

ODJFS P&T Committee Meeting Minutes

April 13, 2011

77 S. High St., Room 1960

Committee members present: Susan Baker, CNP; Ioanna Giatis, DO; Cheryl Huffman, MD; Robert Hunter, DO (chair); Karen Jacobs, DO; Margaret Scott, RPh; Mary Jo Welker, MD.

Stephanie Levine, RPh, represented ACS State Healthcare. Approximately 50 stakeholders were present, most representing pharmaceutical manufacturers and advocacy associations.

The meeting was called to order at 10:12 AM.

1. Interested party presentations

No interested party presentations were requested.

2. Old Business: Conflict of interest statements

Ms. Scott asked the Committee members who had not attended the January meeting (Baker, Giatis, Huffman) to sign a copy. The policy is attached to the minutes from the January 12th meeting.

3. New Business:

a. Drugs under consideration

1. Long-Acting Opioids: Butrans (buprenorphine) transdermal system CIII, Purdue
Purdue Pharma sent a letter of support for Butrans.

Dr. Levine said that the recommendation of ACS, JFS, and the managed care plans is non-preferred status.

Committee discussion:

No members raised discussion points.

The committee vote was unanimous to accept the recommendation that Butrans be put in non-preferred status.

2. Attention Deficit Hyperactivity Disorder Agents, Long-Acting: Kapvay
(clonidine HCl) extended release tablets, Shionogi

A representative of Shionogi presented information about the drug.

Dr. Levine said that the recommendation of ACS, JFS, and the managed care plans is non-preferred status.

Committee discussion:

Dr. Welker asked the speaker how many patients discontinued Kapvay due to somnolence. The speaker responded that only one patient in the drug plus stimulant study, and 15 patients in the monotherapy study, discontinued therapy.

Dr. Welker asked about the effect on blood pressure for the study participants.

The speaker said blood pressure effects are dose dependent, a maximum of 6-7 mmHg, with an average of 4 mmHg change.

Dr. Jacobs asked about the dosing of Kapvay as compared to immediate release clonidine. The speaker said that the total daily dose is 0.2mg to 0.4mg in twice daily dosing.

Dr. Welker asked about the cost. Ms. Scott responded that the cost is significantly more than immediate release clonidine, comparable to Intuniv and Strattera, the other non-controlled options for ADHD.

Dr. Hunter asked if there are any comparison trials. The speaker said none have been done.

Dr. Welker noted that all trials had included children only, and confirmed that the indication is for children only.

The committee vote was unanimous to accept the recommendation that Kapvay be put in non-preferred status.

3. Antidepressants: Oleptro (trazodone HCl) extended release tablets, Angelini Labopharm

A representative from Angelini Labopharm and Columbus psychiatrist Dr. Fred Romeo presented information about the drug.

Dr. Levine said that the recommendation of ACS, JFS, and the managed care plans is non-preferred status.

Committee discussion:

Dr. Giatis said she is concerned with sedation and asked how much is seen in practice. Dr. Romeo said that some patients report sedation and somnolence, but it stops after 1 to 2 weeks. He has not had many patients discontinue due to sedation.

Dr. Jacobs noted that the studies were only 8 weeks long, and asked Dr. Romeo how long he has been using the drug. Dr. Romeo said he has been using the drug in practice for about 1 year, and has not seen weight gain or sexual side effects. The representative from Angelini said that a long-term study is being designed to collect data on sexual dysfunction and weight.

Dr. Welker asked Dr. Romeo if he is using much of the 75mg dose. Dr. Romeo said he is using that dose for patients with a history of intolerance and the elderly. The Angelini representative said that the package insert recommends a starting dose of 150mg, but clinical experience shows that doctors are starting low and going slow.

Dr. Welker asked about the cost. Ms. Scott responded that the cost is significantly more than immediate release trazodone, comparable to other branded antidepressants.

Dr. Jacobs asked if the psychiatrist exemption from prior authorization would apply. Ms. Scott responded that it would.

Dr. Welker said that many primary care providers may be comfortable using the drug as first-line therapy, and asked why the recommendation is non-preferred.

Ms. Scott responded that the factors considered were cost, the availability of immediate-release trazodone, and that the drug wasn't considered first-line. Dr. Welker asked if immediate-release trazodone would satisfy the criteria. Ms. Scott said that the criteria could be changed to include immediate-release trazodone.

The committee vote was unanimous to accept the recommendation that Oleptro be put in non-preferred status.

4. Anti-Parasitics: Natroba (spinosad) topical suspension, ParaPro

A representative from ParaPro presented information about the drug.

Dr. Levine said that the recommendation of ACS, JFS, and the managed care plans is non-preferred status.

Committee discussion:

Dr. Huffman said she was concerned about the recommendation to not comb for nits, because the school nurses would send children home if they see nits. The speaker said that education on this point may be needed.

Dr. Welker asked what the prior authorization criteria were. Ms. Scott responded that she thought it was use of one product for 14 days (NOTE: actual criteria are use of one product for 1 month).

The representative from ParaPro said that nit combing can be done but is not required. The company is doing education with the national school nurses association.

Dr. Jacobs said that there may be a savings due to re-treatment costs of other products.

The committee voted 5 to 2 to recommend preferred status for Natroba.

b. New drug classes for preferred drug list.

The proposal given to the committee is attached to these minutes. Ms. Scott said that the 2011 Executive Budget sent by Governor Kasich to the legislature proposes to reverse the pharmacy carve-out, with responsibility for pharmacy coverage reverting to the Medicaid managed care plans beginning October 1, 2011. The new PDL classes would only be for the remaining fee-for-service population. Several committee members asked if the managed care plans would follow the same PDL. Ms. Scott said that discussions are underway with the managed care plans to have a substantial number of drugs with the same policy.

The committee did not have comments on all classes, only those classes with comments are noted here.

1. CNS Agents: Fibromyalgia Agents

Dr. Jacobs recommended adding serotonin-norepinephrine reuptake inhibitors (SNRI), and Dr. Giatis recommended adding non-steroidal anti-inflammatory drugs (NSAIDs) and tramadol to the list of drug classes to meet the prior therapy requirement.

2. CNS Agents: Medication Assisted Treatment Agents

Dr. Welker asked how much documentation would be needed from the prescriber to meet criteria.

3. Gastrointestinal Agents: Ulcerative Colitis Agents

Dr. Welker noted that a 6-month authorization is too short.

The meeting was adjourned at 11:38 AM.

Following the meeting, ODJFS accepted the recommendations of the committee for Butrans, Kapvay, and Oleptro. The recommendation for Natroba is under review. Comments on the PDL criteria will be incorporated into the proposals that will be discussed at the meeting on June 29.

ODJFS P&T Committee Meeting
April 2011

Proposed New Classes:

Analgesics-Gout

Cardiovascular – Sympatholytic Antihypertensives

CNS – Fibromyalgia Agents

CNS – Medication Assisted Treatment Agents

Endocrine – Estrogenic Agents

GI – H. Pylori Agents

GI – Ulcerative Colitis Agents

Analgesic Agents: Gout

LENGTH OF AUTHORIZATIONS: [to be discussed]

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
- History of unacceptable/toxic side effects to medications not requiring prior approval

Document clinically compelling information

ADDITIONAL INFORMATION

1. The requested medication may be approved if the following is true:
 - If non-preferred, agents to reduce uricemia will be approved after adequate trial (at least 3 months) of allopurinol without achievement of serum urate level below 6mg/dL **OR** intolerance **OR** contraindication to allopurinol.
 - If non-preferred, analgesic agents will be approved if any one of the following is true:
 - Diagnosis of Familial Mediterranean Fever (6 month approval); **OR**
 - Trial of one of the following:
 - NSAID (i.e., indomethacin, naproxen, ibuprofen, sulindac, ketoprofen)
 - Oral corticosteroid

Agents Under Review:

Agents for management of hyperuricemia

- Allopurinol
- Probenecid
- Probenecid/Colchicine
- Uloric® (febuxostat)

Analgesic Agents

- Colcrys® (colchicine)

Cardiovascular Agents: Hypertension & Heart Failure Sympatholytic Antihypertensives

LENGTH OF AUTHORIZATIONS: 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - Allergy to medications not requiring prior approval
 - Contraindication to or drug interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. The requested medication may be approved if both of the following are true:
 - If there has been a therapeutic failure to no less than a one-month trial of at least one medication within the same class not requiring prior approval
 - The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated

Document clinically compelling information

ADDITIONAL INFORMATION TO AID IN FINAL DECISION

- If there is a specific indication for a medication requiring prior approval, for which medications not requiring prior approval are not indicated, then may approve the requested medication. This medication should be reviewed for need at each request for reauthorization.

CARDIOVASCULAR AGENTS: Sympatholytic Antihypertensives

Agents Under Review:

- Clonidine
- Guanfacine
- Methyldopa
- Methyldopa/HCTZ
- Nexiclon XR (clonidine extended release)
- Reserpine

CNS Agents: Fibromyalgia Agents

LENGTH OF AUTHORIZATIONS: 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - Allergy to at least two medications not requiring prior approval
 - Contraindication to all medications not requiring prior approval
 - History of unacceptable/toxic side effects to at least two medications not requiring prior approval
2. Has the patient failed therapeutic trials of two weeks with two medications not requiring prior approval? If so, document and approve the requested medication.

Document clinically compelling information

ADDITIONAL INFORMATION

- Medication will be approved after trial of agents from no less than 3 of the following drug classes in the past 90 days (guidelines suggest use of multiple agents concurrently to manage the signs of fibromyalgia):
 - Tricyclic antidepressants
 - SSRIs
 - Short- and/or long-acting opioids
 - Skeletal muscle relaxants
 - Trazodone
 - Gabapentin
- If there is a specific indication for a medication requiring prior approval, for which medications not requiring prior approval are not indicated, then may approve the requested medication.
 - If non-preferred, duloxetine may be authorized for the following:
 - Diabetic peripheral neuropathic pain
 - Major Depressive Disorder (if duloxetine is a preferred antidepressant)
 - Generalized Anxiety Disorder (if duloxetine is a preferred antidepressant)
 - If non-preferred, pregabalin may be authorized for the following:
 - Diabetic peripheral neuropathic pain
 - Post-herpetic neuralgia
 - Seizure disorder

This medication should be reviewed for need at each request for reauthorization.

CNS AGENTS: Fibromyalgia Agents

Agents Under Review:

- Cymbalta® (duloxetine)
- Lyrica® (pregabalin)
- Savella® (milnacipran)

CNS Agents: Medication Assisted Treatment Agents

LENGTH OF AUTHORIZATIONS: 30 days for initial authorization
6 months for subsequent authorizations

All products in this class require clinical prior authorization:

1. Patient has diagnosis of opioid addiction (NOT approvable for pain)
2. Prescribing physician has a DATA 2000 waiver ID ("X-DEA" number)
3. Patient has been referred counseling for addiction treatment (re-authorizations should indicate how often the patient is receiving counseling)
4. Maximum dose 24mg per day (16mg is target, no patient should receive more than 32mg)
5. Prescriber has reviewed Ohio Automated Rx Reporting System (OARRS) for opioid prescription use
6. Periodic drug screens are addressed in treatment plan (will be performed by prescriber or by counseling team)
7. For reauthorizations – the dose has been reduced in the previous 6 months, or the patient has been evaluated for a dose reduction and the prescriber and patient agree that a dose reduction would not be beneficial/may be harmful

For buprenorphine only:

1. Patient is pregnant or breast-feeding a methadone-dependent baby
2. Patient has documented allergy to naloxone (very rare)

CNS AGENTS: Medication Assisted Treatment Agents

Drugs Under Review:

- Buprenorphine SL
- Suboxone® SL film (buprenorphine/naloxone)
- Suboxone® SL tablets (buprenorphine/naloxone)
- Subutex® SL tablets (buprenorphine)

Endocrine Agents: Estrogenic Agents

LENGTH OF AUTHORIZATIONS: 1 year

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - Allergy to medications not requiring prior approval
 - Contraindication to or drug interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. The requested medication may be approved if there has been a therapeutic failure to at least two trials of thirty days each with medications not requiring prior approval

Document clinically compelling information

ENDOCRINE AGENTS: Estrogenic Agents

Agents Under Review:

- Conjugated estrogens tablet (Cenestin®, Enjuvia®, Premarin®)
- Conjugated estrogens vaginal cream (Premarin®)
- Conjugated estrogens/medroxyprogesterone tablet (Prempro®, Premphase®)
- Esterified estrogens tablet (Menest®)
- Estradiol patch (Alora®, Climara®, Estraderm®, Menostar®, Vivelle-Dot®)
- Estradiol tablets (Estrace®, Femtrace®)
- Estradiol transdermal emulsion (Estrasorb®)
- Estradiol transdermal gel (Divigel®, Elestrin®, Estrogel®)
- Estradiol transdermal solution (Evamist®)
- Estradiol vaginal cream (Estrace®)
- Estradiol vaginal ring (Estring®, Femring®)
- Estradiol vaginal tablet (Vagifem®)
- Estradiol/drospirenone tablet (Angeliq®)
- Estradiol/levonorgestrel patch (Climara Pro®)
- Estradiol/norethindrone acetate tablet (Activella®, Mimvey®)
- Estradiol/norethindrone patch (CombiPatch®)
- Estradiol/norgestimate tablet (Prefest®)
- Estropipate tablet (Ogen®)
- Ethinyl estradiol/norethindrone acetate tablet (FemHRT®)

Gastrointestinal Agents: H. Pylori Packages

LENGTH OF AUTHORIZATIONS: 1 course of treatment

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - Allergy to medications not requiring prior approval
 - Contraindication to or drug interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval

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Also consider whether components are appropriate vs. package

GASTROINTESTINAL AGENTS: H. Pylori Agents

Agents Under Review

- Helidac® (Bismuth Subsalicylate/Metronidazole/Tetracycline)
- Prevpac® (Lansoprazole/Amoxicillin/Clarithromycin)
- Pylera® (Bismuth Subcitrate Potassium/Metronidazole/Tetracycline)

Gastrointestinal Agents: Ulcerative Colitis Agents

LENGTH OF AUTHORIZATIONS: 6 months

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - Allergy to medications not requiring prior approval
 - Contraindication to or drug interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. The requested medication may be approved if there has been a therapeutic failure to at least two trials of thirty days each with medications not requiring prior approval

ADDITIONAL INFORMATION

1. Ulcerative Colitis Agents are available in both oral (IR, ER) and rectal (enema, suppository) formulations. Patients with mild or moderate disease may be treated with either topical or oral agents.
2. The efficacy among the different 5-ASA derivatives appears to be comparable.

GASTROINTESTINAL AGENTS: Ulcerative Colitis Agents

Agents Under Review:

- Balsalazide (Colazal®)
- Mesalamine capsule extended release (Pentasa®)
- Mesalamine capsule extended release 24 hour (Apriso®)
- Mesalamine enema (Rowasa®, SFRowasa®)
- Mesalamine suppository (Canasa®)
- Mesalamine tablet delayed release (Asacol®, Asacol HD®, Lialda®)
- Olsalazine sodium capsule (Dipentum®)
- Sulfasalazine delayed release tablet (Azulfidine EN-tabs®)
- Sulfasalazine tablet (Azulfidine®)