COLORADO MEDICAID DUR BOARD OPEN MEETING
M I N U T E S
February 19, 2013

Members Present
Jim Regan, MD
Sam Johnson, PharmD
Pam Reiter, PharmD
James 'Rick' Kant, RPh
Deborah Lehman, MD

Members Absent
Kerri Miller (Industry Representative)
Karen Weber, MD
LeWayne Garrison, RPh
Edra Weiss, MD
Gina Moore, PharmD (CO DUR)

Medicaid Pharmacy Department
Jim Leonard, PharmD
Robert Lodge, PhamD
Robert L Page, PharmD, MSPH (CO DUR)
Vahram Ghushchyan, PhD (CO DUR)

UNFINISHED BUSINESS, GENERAL ORDERS, and NEW BUSINESS

The quarterly meeting of the Medicaid DUR Board was held on February 19, 2013 at 225 16th Avenue, 1st floor conference room, Denver. A quorum being present, the meeting was officially called to order at 7:15 PM.

J Regan asked if there were any changes or needed discussion of the minutes from the November meeting. Motion to approve the minutes was made by S Johnson. R Kant seconded the motion. The minutes were approved with the amended change.

J. Leonard 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.

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

J Regan 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

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

1. Alzheimer's Agents

Preferred: Aricept® (Donepezil)
Aricept® ODT (Donepezil)
Donepezil
Donepezil ODT
Galantamine
Galantamine ER
Namenda

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2012	November 2012	December 2012
Aricept (tablet, ODT)®	7%	3%	2%
Donepezil (tablet, ODT)	57%	60%	64%
Exelon patch®	3%	4%	1%
Galantamine ER Capsule	1%	1%	2%
Galantamine (Capsule, tablet)	2%	1%	1%
Namenda (Tablet, solution)	30%	31%	30%

Prior Authorization Criteria:
Non-preferred products will be approved if the client has failed treatment with one of the preferred products in the last 12 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects
or significant drug-drug interactions)

Clients currently stabilized on a non-preferred product can receive approval to continue on that agent for one year if medically necessary and if there is a diagnosis of dementia.

All preferred products will be approved without a prior authorization if the client has a diagnosis of dementia. (This process will be implemented by the SMART PA system. The four recognized codes are 331.0, 294.1,
294.10 and 294.11)

Testimony was heard from the following Companies:
None.

Discussion:
A motion was made to accept the criteria as written by S Johnson. D Lehman seconded the motion. The passed motion unanimously.

2. Atypical Antipsychotics

Preferred: Abilify® (Aripiprazole)
Clozaril® (Clozapine)
Clozapine

Geodon® (Ziprasidone)
Latuda® (Lurasidone)
Olanzapine
Risperdal®(Risperidone)
Risperidone
Quetiapine
Seroquel immediate release® (Quetiapine)
Saphris® (Asenapine)
Ziprasidone
Zyprexa® (Olanzapine)

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2012	November 2012	December 2012
Abilify (Solution, Tablet, Discmelt)®	23%	23%	23%
Clozapine	5%	5%	5%
Clozapine ODT	<1%	<1%	<1%
Clozaril®	<1%	<1%	<1%
Fanapt®	<1%	<1%	<1%
Fazaclo®	<1%	<1%	<1%
Geodon®	<1%	<1%	<1%
Inega ER®	2%	2%	2%
Inega Sustenna®	<1%	<1%	<1%
Latuda®	1%	1%	1%
Olanzapine	11%	11%	11%
Quetiapine	19%	19%	19%
Risperdal (Tablet, Solution)	<1%	<1%	<1%
Risperdal ODT	<1%	<1%	<1%
Risperidone (Tablet, Solution)	25%	25%	24%
Risperidone ODT	<1%	<1%	<1%
Saphris®	1%	1%	1%
Seroquel®	5%	5%	5%
Ziprasidone	6%	6%	6%
Zyprexa®	<1%	<1%	<1%
Zyprexa®, Zydis®	<1%	<1%	<1%

Prior Authorization Criteria:
Non-preferred products will only be approved for their FDA approved indications and age limits and only if the client has failed on three preferred products in the last 5 years. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions).

Table 1. FDA Approved Indications for Nonpreferred Products

Drug	Indication
Fanapt®	• Acute treatment of schizophrenia in adults
Fazaclo®	• Treatment-resistant schizophrenia

	• Reducing the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder
Invega®	• Acute and maintenance of schizophrenia • Acute treatment of schizophrenia (monotherapy) • Acute treatment of schizophrenia (adjunct to mood stabilizers and/or antidepressants
Latuda®	• Treatment of schizophrenia
Seroquel XR®	• Treatment of schizophrenia • Acute treatment of manic or mixed episodes associated with bipolar I disorder, both as monotherapy and as an adjunct to lithium or divalproex • Maintenance treatment of bipolar I disorder as an adjunct to lithium or divalproex • Adjunctive treatment of major depressive disorder (MDD)

Age Limits: All products including preferred products will require a prior authorization for clients younger than the FDA approved age for the agent . Clients younger than the FDA approved age for the agent who are currently stabilized on an atypical antipsychoticwill be eligible for grandfathering.

New Atypical Antipsychotic prescriptions for clients under 5 years of age will be reviewed on an individual basis by a clinical healthcare professional at the Department. Prior authorization approval will be based upon medical necessity, evidence to support therapy,proposed monitoring and additional risk/benefit information supplied by the prescriber. Clients under the age of 5 will be reviewed annually for appropriateness of therapy and proper monitoring.

Grandfathering: Clients currently stabilized on a non-preferred atypical antipsychotic can receive approval to continue on that agent for two years even if the client does not meet the age, dosing or FDA approved indication requirements. Verification may be provided from the prescriber or the pharmacy.

Quantity Limits: All products including preferred products will have quantity limits. In order to receive approval for off-label dosing, the client must have an FDA approved indication and must have tried and failed on the FDA approved dosing regimen. See Table 2.

Table 2. Quantity Limits

Brand	Generic	Quantity Limits
Abilify	Aripiprazole	Maximum of one tablet per day
	Clozapine	Maximum dosage of 900mg per day
Clozaril	Clozapine	Maximum dosage of 900mg per day
Fazaclo	Clozapine	Maximum dosage of 900mg per day
Fanapt	Iloperidone	Maximum of two tablets per day
Geodon	Ziprasidone	Maximum two tablets per day
Invega	Paliperidone	Maximum of one tablet per day
Latuda	Lurasidone	Maximum of one tablet per day
Risperdal	Risperidone	Maximum two tablets per day except the 4 mg tablets will be approved for up to 4 tablets per day
	Risperiodne	Maximum two tablets per day except the 4 mg tablets will be approved for up to 4 tablets per day
Saphris	Asenapine	Maximum of two tablets per day
Seroquel	Quetiapine	Maximum of three tablets per day
Seroquel XR	Quetiapine XR	Maximum one tablet per day except 300mg and 400mg tablets will be approved for up to two tablets per day
Zyprexa	Olanzapine	Maximum one tablet per day

SEROQUEL XR will be approved if the client is 18 years of age or older, has tried and failed treatment with three preferred products in the last five years and is being treated for one of the following indications:

- Schizophrenia
- Acute treatment of manic or mixed episodes associated with bipolar I disorder, both as monotherapy and as an adjunct to lithium or divalproex
- Acute treatment of depressive episodes associated with bipolar I disorder
- Maintenance treatment of bipolar I disorder as an adjunct to lithium or divalproex
- Adjunctive treatment of major depressive disorder (MDD)

If a client has been stabilized on SEROQUEL for at least 30 days with a positive response but is unable to tolerate the side effects, Seroquel XR may be approved without failure of two additional agents.

ZYPREXA ZYDIS will be approved for the treatment of schizophrenia or bipolar 1disorder if the client is 13 years of age or older and has tried and failed treatment with three preferred products (one of which must be an olanzapine tablet) in the last 5 years.

For clients that are stabilized on ZYPREXA tablets with a documented need for occasional supplementation to treat acute symptoms, up to 5 tablets per month will be allowed without three product failures

Testimony was heard from the following Companies:
Julie Porter, PharmD, Novartis.

Discussion:
A motion was made to accept the criteria as written by S Johnson. D Lehman seconded the motion. The passed motion unanimously.

3. Growth Hormones

Preferred: Norditropin® (Somatropin)
Omnitropin® (Somatropin)
Saizen® (Somatropin)

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2012	November 2012	December 2012
Genotropin®	<1%	<1%	0%
Humatrope®	<1%	<1%	0%
Norditropin®	79%	81%	84%
Norditropin Nordiflex®	3%	3%	2%
Omnitrope®	3%	5%	4%
Saizen®	13%	11%	10%

Prior Authorization Criteria:
Non-preferred Growth Hormones will be approved if **both** of the following criteria are met:

- Client failed treatment with two preferred products within the last 12months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)

- Client has a qualifying diagnosis:
  - ✓ Prader-Willi
  - ✓ Chronic renal insufficiency/failure
  - ✓ Turner's Syndrome
  - ✓ Hypopituitarism: as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy or trauma
  - ✓ Wasting associated with AIDS or cachexia
  - ✓ Noonan Syndrome

Testimony was heard from the following Companies:
None.

Discussion:
A motion was made to accept the criteria as written by S Johnson. R Kant seconded the motion. The passed motion unanimously.

4. Intranasal Steroids

Preferred: Fluticasone Propionate
Nasonex ®(Mometasone Furoate Monohydrate)
Triamcinolone Acetonide

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2012	November 2012	December 2012
Flunisolide	<1%	<1%	<1%
Fluticasone Propionate	90%	91%	91%
Nasacort AQ®	<1%	<1%	<1%
Nasonex®	<1%	<1%	<1%
Omnaris®	<1%	<1%	<1%
Qnasl®	<1%	<1%	<1%
Rhinocort AQ®	<1%	<1%	<1%
Triamcinolone Acetonide	8%	8%	8%
Veramyst®	<1%	<1%	<1%
Zetonna®	0%	<1%	<1%

Prior Authorization Criteria:
Non-preferred Intranasal Corticosteroids will be approved if the client has failed treatment with 2 preferred products in the last 12 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions).

RHINOCORT AQ® will be approved for pregnant clients without failure of Preferred products.

Brand name FLONASE® will require a letter of medical necessity.

Testimony was heard from the following Companies:
None.

Discussion:
A motion was made to accept the criteria as written by S Johnson. P Reiter seconded the motion. The passed motion unanimously.

5. Leukotriene Modifiers

Preferred: Montelukast

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2012	November 2012	December 2012
Montelukast	99%	99%	99%
Singulair®	<1%	<1%	<1%
Zafirlukast®	<1%	<1%	<1%
Zyflo®	<1%	<1%	<1%
Zyflo CR®	<1%	<1%	<1%

Prior Authorization Criteria:
Non-preferred Leukotrienes will be approved if **both** of the following criteria are met:

- Client failed treatment with MONTELUKAST in the last 12 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)
- Client has a diagnosis of Asthma

Testimony was heard from the following Companies:
None.

Discussion:
A motion was made to accept the criteria as written by P Reiter. S Johnson seconded the motion. The passed motion unanimously.

6. Agents for Multiple Sclerosis

Preferred: Avonex® (Interferon beta-1a)
Betaseron® (Interferon beta-1b)
Rebif® (Interferon beta-1a)
Copaxone® (Galtiramer)

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2012	November 2012	December 2012
Ampyra®	8%	9%	6%
Aubagio®	0%	1%	1%
Avonex®	16%	19%	17%
Betaseron®	6%	9%	4%
Copaxone®	45%	44%	47%
Gilenya®	7%	5%	6%
Rebif®	18%	13%	19%

Prior Authorization Criteria:
Non-preferred Interferon products will be approved if the client has 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 interactions).

GILENYA 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).

AMPRYA – A 30 day supply of AMPYRA will be approved if all of the Following criteria are met:

- Client has a diagnosis of MS;
- Client is ambulatory and has established a baseline Timed 25-foot Walk (T25FW) assessment;
- Client is currently receiving a disease modifying agent (if indicated);
- Client has no history of seizure disorder;
- Client has no history of moderate to severe renal dysfunction (CrCl > 50 ml/min);
- Prescriber is a neurologist or is consulting a neurologist;
- The prescribed dose does not exceed 10 mg twice daily.

Extended coverage of AMPYRA (up to one year) will be approved if documentation shows improvement in ambulation (measured by T25FW assessment).

Testimony was heard from the following Companies:
Julie Porter, PharmD, Novartis.
Carla Keyon, PharmD, Genzyme/Sanofi.
Phillip Kenner, PharmD, Accordia.
Eric Kelts, MD, Neurologist.

Discussion:
R Page referred the Board to a letter from John Corboy, MD from the University of Colorado School of Medicine, Department of Neurology to reconsider step therapy for the newer MS drugs. J Regan suggested that for Ampyra that a two 30 day supply should be provided for clients. J Regan suggested the following critera for Augabio: “Augabio will be approved if the client has failed treatment with one interferon and Copaxone. Female patients must have a negative pregnancy test and must be using reliable contraception.” Discussion was had regarding the

definition of “failure” or lack of efficacy. R Page suggested the following criteria: 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. A motion was made to accept the criteria as amended by S Johnson. D Lehman seconded the motion. The passed motion unanimously.

7. Sedative Hypnotics

Preferred: Lunesta® (Eszopiclone)
Zaleplon
Zolpidem

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2012	November 2012	December 2012
Ambien®	<1%	<1%	<1%
Edluar®	<1%	<1%	<1%
Lunesta®	13%	14%	14%
Rozerem®	<1%	<1%	<1%
Zalepon®	2%	1%	2%
Zolpidem ER	2%	2%	3%
Zolpidem	82%	82%	82%

Prior Authorization Criteria:
Non-preferred sedative hypnotics will be approved for clients who have failed treatment with three preferred agents in the last 12 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects,
or significant drug-drug interaction)

ROZEREM will be approved for clients with a history/concern of substance abuse or for documented concern of diversion within the household without failed treatment on a preferred agent

Children: Prior authorizations will be approved for clients 18 years of age and older.

Duplications: Only one agent in this drug class will be approved at a time. Approval will not be granted for clients currently taking a long-acting benzodiazepine such as clonazepam or temazepam.

Testimony was heard from the following Companies:
None.

Discussion:
J Regan suggested that non-preferred sedative hypnotics should be approved for clients who have failed treatment with 2 rather than 3 preferred agents. A motion was made to accept the criteria as amended by D Lehman. S Johnson seconded the motion. The passed motion unanimously.

8. Statin and Combinations

Preferred: Atorvastatin
Crestor® (Rosuvastatin)
Pravastatin
Simvastatin

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2012	November 2012	December 2012
Advicor®	0%	0%	<1%
Amlodipine-Atorvastatin	0%	0%	0%
Atorvastatin	40%	41%	41%
Crestor®	15%	15%	16%
Lipitor®	<1%	<1%	<1%
Livalo®	<1%	0%	<1%
Lovastatin	<1%	<1%	<1%
Pravastatin	12%	12%	12%
Simcor®	<1%	0%	0%
Simvastatin	32%	31%	31%
Vytorin®	<1%	<1%	<1%

Non-preferred Statin/Statin combinations will be approved if the client has failed treatment with two preferred products in the last 24 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)

Children**:** ALTOPREV®, ADVICOR®, LIVALO®, and VYTORIN® will be approved for clients 18 years of age and older.

Simvastatin 80mg dose products will only be covered for clients who have been stable for more than 12 months at that dose. Providers should consider alternate preferred statins in clients who have not met cholesterol goals on simvastatin at doses up to 40mg per day. Please refer to the FDA communication titled, "FDA Drug Safety Communication: New restrictions, contraindications and dose limitations for Zocor (simvastatin) to reduce the risk of muscle injury" for updated guidance on contraindications, dose limits and relative LDL lowering doses of alternatives.

Testimony was heard from the following Companies:
None.

Discussion:
A motion was made to accept the criteria as written by R Kant. S Johnson seconded the motion. The passed motion unanimously.

9. Ophthalmic Allergy

Preferred: Cromolyn
Patanol® (Olopatadine)
Pataday®(Olopatadine)
Zadiotor® (Ketotifen)

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2012	November 2012	December 2012
Azelastine	9%	10%	10%
Bepreve®	0%	<1%	0%
Cromolyn	3%	5%	4%
Epinastine	<1%	<1%	<1%
Ketotifen	<1%	<1%	<1%
Pataday®	51%	50%	51%
Patanol®	37%	36%	34%

Prior Authorization Criteria:
Non-preferred Ophthalmic Allergy medications will be approved if the client has 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 interactions)

Testimony was heard from the following Companies:
None.

Discussion:
A motion was made to accept the criteria as written by R Kant. S Johnson seconded the motion. The passed motion unanimously.

10. Xeljanz® (tofacitinib)

XELJANZ will be approved for the treatment of RA in clients who have had treatment failure with methotrexate with at least two separate TNF inhibitors (e.g., Humira or Enbrel)(Failure is defined as: lack of efficacy of a three month trial, allergy,intolerable side effects, or significant drug-drug interaction.

XELJANZ will be not be approved for combination therapy with a biologic disease modifying agent.

Quantity Limits: 2 tablets per day or 60 tablets for a 30 day supply

Testimony was heard from the following Companies:
None.

Discussion:
A motion was made to accept the criteria as written by R Kant. P Reiter seconded the motion. The passed motion unanimously.

11. Juxtapid® (lomitapide)

JUXTAPID will be approved for only if all the following criteria are met:

- Client is 18 years of age and older
- Client has a documented diagnosis of homozygous familial hypercholesterolemia (HoFH)
- Client has failed therapy with high dose statin therapy (e.g, atorvastatin 40 mg or higher, Crestor 20 mg or higher).
- Prescribing physician is a enrolled in the JUXTAPID REMS program

Testimony was heard from the following Companies:
Patrick Jensen, PharmD. Aegerion Pharmaceuticals

Discussion:
A suggestion was made to add to the criteria that for women of child bearing age, a negative pregnancy test should be required and that the client should be using a reliable form of contraception. A motion was made to accept the criteria as amended by P Reiter. R Kant seconded the motion. The passed motion unanimously.

12. Gattex® (teduglutide)

GATTEX will only be approved if all the following criteria are met:

- Client is 18 years of age and older
- Client has documented short bowel syndrome
- Client is dependent on parenteral nutrition support and has been on parenteral nutrition for twelve consecutive months.
- Prescribing physician is a Gastroenterologist.
- Medical necessity for teduglutide has been provided to the Department and approved by the Department.
- Initial prior authorizations will be time limited to two months.

Testimony was heard from the following Companies:
None.

Discussion:
A motion was made to accept the criteria as written by S Johnson. R Kant seconded the motion. The passed motion unanimously.

13. Pediatric Max Doses for Atypical Antipsychotic

Drug	FDA Approved Indication	FDA Approved Age	Maximal FDA Approved Dose
Asenapine (Saphris®)	NOT APPROVED		
Aripiprazole (Abilify®)	Autism/Psychomotor Agitation Bipolar Disorder/Mixed Mania	6-17 years 10-17 years	15mg/day 30mgday

	Schizophrenia	13-17 years	30mg/day
Clozapine (Fazaclo®, Clozaril®)	NOT APPROVED		
Iloperidone (Fanapt®)			
Lurasidone (Latuda®)			
Olanzapine (Zyprexa®)	Schizophrenia Bipolar Disorder/Mixed Mania	13-17 years 13-17 years	10mg/day 10mg/day
Olanzapine (Zyprexa Zydis®)			
Paliperidone (Invega ER®)	Schizophrenia	12-17 years	12mg/day
Risperidone (Risperdal®)	Autism/Psychomotor Agitation Bipolar Disorder/Mixed Mania Schizophrenia	5-16 years 10-17 years 13-17 years	3mg/day 6mg/day 6mg/day
Quetiapine Fumarate (Seroquel®)	Schizophrenia Bipolar Disorder/Mixed Mania	13-17 years 10-17 years	800 mg/day 800 mg/day
Quetiapine Fumarate (Seroquel XR®)	NOT APPROVED		
Ziprasidone (Geodon®)	NOT APPROVED		

Discussion:
A motion was made to accept the criteria as written by S Johnson. R Kant seconded the motion. The passed motion unanimously.

Upcoming Meeting

J Leonard stated he would be leaving the Department and that Robert Lodge PharmD would be the intern Department representative for DUR. As many Board members were absent, R Page stated that he would email Board members and get their availability.

A motion was made by R Kant to adjourn the meeting and was seconded by J Regan. The meeting was adjourned at 9:10 PM.

I, Jim Regan 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: _____
Jim Regan, MD Committee Chair

Date: _____