New York State Medicaid Pharmacy and Therapeutics Committee Meeting Agenda

The Pharmacy & Therapeutics (P&T) Committee will meet
November 15, 2012, from 9:00 am to 4:00 pm,
Meeting Room 3*, Concourse, Empire State Plaza, Albany, New York
*Please note meeting room change

Agenda Items

A. Preferred Drug Program: Initial Review

The Committee will review the following therapeutic classes under the Preferred Drug Program and recommend preferred and non-preferred status.

1. Second Generation Anticonvulsants

Drugs Affected: Banzel (rufinamide), felbamate, Felbatol (felbamate), gabapentin, Gabitril (tiagabine), Keppra/Keppra XR (levetiracetam), Lamictal/Lamictal XR(lamotrigine), lamotrigine, levetiracetam, levetiracetam ER, Lyrica (pregablin), Neurontin (gabapentin), Potiga (ezogabine), Sabril (vigabatrin), Topamax (topiramate), topiramate, Vimpat (lacosamide), Zonegran (zonisamide), zonisamide

2. Other Agents for ADHD

Drugs Affected: Intuniv (guanfacine ER), Kapvay (clonidine ER), Strattera (atomoxetine)

B. Preferred Drug Program: Re-review

The Committee will re-review therapeutic classes subject to the Preferred Drug Program periodically as described and listed below. The following therapeutic classes to be re-reviewed 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 Committee will review new clinical and financial information as required, to recommend preferred and non-preferred status.
- The Committee 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 or drug product information, new indications, new safety information or new published clinical trials (comparative, or placebo controlled when no head-to-head trials are available). Information in abstract form alone, posters, and unpublished data is poor quality evidence for the purpose of re-review and submission is discouraged.
- Those wishing to submit new clinical information must do so in an electronic format by **October 31, 2012** or the Committee may not have ample time to review the information.

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. **Carbamazepine Derivatives** (previous review date December 13, 2007)
   Drugs Affected: carbamazepine, carbamazepine ER/XR, Carbatrol (carbamazepine), Epitol (carbamazepine), Equetro (carbamazepine), oxcarbazepine, Tegretol/Tegretol XR(carbamazepine), Trileptal (oxcarbazepine)

2. **Growth Hormone** (previous review date June 16, 2009)
   Drugs Affected: Genotropin (somatropin), Humatrope (somatropin), Norditropin (somatropin), Nutropin/Nutropin AQ (somatropin), Omnitrope (somatropin), Saizen (somatropin), Tev-Tropin (somatropin), Zorbtive (somatropin)

C. Clinical Drug Review Program (CDRP)

1. The Committee will consider adding Truvada (emtricitabine-tenofovir) to the CDRP when used for HIV Pre-Exposure Prophylaxis (PrEP).

2. The Committee will consider adding the following therapeutic classes to the CDRP based on previous recommendations of the Drug Utilization Review (DUR) Board. DUR Board recommendations are available on the DoH web-site: http://www.health.ny.gov/health_care/medicaid/program/dur/index.htm

   a. Central Nervous System Stimulants
   Drugs Affected: Adderall (amphetamine salt combo), Adderall XR (amphetamine salt combo XR), amphetamine salt combo IR, amphetamine salt combo ER, Concerta (methylphenidate), Daytrana (methylphenidate), Desoxyn (methamphetamine), Dexedrine Spansule (dextroamphetamine), dexmethylphenidate, dextroamphetamine sulfate, dextroamphetamine sulfate ER, Focalin (dexmethylphenidate), Focalin XR (dexmethylphenidate XR), Metadate CD (methylphenidate CD), Metadate ER (methylphenidate ER), methamphetamine, Methylin (methylphenidate), Methylin ER (methylphenidate ER), methylphenidate, methylphenidate ER/SR, Nuvigil (armodafinil), Procentra (dextroamphetamine sulfate), Provigil (modafinil), Ritalin (methylphenidate), Ritalin LA (methylphenidate LA), Ritalin SR (methylphenidate SR), Vyvanse (lisdexamfetamine dimesylate)

   b. Anabolic Steroids
   Drugs Affected: Anadrol (testosterone), Androderm (testosterone), Androgel (testosterone), Android (methyltestosterone), Androxy (fluoxymesterone), Axiron (testosterone), Depo-testosterone, Fortesta (testosterone), Methitest (methyltestosterone), Oxandrin (oxandrolone), oxandrolone, Testim (testosterone), testosterone cypionate, testosterone enanthate, Testred (methyltestosterone)

Agenda Timeline (subject to change based on meeting proceedings)

9:00 - 9:10	Welcome and Introductions
9:10 - 10:40	Public Comment Period
10:40 - 10:45	Break
10:45 - 12:00	PDP Clinical Reviews
12:00 - 1:30	Lunch Break/Executive Session (PDP Financial Reviews)
1:30 - 1:45	PDP Recommendations
1:45 - 3:15	CDRP Reviews and Recommendations
3:15 - 4:00	Updates and Adjournment

- Interested parties must notify the Department of Health (DoH) by **November 6, 2012** of their request to address the P&T Committee during the public comment period. Requests may be made by calling 518-486-3209 or e-mailing pandtc@health.state.ny.us. (Please reference P&T Committee).
- 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 (two minutes) and the total comment period will not exceed ninety (90) minutes. DoH reserves the right to limit the number of interested parties providing public comment in order to meet timelines and accomplish meeting objectives.
- All written statements must be received in an electronic format by **October 31, 2012**. Written statements should summarize key points and may not exceed two (2) pages in length.
- Clinical information must be submitted in an electronic format by **October 31, 2012,** 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.
- Any information regarding the P&T Committee meeting must be sent to the DoH to ensure distribution to all Committee members. Interested parties should not contact or send any information directly to Committee members.

Posted 10/15/2012

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