New York State Medicaid Drug Utilization Review Board Meeting Agenda

The Drug Utilization Review (DUR) Board will meet June 27, 2013, from 9:00 a.m. to 4:30 p.m., Meeting Room 3, Concourse, Empire State Plaza, Albany, New York

Pursuant to statutory changes included in the 2013-2014 Executive Budget, the responsibilities of the former Pharmacy & Therapeutics (P&T) Committee, including those associated with the Preferred Drug Program (PDP), have been transitioned to the Drug Utilization Review (DUR) Board. As indicated below, the DUR Board will review/re-review PDP therapeutic classes and recommend preferred or non-preferred status.

As a result of the statutory changes mentioned above and cancellation of the April P&T Committee meeting, the April 18, 2013 P&T Committee meeting agenda is being re-issued (here) under the responsibilities of the DUR Board.

Clinical information submitted in reference to the April P&T Committee meeting should NOT be resubmitted as the Department currently has the information on file and will forward this information from the P&T Committee to the DUR Board. The Department will accept other clinical information as detailed below. To confirm previously received clinical information, persons responsible for the submission may contact DUR Board support staff at dur@health.state.ny.us or 518-486-3209.

All interested parties requesting the opportunity to address the DUR Board during the public comment period at the June meeting, including those that had previously requested to address the P&T Committee during the April meeting, will be required to proceed through the standard registration process to confirm intent to address the DUR Board. Therefore, even if registration for the April meeting had been processed, it is necessary to initiate another new request specifically for the June meeting as detailed below.

Agenda Items

A. Preferred Drug Program: Initial Review

Description: The Board will review the following therapeutic classes and recommend preferred or non-preferred status for products within each class.

1. **Gastrointestinal Preparatory Agents**
   Drugs Affected: Clearlax (PEG 3350), Colyte (PEG 3350/KCl/sodium bicarbonate/sodium chloride/sodium sulfate), Gavilax (PEG 3350), Gavilyte C/Gavilyte G (PEG 3350/KCl/sodium bicarbonate/sodium chloride/sodium sulfate), Gavilyte N (PEG 3350/KCL/sodium bicarbonate/sodium chloride), Golytely (PEG 3350/KCl/sodium bicarbonate/sodium chloride/sodium sulfate), Halflytely-Bisacodyl kit (PEG 3350/KCl/sodium bicarbonate/sodium chloride/bisacodyl), Miralax (polyethylene glycol 3350), Moviprep (PEG 3350/electrolytes/sodium ascorbate/ascorbic acid), Nulytley (PEG 3350/sodium chloride/sodium Bicarbonate/KCL), Osmoprep (sodium phosphate dibasic/sodium phosphate monobasic), polyethylene glycol 3350, PEG 3350/Electrolyte, Prepopik Powder (sodium picosulfate/magnesium oxide/citric acid), Suprep (sodium sulfate/potassium sulfate/magnesium sulfate), Trilyte (PEG 3350/KCl/sodium bicarbonate/sodium chloride)

2. **Gastrointestinal Antibiotics**
   Drugs Affected: Alinia (nitazoxanide), Dificid (fidaxomicin), Flagyl/Flagyl ER (metronidazole), metronidazole, neomycin, paromomycin, Tindamax (tinidazole), tinidazole, Vancocin (vancomycin), vancomycin, Xifaxan (rifaximin)

3. **Glucocorticoids – Oral**
   Drugs Affected: budesonide EC, Celestone (betamethasone), Cortef (hydrocortisone), cortisone, dexamethasone, Dexamethasone Intensol (dexamethasone), Dexpak (dexamethasone), Entocort EC (budesonide), Flo-Pred (prednisolone), hydrocortisone, Medrol (methylprednisolone), methylprednisolone, Millipred (prednisolone), Orapred/Orapred ODT (prednisolone sodium phosphate), prednisolone, prednisone, Prednisone Intensol (prednisone), Rayos DR (prednisone), Veripred (prednisolone)

4. **Topical Anti-infectives**
   Drugs Affected: Acanya (clindamycin/benzoyl peroxide), Akne-Mycin (erythromycin), Benzaclin (clindamycin/benzoyl peroxide), Benzamycin (erythromycin/benzoyl peroxide), Cleocin T (clindamycin), Clindacin P(clindamycin), Clindagel (clindamycin), clindamycin phosphate, clindamycin/benzoyl peroxide, Duac (clindamycin/benzoyl peroxide), erythromycin, erythromycin/benzoyl peroxide, Evoclin (clindamycin)

B. Preferred Drug Program: Re-review

Description: The Board will re-review therapeutic classes listed below. The following therapeutic classes contain new relevant clinical and/or financial information. Therapeutic classes not included on this agenda may be re-reviewed at a later date pending new relevant clinical information.

- The Board will review new clinical and financial information as required, to recommend preferred and non-preferred drugs. [1]
- The Board will **only** consider clinical information which is new since the previous review of the therapeutic class and then consider financial information.
- New clinical information may include a new drug, new product information, new indications, new safety information or new published clinical trials (comparative evidence is preferred, or placebo controlled when no head-to-head trials are available). Information in abstract form alone, posters, or unpublished data are poor quality evidence for the purpose of re-review and submission is discouraged.

- Those wishing to submit new clinical information may do so in an electronic format by **June 12, 2013**.

[1] The current preferred and non-preferred status of drugs subject to the Preferred Drug List (PDL) may be viewed at https://newyork.fhsc.com/downloads/providers/NYRx_PDP_PDL.pdf

1. **Opioids - Long Acting** (previous review date: June 15, 2012)
   Drugs Affected: Avinza (morphine sulfate ER), Butrans (buprenorphine), Conzip (tramadol ER), Duragesic (fentanyl patch), Exalgo (hydromorphone HCL ER), fentanyl patch, Kadian (morphine sulfate SR), morphine sulfate SR/ER, MS Contin (morphine sulfate CR), Nucynta ER (tapentadol ER), Opana ER (oxymorphone ER), Oramorph SR (morphine sulfate SR), oxycodone HCl CR, Oxycontin (oxycodone HCl CR), oxymorphone ER, Ryzolt (tramadol ER), tramadol ER, Ultram ER (tramadol ER)

2. **Hepatitis C- Protease Inhibitors** (previous review date: April 19, 2012)
   Drugs Affected: Incivek (telaprevir), Victrelis (boceprevir)

3. **Tetracylines** (previous review date: April 15, 2011)
   Drugs Affected: Adoxa (doxycycline monohydrate), demeclocycline, Doryx (doxycycline hyclate DR), doxycycline hyclate, doxycycline hyclate DR, doxycycline monohydrate, Dynacin (minocycline HCL), minocycline HCL, minocycline ER, Morgidox (doxycycline hyclate), Oracea (doxycycline monohydrate), Periostat (doxycycline hyclate), Solodyn ER (minocycline ER), tetracycline,Vibramycin (doxycycline hyclate)

4. **Beta Blockers** (previous review date: June 15, 2012)
   Drugs Affected: acebutolol, atenolol, atenolol/chlorthalidone, betaxolol, bisoprolol fumarate, bisoprolol fumarate/HCTZ, Bystolic (nebivolol), carvedilol, Coreg (carvedilol), Coreg CR (carvedilol CR), Corgard (nadolol), Corzide (nadolol/bendroflumethiazide), Dutoprol (metoprolol succinate/ HCTZ), Inderal LA (propranolol LA), Innopran XL (propranolol XL), Kerlone (betaxolol), labetalol, Levatol (penbutolol), Lopressor (metoprolol tartrate), Lopressor HCT (metoprolol tartrate/HCTZ), metoprolol succinate XL, metoprolol tartrate/HCTZ, metoprolol tartrate, nadolol, nadolol/bendroflumethiazide, pindolol, propranolol, propranolol/HCTZ, propranolol SA, Sectral (acebutolol), Tenoretic (atenolol/chlorthalidone), Tenormin (atenolol), timolol maleate, Toprol XL (metoprolol succinate XL), Trandate (labetalol), Zebeta (bisoprolol fumarate), Ziac (bisoprolol fumarate/HCTZ)

5. **Triglyceride Lowering Agents** (previous review date: April 19, 2012)
   Drugs Affected: Antara (fenofibrate), fenofibrate, fenofibric acid, Fibricor (fenofibric acid), gemfibrozil, Lipofen (fenofibrate), Lofibra (fenofibrate), Lopid (gemfibrozil), Lovaza (omega-3 acid ethyl esters), Tricor (fenofibrate), Triglide (fenofibrate), Trilipix (fenofibric acid delayed release), Vascepa (icosapent ethyl)

6. **Anticonvulsants – Second Generation** (previous review date: November 15, 2012)
   Drugs Affected: Banzel (rufinamide), felbamate, Felbatol (felbamate), gabapentin, Gabitril (tiagabine), Keppra/Keppra XR (levetiracetam), Lamictal/Lamictal XR(lamotrigine), lamotrigine, lamotrigine ER, levetiracetam, levetiracetam ER, Lyrica (pregablin), Neurontin (gabapentin), Onfi (clobazam), Potiga (ezogabine), Sabril (vigabatrin), tiagabine, Topamax (topiramate), topiramate, Vimpat (lacosamide), Zonegran (zonisamide), zonisamide

7. **Carbamazepine Derivatives** (previous review date: November 15, 2012)
   Drugs Affected: carbamazepine, carbamazepine ER/XR, Carbatrol (carbamazepine), Epitol (carbamazepine), Equetro (carbamazepine), oxcarbazepine, Oxtellar XR (oxcarbazepine), Tegretol/Tegretol XR (carbamazepine), Trileptal (oxcarbazepine)

8. **Multiple Sclerosis Agents** (previous review date: April 15, 2011)
   Drugs Affected: Aubagio (teriflunomide), Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone (glatiramer acetate), Extavia (interferon beta-1b), Gilenya (fingolimod), Rebif (interferon beta-1a), Tecfidera (dimethyl fumarate)

9. **Non-Ergot Dopamine Receptor Agonists** (previous review date: June 11, 2010)
   Drugs Affected: Mirapex/Mirapex ER (pramipexole), Neupro (rotigotine), pramipexole, Requip/Requip XL (ropinirole), ropinirole, ropinirole ER

10. **Sedative Hypnotics/Sleep Agents** (previous review date: April 15, 2011)
    Drugs Affected: Ambien/Ambien CR (zolpidem), chloral hydrate, Doral (quazepam), Edluar (zolpidem), estazolam, flurazepam, Halcion (triazolam), Intermezzo (zolpidem), Lunesta (eszopiclone), Restoril (temazepam), Rozerem (ramelteon), Silenor (doxepin), Somnote (chloral hydrate), Sonata (zaleplon), temazepam, triazolam, zaleplon, zolpidem, zolpidem ER, Zolpimist (zolpidem)

11. **Selective Serotonin Reuptake Inhibitors** (previous review date: April 19, 2012)
    Drugs Affected: Celexa (citalopram), citalopram, escitalopram, fluoxetine, fluvoxamine, Lexapro (escitalopram), Luvox CR (fluvoxamine), paroxetine, paroxetine CR, Paxil (paroxetine), Paxil CR (paroxetine CR), Pexeva (paroxetine), Prozac (fluoxetine), Sarafem (fluoxetine), sertraline, Viibryd (vilazodone), Zoloft (sertraline)

12. **Anabolic Steroids – Topical** (previous review date: June 15, 2012)
    Drugs Affected: Androderm (testosterone), Androgel (testosterone), Axiron (testosterone), Fortesta (testosterone), Testim (testosterone)

13. **Bisphosphonates - Oral** (previous review date: June 16, 2011)
    Drugs Affected: Actonel (risedronate), alendronate, Atelvia (risedronate delayed-release), Binosto (alendronate), Boniva (ibandronate), Fosamax (alendronate), Fosamax Plus D (alendronate plus cholecalciferol), ibandronate

14. **Dipeptidyl Peptidase-4 Inhibitors** (previous review date: June 15, 2012)
    Drugs Affected: Janumet (sitagliptin/metformin HCL), Janumet XR (sitagliptin/metformin HCL), Januvia (sitagliptin), Jentadueto (linagliptin/metformin), Juvisync (sitagliptin/simvastatin), Kazano (alogliptan benzoate/metformin HCL), Kombiglyze XR (saxagliptin/metformin ER), Nesina (alogliptan benzoate), Onglyza (saxagliptin), Oseni (alogliptan benzoate/pioglitazone HCL), Tradjenta (linagliptin)

15. **Growth Hormone** (previous review date: November 15, 2012)
    Drugs Affected: Genotropin (somatropin), Humatrope (somatropin), Norditropin (somatropin), Nutropin/Nutropin AQ (somatropin), Omnitrope (somatropin), Saizen (somatropin), Tev-Tropin (somatropin), Zorbtive (somatropin)

16. **Anticoagulant – Injectable** (previous review date: April 29, 2010)
    Drugs Affected: Arixtra (fondaparinux sodium), enoxaparin, fondaparinux, Fragmin (dalteparin sodium), Innohep (tinzaparin sodium), Lovenox (enoxaparin sodium)

17. **Anticoagulants - Oral** (previous review date: April 19, 2012)
    Drugs Affected: Coumadin (warfarin), Eliquis (apixaban), Jantoven (warfarin), Pradaxa (dabigatran), warfarin, Xarelto (rivaroxaban)

18. **Platelet Inhibitors** (previous review date: April 19, 2012)
    Drugs Affected: Aggrenox (dipyridamole ER/aspirin), Brilinta (ticagrelor), clopidogrel, dipyridamole, Effient (prasugrel), Persantine (dipyridamole), Plavix (clopidogrel), ticlopidine

19. **Immunomodulators - Systemic** (previous review date: June 15, 2012)
    Drugs Affected: Cimzia (certolizumab pegol), Enbrel (etanercept), Humira (adalimumab), Kineret (anakinra), Orencia (abatacept subQ), Simponi (golimumab), Xeljanz (tofacitnib)

20. **NSAIDs - Ophthalmic** (previous review date: April 15, 2011)
    Drugs Affected: Acular (ketorolac), Acular LS (ketorolac), Acuvail (ketorolac tromethamine), Bromday (bromfenac), bromfenac, diclofenac, flurbiprofen, Ilevro (nepafenac), ketorolac, Nevanac (nepafenac), Ocufen (flurbiprofen), Prolensa (bromfenac), Voltaren (diclofenac)

21. **Alpha Reductase Inhibitors for BPH** (previous review date: June 15, 2012)
    Drugs Affected: Avodart (dutasteride), finasteride, Jalyn (dutasteride/tamsulosin), Proscar (finasteride)

22. **Urinary Tract Antispasmodics** (previous review date: June 15, 2012)
    Drugs Affected: Detrol/Detrol LA (tolterodine), Ditropan XL (oxybutynin), Enablex (darifenacin), Gelnique (oxybutynin gel), Myrbetriq (mirabegron), oxybutynin, oxybutynin ER, Oxytrol (oxybutynin), Sanctura (trospium), Sanctura XR (trospium), Toviaz (fesoterodine fumarate), trospium, trospium ER, Vesicare (solifenacin)

23. **Anticholinergics Inhaled/COPD Agents** (previous review date: April 19, 2012)
    Drugs Affected: Atrovent HFA (ipratropium), Combivent (ipratropium/albuterol), Combivent Respimat (ipratropium/albuterol), Daliresp (roflumilast), Duoneb (ipratropium/albuterol), ipratropium, ipratropium/albuterol, Spiriva (tiotropium), Tudorza Pressair (aclidium bromide)

24. **Antihistamines – Second Generation** (previous review date: April 15, 2011)
    Drugs Affected: Allegra/Allegra-D (fexofenadine/fexofenadine PSE), cetirizine/cetirizine-D OTC, cetirizine Rx, Clarinex/Clarinex-D (desloratadine/desloratadine PSE), desloratadine, fexofenadine/fexofenadine-D, levocetirizine, loratadine/loratadine D OTC, Semprex-D (acrivastine/PSE), Xyzal (levocetirizine)

25. **Corticosteroids - Inhaled** (previous review date: September 16, 2010)
    Drugs Affected: Alvesco (ciclesonide), Asmanex (mometasone), Flovent HFA (fluticasone), Flovent Diskus (fluticasone), Pulmicort Flexhaler (budesonide), QVAR (beclomethasone)

26. **Corticosteroids - Intranasal** (previous review date: June 16, 2011)
    Drugs Affected: Beconase AQ (beclomethasone dipropionate), Dymista (azelastine hydrochloride and fluticasone propionate), Flonase (fluticasone propionate), flunisolide, fluticasone propionate, Nasacort AQ (triamcinolone acetonide), Nasonex (mometasone furoate), Omnaris (ciclesonide), QNASL (beclomethasone), Rhinocort Aqua (budesonide), triamcinolone, Veramyst (fluticasone furoate), Zetonna (ciclesonide)

Agenda Timeline (subject to change based on meeting proceedings)

9:00- 9:30	Welcome, Introductions and DOH Updates
9:30 - 11:00	Public Comment Period
11:00 - 11:15	Break
11:15 - 12:30	PDP clinical review(s) and re-reviews
12:30- 1:30	Lunch Break/Executive Session (PDP financial review)
1:30 - 1:45	Summary of final recommendations
1:45 - 3:00	PDP clinical re-reviews (cont.)
3:00 - 3:30	Afternoon Break/Executive Session (PDP financial review)
3:30 - 3:45	Summary of final recommendations
3:45 - 4:30	Final Comments and Adjournment

Interested parties may request to address the Board during the public comment period. All requests must be made by **June 19, 2013** through the Medicaid Pharmacy Program staff**.** Requests may be made by calling 518-486-3209 or e-mailing **dur@health.state.ny.us** (Please reference June DURB Meeting).

Public comments are limited to therapeutic classes on the agenda and new clinical information for the PDP classes being re-reviewed. Comments must be brief (2 minutes) and the total comment period will not exceed 90 minutes.

Clinical information must be received in an electronic format by **June 12, 2013,** or the Committee may not have ample time to review the information. For the therapeutic classes subject to the PDP re-review, submitted clinical information must be new since the previous review of the therapeutic class. Any studies cited should be referenced, with the primary source of funding included.

As indicated above, clinical information submitted in reference to the April P&T Committee meeting should NOT be resubmitted. To confirm previously received clinical information, persons responsible for the submission may contact DUR Board support staff at dur@health.state.ny.us or 518-486-3209.

Written statements must be received in an electronic format by **June 19, 2013**. Written statements should summarize key points and may not exceed two (2) pages in length.

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