

**COLORADO MEDICAID DUR BOARD MEETING
M I N U T E S
May 21, 2013**

Members Present

LeWayne Garrison, RPh
Deborah Lehman, MD
Sam Johnson, PharmD
James 'Rick' Kant, RPh
Pam Reiter, PharmD
Edra Weiss, MD
Tim Hartman, PharmD (Industry Representative)

Members Absent

Karen Weber, DO
James Regan, MD

Medicaid Pharmacy Department

Robert Lodge, PharmD
Gina Moore, PharmD (CO DUR)
Robert L Page, PharmD, MSPH (CO DUR)

UNFINISHED BUSINESS, GENERAL ORDERS, and NEW BUSINESS

The quarterly meeting of the Medicaid DUR Board was held on May 24th, 2013 at 225 16th Avenue, 1st floor conference room, Denver. A quorum being present, the meeting was officially called to order at 6:40 PM by S Johnson.

S Johnson asked if there were any changes or needed discussion of the minutes from the February meeting. A motion to approve the minutes was made by R Kant. E Weiss seconded the motion. The minutes were approved.

R Lodge gave an update on the DUR Board previously approved non-preferred criteria, reviewed from the last meeting. All recommendations made by the DUR Board were approved and implemented. The following updates were noted by J. Leonard:

S Johnson asked the Board if any conflicts of interest existed for the drugs and classes reviewed. None were reported by the Board.

S Johnson announced the rules for Oral Presentations:

- Presentations shall be restricted to products being reviewed for prior authorization criteria.
- Presentations shall be limited to a maximum of five minutes per drug product. Only one presentation per product will be permitted for a manufacturer. Persons must sign up no later than 24 hours in advance with the DUR Account Manager in order to speak at the DUR Board Meeting.
- Persons giving oral presentations must disclose all relationships to pharmaceutical manufacturers.
- Persons will be called in the order in which they signed in for each set of prior authorization criteria.
- Presentations must be limited to verbal comments. No visual aids, other than designated handouts are permitted.

NEW BUSSINESS

G. Moore presented the proposed PA criteria for each of the classes listed below to the DUR Board for approval:

Proposed PA Criteria

1. Fibromyalgia Agents

Preferred: Lyrica® (Pregabalin)
Sevella® (Milnacipran)

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class*		
	January 2013	February 2013	March 2013
Gabapentin	60%	60%	60%
Lyrica® (Pregabalin)	19%	21%	21%
Cymbalta®	19%	18%	18%
Sevella® (Milnacipran)	2%	1%	1%

*Based on patients > 18 years of age without an ICD-9 for 345.xx

Prior Authorization Criteria:

Cymbalta® will be approved for fibromyalgia if ALL the following criteria have been met:

1. Failure of an adequate trial of at least two of the following:
tramadol, a tricyclic antidepressant, appropriately titrated dosed gabapentin (1200-2400 mg in divided doses). An adequate trial will be 8 weeks. AND
2. Documented non-pharmacologic therapies to the Department (e.g., cognitive behavioral therapies, exercise).

Lyrica will have a maximum dosage limitation of 600 mg/day.

Discussion:

R. Kant motioned to approve as written. L Garrison seconded the motion. The passed motion unanimously.

2. Angiotensin Receptor Blockers/ARB Combinations/Renin Inhibitors/ Renin Inhibitor Combinations

Preferred: Avapro® (irbesartan)
Diovan® (valsartan)
Benicar® (olmesartan)
Losartan
Benicar -HCT® (olmesartan/HCTZ)
Diovan-HCT® (valsartan/HCTZ)
Avalide-HCT® (irbesartan/HCTZ)
Losartan-HCTZ

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2013	February 2013	March 2013
Losartan (generic)	63%	63%	65%
Diovan® (valsartan)	26%	26%	26%
Avapro® (irbesartan)	6%	7%	6%
Benicar® (olmesartan)	3%	3%	5%
Micardis® (telmisartan)	<1%	<1%	<1%
Atacand® (candesartan)	<1%	<1%	<1%
Irbesartan (generic)	<1%	<1%	<1%
Edarbi® (azilsartan)	<1%	0	0

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2013	February 2013	March 2013
Diovan HCT® (valsartan/HCTZ)	47%	47%	47%
Losartan-HCTZ (generic)	38%	38%	38%
Benicar-HCT® (olmesartan/HCTZ)	10%	12%	11%
Avalide-HCT® (irbesartan/HCTZ)	2%	2%	3%
Exforge® (valsartan/amlodipine)	1%	1%	<1%
Tarka® (trandolapril/Verapamil)	1%	1%	0%
Micardis-HCT® (telmisartan/HCTZ)	1%	0%	1%
Exforge-HCT® (valsartan/amlodipine/HCTZ)	0%	0%	0%
Tribenzor® (olmesartan/amlodipine)	1%	0%	0%
Edarbyclor® (azilsartan/chlorthalidone)	<1%	0%	0%
Irbesartan/HCTZ	0%	0%	0%
Twynsta® (telmisartan/amlodipine)	0%	0%	0%
Teveten-HCT (eprosartan/HCTZ)	0%	0%	0%

HCTZ: hydrochlorothiazide

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2013	February 2013	March 2013
Tekturna® (Aliskiren)	100%	100%	100%
Valutrna® (Aliskiren/Valsartan)	0%	0%	0%
Tekturna HCT® (Aliskiren/Valsartan)	0%	0%	0%
Amturnide® (Aliskiren/Amlodipine/HCTZ)	0%	0%	0%

HCTZ: hydrochlorothiazide

Prior Authorization Criteria:

Non-preferred ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products will be approved for clients who have failed treatment with three preferred products in the last 12 months (Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.).

Tekturna®, Tekturna HCT®, Valutrna®, and Amturnide® will not be approved in patients with diabetes. Receiving an ACE-inhibitor, ACE-inhibitor combination, ARB, or ARB-combination in combination with a renin inhibitor is contraindicated.

Discussion:

A motion was made to accept the criteria as written by L Garrison. E. Weiss seconded the motion. The motion passed unanimously.

3. Long Acting Opiates

Preferred: Methadone
Morphine ER
Fentanyl Patches

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2013	February 2013	March 2013
Morphine Sulfate ER	44%	44%	45%
Oxycontin® (oxycodone ER)	20%	20%	20%
Fentanyl Patch (generic)	17%	17%	17%
Methadone (generic)	15%	15%	15%
Opana ER® (oxymorphone)	1%	1%	1%
Nucynta ER® (tapentadol)	<1%	<1%	<1%
Kadian ER® (morphine)	<1%	<1%	<1%
Butrans® (buprenorphine)	<1%	<1%	<1%
Avinza® (morphine)	<1%	<1%	<1%
Exalgo ER® (hydromorphone)	<1%	<1%	<1%
Duragesic Patch® (fentanyl)	<1%	<1%	<1%
MS Contin® (morphine)	<1%	<1%	<1%

Prior Authorization Criteria:

*Fentanyl patches are considered first line only for clients unable to take oral long acting opiates or have an allergy to morphine. **(Delete)**

*Fentanyl patches are considered second line and will require failure with one oral first line agent in the last six months. **(Delete)**

Discussion:

A motion to approve both of the two previous criteria was made by L Garrison and seconded by E Weiss. The motion was approved.

Prior Authorization Criteria:

Non-preferred, long-acting oral opioids will be approved for clients who have failed treatment with ~~two line~~ one preferred agent in the last six months. (Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.)

Discussion:

The Board recommended that the client need only fail one agent rather than two preferred agents. A motion to approve criteria as amended above was made by R Kant and seconded by P Reiter. The motion was approved as amended.

Prior Authorization Criteria:

Oxycontin®, Opana ER®, and Nucynta ER® will only be approved for twice daily dosing.

Discussion:

A motion to approve this criterion was made by L Garrison and seconded by E Weiss. The motion was approved.

Prior Authorization Criteria:

No more than one oral long acting opioid will be approved.

Discussion:

The Board recommended that the word “oral” be included to reflect that in rare instances a client might require fentanyl patches in addition to a long acting oral agent. A motion to approve this criterion as amended was made by E Weiss and seconded by R Kant. The motion was approved.

Prior Authorization Criteria:

Medicaid is not mandating that a patient switch from a non-preferred drug to **methadone**. Methadone requires special training due to its complex pharmacokinetic profile. However, if a patient has tried and failed methadone in the past, then it may be considered one trial for the rationale “a trial of ~~two~~ one preferred drugs”.

Discussion:

The Board recommended that the words “and failed” be included to clarify the above criterion, and also to change the wording to a trial of only one preferred drug is necessary consistent with the approved criterion that only requires a trial of one preferred agent. A motion to approve this criterion as amended was made by R Kant and seconded by D Lehman. The motion was approved.

Prior Authorization Criteria:

Use of opioid analgesics during pregnancy has been associated with neonatal abstinence syndrome. Providers **MUST** should counsel women of childbearing age regarding the risks of becoming pregnant while receiving opioids, including the risk of neonatal abstinence syndrome.

Discussion:

The Board recommended that the words “must” be changed to “should” as this criterion would be difficult to enforce with the current system. A motion to approve this criterion as amended was made by E Weiss and seconded by R Kant. The motion was approved.

Grandfathering:

Grandfathering for non-preferred long-acting opiates will be phased out during the Spring of 2013. Please consult the main HCPF pharmacy page (<http://www.colorado.gov/cs/Satellite/HCPF/HCPF/1197969485891>) or the provider bulletin for additional information. (delete)

Phasing out of grandfathering will begin 2 months following implementation of the opiate education program. The Department will notify all providers once this goes in effect.

Discussion:

The Board recommended that the words “phasing out of” be added prior to grandfathering for clarification of this criterion. A motion to approve this criterion as amended was made by L Garrison and seconded by P Reiter. The motion was approved.

Grandfathering:

Non-preferred long-acting opiates will approved for clients who have failed treatment with two preferred products in the last six months. (Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.)

(deleted)

Discussion:

A motion to approve deletion of this criterion was made by R Kant and seconded by E Weiss. The motion was approved.

4. Topical Immunomodulators

Preferred: None

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2013	February 2013	March 2013
Elidel® (pimecrolimus)	63%	60%	73%
Protopic® (tacrolimus)	37%	40%	27%

Prior Authorization Criteria:

Prior authorization is required for children < 2 years of age.

Elidel or Protopic will only be approved after a client who has had an adequate trial (e.g., one month or longer) of a topical steroid and failed treatment. (Failure is defined as a lack of efficacy, allergy, intolerable side effects, or significant drug-drug interactions.

Prior authorization will be required for clients warranting \geq 6 weeks of therapy with either Elidel or Protopic.

Discussion:

There was no discussion other than to insert the word “has” in the second sentence for grammatical purposes. E Weiss made the motion for approval which was seconded by L Garrison. The motion passed unanimously.

5. Skeletal Muscle Relaxants

Preferred: Baclofen
Cyclobenzaprine
Tizanidine

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2013	February 2013	March 2013
Cyclobenzaprine (generic)	65%	65%	64%
Baclofen (generic)	18%	18%	18%
Tizanidine (generic)	15%	15%	16%
Methocarbamol (generic)	<1%	<1%	<1%
Amrix ER®(cyclobenzaprine)	<1%	<1%	<1%
Dantrolene (generic)	<1%	<1%	<1%
Carisoprodol (generic)	<1%	<1%	<1%
Orphenadrine (generic)	<1%	<1%	<1%
Chlorzoxazone (generic)	<1%	<1%	<1%
Dantrium® (dantrolene)	<1%	<1%	<1%
Skelaxin® (metaxalone)	0%	0%	0%
Zanaflex® (tizanidine)	0%	0%	0%
Metaxalone (generic)	0%	0%	0%

Prior Authorization Criteria:

All agents in this class will require a prior authorization for clients over ~~75~~ 65 years of age. Approval will only be given if the client has had at least a 7 day trial with an opiate or has a diagnosis of spasticity. The maximum allowable approval will be for a 7 days' supply.

Discussion:

The Board suggested that the age for a prior authorization to be required be changed to 65 years of age to be consistent with the new Beers Criteria. R Kant made a motion to approve this change and was seconded by D Lehman. The motion passed.

Prior Authorization Criteria:

Non-preferred skeletal muscle relaxants will be approved for clients who have documented lack of efficacy with two preferred agents in the last 6 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interactions.)

Authorization for any carisoprodol product will be given for a maximum 3 week one time authorization for clients with acute, painful musculoskeletal conditions who have failed treatment with two preferred products.

Tapering:

Due to potential withdrawal symptoms, tapering is recommended when discontinuing high doses of carisoprodol. A one month approval will be granted for clients tapering off of carisoprodol.

*A PA will only be granted for any carisoprodol product for short-term use or tapering

Discussion:

R Kant motioned to accept PA criteria as written. These were seconded by L Garrison and passed unanimously.

6. Newer Generation Antihistamines/Antihistamine Combinations

Preferred: Loratadine
Cetirizine

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2013	February 2013	March 2013
Cetirizine (generic)	65%	67%	66%
Loratadine (generic)	30%	29%	30%
Levocetirizine (generic)	2%	2%	2%
Fexofendadine (generic)	1%	1%	1%
Allegra® (fexofendadine)	<1%	<1%	<1%
Xyzal® (levocetirizine)	<1%	<1%	<1%
Clarinetx® (desloratadine)	<1%	<1%	<1%
Claritin® (loratadine)	<1%	<1%	<1%
Alavert® (loratadine)	0%	0%	0%

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2013	February 2013	March 2013
Fexofenadine-PSE (generic)	50%	50%	41%
Clartin-D® (loratadine/PSE)	25%	17%	29%
Cetirizine-PSE (generic)	13%	17%	13%
Clarinetx-D (deloratadine/PSE)	0%	17%	13%
Allegra-D® (fexofendadine/PSE)	13%	0%	0%

PSE: pseudoephedrine

Prior Authorization Criteria:

Non-preferred antihistamines will be approved for clients who have failed treatment with both two preferred products in the last 6 months and including nasal steroids (for children age 4 and older). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.)

Grandfathering:

Clients already stabilized on a non-preferred newer generation antihistamine or a newer generation antihistamine combination will only be grandfathered through January 1, 2013. **(delete)**

Discussion:

There Board suggested that the grandfather provision be deleted since the date had passed. R Kant made the motion to accept the criteria as amended which was seconded by E Weiss. The motion passed unanimously.

7. Inhaled Anticholinergics/Anticholinergic Combinations

Preferred: Solutions:
Albuterol/Ipratropium
Ipratropium

Inhalers:
Atrovent HFA®(ipratropium)
Combivent® (albuterol/ipratropium)
Spiriva handihaler® (tiotropium)

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2013	February 2013	March 2013
Spiriva Handihaler® (tiotropium)	80%	77%	80%
Ipratropium (generic)	7%	10%	10%
Atrovent HFA®(ipratropium)	13%	11%	10%
Tuorza Pressair (aclidinium)	<1%	<1%	<1%

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2013	February 2013	March 2013
Combivent® (albuterol/ipratropium)	61%	57%	62%
Albuterol/Ipratropium (generic)	39%	43%	38%

Prior Authorization Criteria:

Non-preferred anticholinergic inhalants and anticholinergic combination inhalants will require a brand-name prior authorization stating medical necessity.

Speaker:

Amanda DeBruin, PharmD from Forest Pharmaceuticals.

Discussion:

R Kant motioned that the criteria be accepted as written which was seconded by L Garrison. The motion passed unanimously.

8. Short Acting Inhaled Beta-2 Agonists

Preferred: Solutions
Albuterol

Inhalers
Proair HFA® (albuterol)

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2013	February 2013	March 2013
Proair HFA®(albuterol)	38%	36%	38%
Ventolin HFA®(albuterol)	31%	30%	31%
Albuterol HFA (generic)	20%	22%	21%
Xopenex® (levalbuterol)	1%	1%	1%
Xopenex HFA® (levalbuterol)	<1%	<1%	<1%
Proventil® (albuterol)	<1%	<1%	<1%
Maxair® (Pirbuterol)	<1%	<1%	<1%
Peformomist® (formoterol)	<1%	<1%	<1%
Levalbuterol (generic)	<1%	<1%	<1%
Relion® (albuterol)	0%	0.0%	0.0%
Terbutaline (generic)	0%	0.0%	0.0%

Prior Authorization Criteria:

Non-preferred, short acting beta2 agonists will be approved for clients who have failed treatment with one preferred agent. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction).

Discussion:

None. E Weiss motioned that the criteria be accepted which was seconded by L Garrison. The motion passed unanimously.

9. Long Acting Inhaled Beta-2 Agonists

Preferred: None preferred

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2013	February 2013	March 2013
Serevent Diskus®(salmeterol)	50%	34%	39%
Foradil®(formoterol)	19%	15%	13%
Perforomist® solution (formoterol)	14%	28%	16%
Brovana® solution (arformoterol)	17%	23%	32%
Arcapta® (indacaterol)	0%	0%	0%

Prior Authorization Criteria:

Long acting beta-2 agonists will be approved for clients with moderate to severe asthma who are currently using an inhaled corticosteroid and require add-on therapy, or for clients with moderate to very severe COPD.

Arcapta Neohaler® will only be approved for once daily use in clients with COPD who have failed an adequate trial of two other long-acting beta-2 agonists.

An adequate trial is defined as at least one week. **(delete)**

Speaker:

Mai Duong, PharmD from Novartis.

Discussion:

R Kant motioned that the criteria be accepted as written which was seconded by L Garrison. The motion passed unanimously.

10. Inhaled CorticosteroidsPreferred:

Solutions

Budesonide

Inhalers

Asmanex® (mometasone)

Flovent HFA® (fluticasone)

Flovent diskus®(fluticasone)

QVAR®(beclomethasone)

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2013	February 2013	March 2013
Flovent HFA® (fluticasone)	58%	56%	57%
Flovent Diskus® (fluticasone)			
QVAR® (beclomethasone)	18%	18%	19%
Budesonide (generic)	16%	19%	16%
Pulmicort® (budesonide)	3%	3%	3%
Asmanex® (mometasone)	3%	2%	3%
Alvesco® (ciclesonide)	2%	3%	2%

Prior Authorization Criteria:

Non-preferred inhaled corticosteroids will be approved in clients with asthma who have failed an adequate trial of two preferred agents. An adequate trial is defined as at least 6 weeks. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interactions.)

Pulmicort Flexhaler will only be approved for female clients with asthma who have a new diagnosis of pregnancy.

Budesonide solution will only be approved for a maximal dose of 2mg/day.

Discussion:

None. The motion to accept the criteria was made by R Kant and seconded by E Weiss. The motion passed unanimously.

11. Inhaled Corticosteroid CombinationsPreferred:

Advair Diskus ® (fluticasone/salmeterol)

Symbicort® (budesonide/formoterol)

Advair HFA® (fluticasone/salmeterol)
Dulera® (mometasone/formoterol)

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	January 2013	February 2013	March 2013
Advair Diskus® (fluticasone/salmeterol)	66%	66%	65%
Advair HFA® (fluticasone/salmeterol)			
Symbicort® (budesonide/formoterol)	27%	27%	28%
Dulera® (mometasone/formoterol)	7%	7%	7%

Prior Authorization Criteria:

Non-preferred inhaled corticosteroid combination inhalants will be approved for clients meeting both of the following criteria:

- Client has a qualifying diagnosis of asthma or COPD; and
- Client cannot take preferred drug due to lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction.

Discussion:

R Kant motioned that the criteria be accepted as written which was seconded by E Weiss. The motion passed unanimously.

12. Invokana (Canaglifozin)—Newer Diabetic Agents

Prior Authorization Criteria:

Invokana will only be approved after a client has failed a three month trial of two of the following: metformin, a sulfonylurea, Januvia or Tradjenta, or Byetta. Failure is defined as: lack of efficacy (e.g., hemoglobin A1C \geq 7%), allergy, intolerable side effects, or significant drug-drug interaction.

Invokana will not be approved for patients requiring dialysis or those who are pregnant, or have type 1 diabetes, end stage renal disease or severe renal impairment defined as a creatinine clearance $<$ 45 ml/min.

Discussion:

There was some discussion whether the wording regarding pregnancy was necessary, but the Board recommended the wording remain as is to be consistent with the package insert. R Kant motioned to approve. L Garrison seconded. The motion passed.

13. Kineret (anakinra)—Targeted Immune Modulators for RA

Prior Authorization Criteria:

Kineret will only be approved without prior authorization for clients with documented neonatal-onset multisystem inflammatory disease (NOMID).

Discussion:

It was noted that this prior authorization criteria was specific for NOMID. The motion to accept the criteria was made by R Kant and seconded by E Weiss. The motion passed unanimously.

14. Ravicti (glycerol phenylbutyrate)

Prior Authorization Criteria:

Ravicti will only be approved for clients meeting the following criteria:

- Client must be 2 years of age or older
- Client must have a documented diagnosis of urea cycle disorder (UCD).
- Client must be on a dietary protein restriction (verified by supporting documentation)
- Client must have tried and failed Buphenyl as evidenced by uncontrolled hyperammonia over the past 365 days.
- Medication must be prescribed by a physician experienced in the management of UCD (e.g., geneticist)

Speaker: Marty Porter, PhD, Hyperion Pharmaceuticals

Discussion:

None. The motion to approve was made by E Weiss and seconded by L Garrison. The motion passed unanimously.

15. Tecfidera (dimethyl fumarate, BG-12)—MS Agents

Prior Authorization Criteria:

Tecfidera will be approved if the client has failed treatment with one interferon and Copaxone. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions). Lack of efficacy is defined by client meeting one of the three following criteria: a clinical relapse within the past 12 month period; progression of disease as verified by MRI; or continued worsening of physical disability.

Discussion:

None. The motion to approve was made by R Kant and seconded by T Hartman. The motion passed unanimously.

15. Colcris (colchicine)

Quantity Limits:

- Chronic hyperuricemia/gout prophylaxis: 60 tablets per 30 days
- Familial Mediterranean Fever: 120 tablets per 30 days

Discussion:

None. The motion to approve was made by R Kant and seconded by L Garrison. The motion passed unanimously.

Upcoming Meeting

A motion was made by E Weiss to adjourn the meeting and was seconded by L Garrison. The meeting was adjourned at 8:10 PM.

I, Sam Johnson as Chair of the Colorado Medicaid DUR Board, hereby attest that these minutes substantially reflect the substance of the discussion during the open session.

By: _____
Sam Johnson, PharmD, Committee Chair

Date: _____