 2013**

The Medicaid DUR Board met on Friday June 27, 2013 from 9:00 AM to 4:30 PM
Meeting Room 3, Concourse, Empire State Plaza, Albany, New York

An archived audio webcast of the meeting proceedings is available on the Department of Health website for at least 30 days from the meeting date: <http://www.health.ny.gov/events/webcasts/>

A. Welcome and Introductions

(Audio Webcast Time 3:00 – 11:15)

Department of Health

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

Monica Toohey, RPh
John Naioti, RPh
Daniel McNamara, RPh

DUR Board

Nancy Balkon, PhD, NP
Leigh Briscoe-Dwyer, PharmD
Donna Chiefari, PharmD
Jeffrey Dubitsky, RPh
Renante Ignacio, MD
Kathleen LeBeau

John McIntyre, MD
Jadwiga Najib, PharmD
John Noviasky, PharmD
Michelle Rainka, PharmD
William Scheer, RPh
John Wikiera

Magellan Medicaid Administration

Eileen Zimmer, PharmD, MBA

B. Public Comment Period

(Audio Webcast Time 11:15 – 1:26:01)

The following speakers provided public comment to the Board:

1. Salvatore Molina & Catherine Summers, MD; Salix Pharmaceuticals - Xifaxin
2. Christiane Arserver, MD; Merck & Co., Inc - Victrelis, Januvia, Janumet, Juvisync, Janumet XR
3. Lisa Borland, PharmD; Vertex Pharmaceuticals - Incivik
4. Jess David Collins, MD; Private Practice - Anti-seizure medication
5. Pamela W Salisbury, MSN, NP-C; Genzyme Corporation - Aubagio
6. Beth D'Ambrosio, PharmD; Novartis - Gilenya
7. Robert Garris, PharmD, MPH; Teva - Copaxone, Qnasl
8. Melanie Beckemeyer, PharmD; UBC - Neupro
9. Jodi H Walker, PharmD, BCPS; Abbvie - Androgel, Humira

10. Maria Dugandzic, PharmD; Boehringer Ingelheim Pharmaceuticals Inc.- Tradjenta, Combivent, Pradaxa
11. Kathryn L Gann, PhD; AstraZeneca - Onglyza, Komiglyze
12. Eric Wittbrodt, PharmD; Takeda - alogliptin
13. Maureen Zani, RN; Private Practice - Growth Hormone
14. Biran Patel, PharmD; Novo Nordisk, Inc - Norditropin
15. JoAnn B Trainer, PharmD; Pfizer - Eliquis
16. Arsalan Khan, PharmD; Janssen Scientific Services- Xarelto
17. Scott S Brehaut, MD; Private Practice - Oral Anticoagulants
18. Martin Unverdorben, MD, PhD; AstraZeneca - Brilinta
19. Furqan Tejani, MD; Private Practice - Antiplatelets
20. Jawad Wunej, PharmD; Eli Lilly & Co. - Effient
21. Timothy J Phalen, PhD; UCB - Cimzia
22. Payal Patel, PharmD; Bristol-Myers Squibb - Orencia
23. Vanessa Castellano, PhD; Pfizer Inc. - Xeljanz
24. Kara L Sperandeo, PharmD; Forest Laboratories, Inc. - Tudorza
25. Michelle Kamdar, PharmD, MPH; GlaxoSmithKline - Flovent

C. Preferred Drug Program Clinical Reviews

(Audio Webcast Time 1:26:02 – 3:32:29)

Eileen Zimmer, PharmD
Robert Correia, PharmD

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| 1. Gastrointestinal Preparatory Agents | (Audio Cast Time 1:27:50) |
| 2. Gastrointestinal Antibiotics | (Audio Cast Time 1:32:50) |
| 3. Glucocorticoids – oral | (Audio Cast Time 1:42:01) |
| 4. Topical Anti-infectives | (Audio Cast Time 1:46:51) |
| 5. Long Acting Opioids | (Audio Cast Time 1:57:28) |
| 6. Protease Inhibitors (for Hepatitis C) | (Audio Cast Time 2:01:40) |
| 7. Tetracyclines ¹ | (No clinical review) |
| 8. Beta Blockers ¹ | (No clinical review) |
| 9. Triglyceride Lowering Agents | (Audio Cast Time 2:04:00) |
| 10. Second Generation Anticonvulsants ¹ | (No clinical review) |
| 11. Carbamazepine Derivatives | (Audio Cast Time 2:09:10) |
| 12. Multiple Sclerosis Agents | (Audio Cast Time 2:13:06) |
| 13. Non-Ergot Dopamine Receptor Agonists | (Audio Cast Time 2:24:50) |
| 14. Sedative Hypnotics/Sleep Agents | (Audio Cast Time 2:31:00) |
| 15. SSRIs ¹ | (No clinical review) |
| 16. Topical Anabolic Steroids ¹ | (No clinical review) |
| 17. Oral Bisphosphonates | (Audio Cast Time 2:35:08) |
| 18. DPP-4 Inhibitors | (Audio Cast Time 2:38:38) |
| 19. Growth Hormones ¹ | (No clinical review) |

20. Injectable Anticoagulants ¹	(No clinical review)
21. Oral Anticoagulants	(Audio Cast Time 2:46:12)
22. Platelet Inhibitors	(Audio Cast Time 2:57:30)
23. Systemic Immunomodulators	(Audio Cast Time 3:06:58)
24. Ophthalmic NSAIDs	(Audio Cast Time 3:17:43)
25. Alpha Reductase Inhibitors (for BPH) ¹	(No clinical review)
26. Urinary Tract Antispasmodics	(Audio Cast Time 3:22:20)
27. Inhaler Anticholinergics/COPD Agents	(Audio Cast Time 3:27:18)
28. 2 nd Generation Antihistamines ¹	(No clinical review)
29. Inhaled Corticosteroids ¹	(No clinical review)
30. Intranasal Corticosteroids	(Audio Cast Time 3:32:29)

¹ Therapeutic classes for which no clinical review was presented as no new pertinent clinical information was found since the previous review of the class.

E. Executive Session (Recess to Excessive Session Audio Webcast Time 3:40:20)

The Board recessed the public session at 1:00 pm 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 3:30 pm.

F. DUR Board Recommendations (Audio Webcast Time 3:42:30 –4:24:59)

Based on the clinical and financial information, the Board unanimously (unless otherwise noted) recommended the following to the Commissioner of Health for final determination:

Recommendations of DUR Board	Audio Webcast time	Commissioner's Final Determination
<p>Long Acting Opioids</p> <p>Preferred fentanyl patch, Kadian, morphine sulfate SR tablet</p> <p>Non-preferred Avinza, Butrans, Conzip, Duragesic, Exalgo, morphine sulfate ER capsule, MS Contin, Nucynta ER, Opana ER, oxymorphone ER, Oxycontin, Ryzolt, tramadol ER, Ultram ER</p>	3:42:30	Approved as Recommended

<p>Protease Inhibitors for Hepatitis C 3:44:00</p> <p>Preferred Incivek, Victrelis</p> <p>Non-preferred None</p>	<p>Approved as Recommended</p>
<p>Tetracyclines 3:44:50</p> <p>Preferred demecloxyline, doxycycline hyclate, minocycline capsule, Morgidox, tetracycline</p> <p>Non-preferred Adoxa, Doryx, doxycycline hyclate DR, doxycycline monohydrate, Dynacin, minocycline tablet, minocycline ER, Oracea, Solodyn, Vibramycin</p>	<p>Approved as Recommended</p>
<p>Beta Blockers 3:45:31</p> <p>Preferred atenolol, atenolol/chlorthalidone, bisoprolol/HCTZ, carvedilol, labetalol, metoprolol tartrate, propranolol, propranolol/HCTZ, Toprol XL</p> <p>Non-preferred acebutolol, betaxolol, bisoprolol, Bystolic, Coreg, Coreg CR, Corgard, Corzide, Dutoprol, Inderal LA, Innopran XL, Kerlone, Levatol, Lopressor, Lopressor HCT, metoprolol succinate XL, metoprolol tartrate/HCTZ, nadolol, nadolol/bendroflumethiazide, pindolol, propranolol SA/ER, propranolol solution, Sectral, Tenoretic, Tenormin, timolol, Trandate, Zebeta, Ziac</p>	<p>Approved as Recommended</p>
<p>Triglyceride Lowering Agents 3:46:25</p> <p>Preferred gemfibrozil, Tricor, Trilipix</p> <p>Non-preferred Antara, fenofibrate tablet, fenofibrate capsule, fenofibric acid, Fibricor, Lipofen, Lofriba, Lopid, Lovaza, Triglide, Vascepa</p>	<p>Approved as Recommended</p>

<p>Anticonvulsants – Second Generation 3:46:50</p> <p>Preferred Felbatol, gabapentin capsule, gabapentin solution, Gabitril 2mg & 4mg, lamotrigine, levetiracetam, levetiracetam ER, Lyrica, topiramate, zonisamide</p> <p>Non-preferred Banzel, felbamate, gabapentin tablet, Gabitril 12mg & 16mg, Keppra, Keppra XR, Lamictal, Lamitcal ODT, Lamictal XR, lamotrigine XR, Neurontin, Onfi, Potiga, Sabril, tiagabine, Topamax, Vimpat, Zonegran</p> <p>Clinical editing to allow patients currently stabilized on Onfi or Vimpat to continue to receive that agent without prior authorization.</p>	<p>Approved as Recommended</p>
<p>Carbamazepine Derivatives 3:47:55</p> <p>Preferred carbamazepine tablet, carbamazepine chewable, Carbatrol, Epitol, Equetro, oxcarbazepine tablet, Tegretol XR, Tegretol suspension, Tegretol chewable, Trileptal suspension</p> <p>Non-preferred carbamazepine ER, carbamazepine XR, carbamazepine suspension, oxcarbazepine suspension, Oxtellar XR, Tegretol tablet, Trileptal tablet</p>	<p>Approved as Recommended</p>
<p>Multiple Sclerosis Agents 3:48:29</p> <p>Preferred Avonex, Betaseron, Copaxone</p> <p>Non-preferred Aubagio, Extavia, Gilenya, Rebif, Tecfidera</p> <p>Clinical editing to allow patients currently stabilized on Rebif to continue to receive that agent without prior authorization.</p>	<p>Approved as Recommended</p>
<p>Non-Ergot Dopamine Receptor Agonists 3:51:40</p> <p>Preferred pramipexole, ropinirole</p> <p>Non-preferred Mirapex, Mirapex ER, Neupro, Requip, Requip XL, ropinirole ER</p>	<p>Approved as Recommended</p>

<p>Sedative Hypnotics/Sleep Agents 3:52:00</p> <p>Preferred estazolam, flurazepam, temazepam 15mg & 30mg, zolpidem</p> <p>Non-preferred Ambien, Ambien CR, Doral, Edluar, Halcion, Intermezzo, Lunesta, Restoril, Rozerem, Silenor, Sonata, temazepam 7.5mg & 22.5mg, triazolam, zaleplon, zolpidem ER, Zolpimist</p>	<p>Approved as Recommended</p>
<p>Selective Serotonin Reuptake Inhibitors 3:52:28</p> <p>Preferred citalopram, escitalopram, fluoxetine, paroxetine, sertraline</p> <p>Non-preferred Celexa, fluoxetine 60mg, fluoxetine DR, fluvoxamine, fluvoxamine ER, Lexpro, Luvox CR, paroxetine CR, Paxil, Paxil CR, Pexeva, Prozac, Sarafem, Viibryd, Zoloft</p> <p>Clinical editing to allow patients currently stabilized on fluvoxamine or fluvoxamine ER to continue to receive that agent without prior authorization.</p> <p>Clinical editing to allow patients with a diagnosis of Obsessive Compulsive Disorder (OCD) to receive fluvoxamine and fluvoxamine ER without prior authorization.</p>	<p>Approved as Recommended</p>
<p>Topical Anabolic Steroids 3:57:23</p> <p>Preferred Androgel, Testim,</p> <p>Non-preferred Androderm, Axiron, Fortesta</p>	<p>Approved as Recommended</p>
<p>Oral Bisphosphonates 3:57:45</p> <p>Preferred alendronate</p> <p>Non-preferred Actonel, Atelvia, Binosto, Boniva, Fosamax, Fosamax plus D, ibandronate</p>	<p>Approved as Recommended</p>

<p>Dipeptidyl Peptidase-4 Inhibitors 3:58:04</p> <p>Preferred Janumet, Janumet XR, Januvia, Jentadueto, Tradjenta</p> <p>Non-preferred Juvisync, Kazano, Kombiglyze XR, Nesina, Onglyza, Oseni</p>	<p>Approved as Recommended</p>
<p>Growth Hormone 3:58:42</p> <p>Preferred Norditropin, Nutropin, Nutropin AQ</p> <p>Non-preferred Gentotropin, Humatrope, Omnitrope, Saizen, Tev-tropin, Zorbtive</p>	<p>Approved as Recommended</p>
<p>Injectable Anticoagulants 3:59:14</p> <p>Preferred Fragmin, Lovenox</p> <p>Non-preferred Arixtra, enoxaparin, fondaparinux</p> <p>Clinical editing to allow patients with a diagnosis of Heparin Induced Thrombocytopenia (HIT) to receive fondaparinux without prior authorization.</p>	<p>Approved as Recommended</p>
<p>Oral Anticoagulants 4:03:05</p> <p>Preferred Coumadin, Jantoven, Pradaxa, warfarin, Xarelto</p> <p>Non-preferred Eliquis</p>	<p>Approved as Recommended</p>

<p>Platelet Inhibitors 4:03:49</p> <p>Preferred clopidogrel, dipyridamole, Effient</p> <p>Non-preferred Aggrenox, Brilinta, Persantine, Plavix, ticlopidine</p> <p>Vote: 1 in-favor, 8 in-opposition, 4 abstentions</p> <p>Board expressed concerns with access to non-preferred products immediately upon hospital discharge to ensure there is no interruption in newly initiated anti-platelet therapy.</p> <p>Board asked the Department to determine system capabilities that may allow prior authorization to be by-passed for non-preferred products upon hospital discharge following PCI.</p>	<p>No changes to the preferred or non-preferred status of the products in the therapeutic class as currently listed on the Preferred Drug List.</p> <p>Therapeutic class to be re-evaluated by the DUR Board during a future meeting.</p> <p>Point of service claims system editing capabilities to be evaluated and potential options to be communicated to the DUR Board.</p>
<p>Systemic Immunomodulators 4:18:48</p> <p>Preferred Enbrel, Humira</p> <p>Non-preferred Cimzia, Kineret, Orencia SQ, Simponi, Xeljanz</p>	<p>Approved as Recommended</p>
<p>Ophthalmic NSAIDs 4:19:14</p> <p>Preferred diclofenac, flurbiprofen, ketorolac, ketorolac LS</p> <p>Non-preferred Acular, Acular LS, Acuvail, Bromday, bromfenac, Ilevro, Nevanac, Ocufen, Prolensa</p>	<p>Approved as Recommended</p>

<p>Alpha Reductase Inhibitors (for BPH) 4:19:37</p> <p>Preferred finasteride</p> <p>Non-preferred Avodart, Jalyn, Proscar</p>	<p>Approved as Recommended</p>
<p>Urinary Tract Antispasmodics 4:19:59</p> <p>Preferred oxybutynin, Oxytrol, Sanctura XR, Toviaz, Vesicare</p> <p>Non-preferred Detrol, Detrol LA, Ditropan XL, Enablex, Gelnique, Myrbetriq, oxybutynin ER, Sanctura, tolterodine, trospium, trospium ER</p>	<p>Approved as Recommended</p>
<p>Inhaled Anticholinergics/COPD Agents 4:20:17</p> <p>Preferred Atrovent HFA, Combivent, ipratropium, ipratropium/albuterol, Spiriva</p> <p>Non-preferred Daliresp, Duoneb, Tudorza</p>	<p>Approved as Recommended</p>
<p>Second Generation Antihistamines 4:20:51</p> <p>Preferred cetirizine OTC tablet, cetirizine OTC 1mg/1ml solution, Claritin OTC, loratadine OTC</p> <p>Non-preferred Allegra/Allegra-D, cetirizine OTC chewable, cetirizine solution Rx, cetirizine OTC 5mg/5ml solution, cetirizine-D OTC, Clarinex, Clarinex-D, Claritin-D OTC, desloratadine, fexofenadine, Rx, fexofenadine OTC, fexofenadine-D OTC, levocetirizine, loratadine-D OTC, Xyzal</p>	<p>Approved as Recommended</p>

<p>Inhaled Corticosteroids 4:21:50</p> <p>Preferred Asmanex, Flovent Diskus, Flovent HFA, Pulmicort Flexhaler, Qvar</p> <p>Non-preferred Alvesco</p>	<p>Approved as Recommended</p>
<p>Intranasal Corticosteroids 4:22:22</p> <p>Preferred Nasacort AQ, Nasonex</p> <p>Non-preferred Beconase AQ, Dymista, Flonase, flunisolide, fluticasone, Omnaris, Qnasl, Rhinocort Aqua, triamcinolone, Veramyst, Zetonna</p>	<p>Approved as Recommended</p>
<p>Gastrointestinal Preparatory Agents 4:23:00</p> <p>Preferred Clearlax, Gavilax, Gavilyte-C, Gavilyte-G, Miralax OTC, PEG 3350 w/ electrolyte, PEG 3350 OTC</p> <p>Non-preferred Colyte, Gavilyte-N, Golytely, Halflytely Kit, Moviprep, Nulytely, Osmoprep, PEG 3350, PEG 3350 pack OTC, PEG 3350 w/flavor packs, Prepopik powder pack, Suprep, Trilyte</p>	<p>Approved as Recommended</p>
<p>Gastrointestinal Antibiotics 4:23:34</p> <p>Preferred metronidazole tablet, neomycin, Vancocin</p> <p>Non-preferred Alinia, Dificid, Flagyl, Flagyl ER, metronidazole capsule, paromomycin, Tindamax, tinidazole, vancomycin, Xifaxan</p>	<p>Approved as Recommended</p>

<p>Glucocorticoids – oral 4:23:54</p> <p>Preferred cortisone, dexamethasone tablet, dexamethasone solution, Entocort EC, hydrocortisone, methylprednisolone dose pack, methylprednisolone 4 mg & 32mg tablet, prednisone, prednisolone</p> <p>Non-preferred budesonide EC, Cortef, dexamethasone elixir, dexamethasone intensol, Dexpak, Flo-Pred, Medrol tablet, Medrol dose pack, Millipred, Orapred, Orapred ODT, prednisone intensol, Rayos DR, Veripred</p>	<p>Approved as Recommended</p>
<p>Topical Anti-infectives 4:24:29</p> <p>Preferred clindamycin solution, clindamycin lotion, erythromycin gel, erythromycin solution</p> <p>Non-preferred Acanya, Akne-mycin, Benzaclin, Benzamycin, Clindacin Pledgets, Cleocin T, Clindagel, clindamycin/benzoyl peroxide, clindamycin gel, clindamycin foam, clindamycin swab, Duac, erythromycin swab, erythromycin/benzoyl peroxide, Evoclin</p>	<p>Approved as Recommended</p>

G. Final Comments and Adjournment

(Audio Webcast Time 4:25:00 – 4:26:15)

Nancy Balkon, PhD, NP
John McIntyre, MD
Anthony Merola, RPh, MBA

Meeting adjourned at 4:30 PM

H. Final Determinations

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

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.

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 \$2.6M. The savings are achieved through changes in utilization to equally effective and less expensive products including the receipt of supplemental rebates from pharmaceutical manufacturers.