COLORADO
Department of Health Care Policy & Financing

MINUTES OF THE QUARTERLY OPEN MEETING OF THE COLORADO MEDICAID DUR BOARD

University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences at the Anschutz Medical Campus, 12850 E. Montview Boulevard, Aurora

November 18, 2014 7:00 PM to 9:00 PM

1. Call to Order

The meeting was officially called to order at 7:15 PM by S Johnson.

2. Roll Call

The Board Coordinator called the roll. There were sufficient members for a quorum with ten members participating.

A. Members Present: LeWayne Garrison, Sam Johnson, PharmD, James 'Rick' Kant, RPh, Deborah Lehman, MD, James Regan, MD, Pam Reiter, PharmD , Edra Weiss, MD, David Block (Industry Representative)

B. Medicaid Pharmacy Staff: Medicaid Pharmacy Department: Robert Lodge, PharmD, Jon Campbell, PhD (CO DUR), Gina Moore, PharmD, Nila Mahyari, PharmD

Robert Page participated by telephone call

C. Members Excused:

3. Announcements

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.

4. Approval of Minutes

After an introduction of DUR Board members, S Johnson asked if there were any changes or needed discussion of the minutes from the last meeting. A motion to approve the minutes was made by K Weber. J Weiss seconded the motion. The minutes were approved.

5. Department Updates

R Lodge noted further updates from the last DUR meeting:

- Stimulants were reviewed by the P&T Committee and both generic and brand are now available.
- Truvada now has open access for any indication as it is too challenging to differentiate among patient populations.
- Regarding long-acting opioid limits, there has not been implementation of limits as of yet but will revisit at next meeting.

6. Open Comments

NEW BUSSINESS

Proposed Criteria

1. Oral Fluoroquinolones

Preferred: Ciprofloxacin tablet
Levofloxacin tablet
Cipro ® (ciprofloxacin) oral suspension

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	July 2014	August 2014	September 2014
CIPROFLOXAIN TABLET	65%	63%	58%

LEVOFLOXACIN TABLET	35%	37%	41%
LEVOFLOXACIN SOLUTION	<1%	<1%	<1%
MOXIFLOXACIN TABLET	<1%	<1%	<1%
NOROXIN	<1%	<1%	<1%

Prior Authorization Criteria:

Non-preferred products will be approved for members who have failed an adequate trial (7 days) with at least one preferred product. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.)

Ciprofloxacin suspension approved for members < 5 years of age without prior authorization.

For members ≥ 5 years of age, ciprofloxacin suspension will only be approved for those who cannot swallow a whole or crushed tablet.

Levofloxacin solution will be approved for members who are confined to administration via feeding tube OR
who have failed an adequate trial (7 days) of ciprofloxacin suspension. (Failure is defined as: lack of efficacy, presence of feeding tube, allergy, intolerable side effects, or significant drug-drug interaction.)

Discussion:

There was discussion to amend criteria as highlighted in blue above. A motion to approve the highlighted changes was made by P Reiter and seconded by L Garrison. The motion passed.

2. Oral Anti-herpetic Agent

Preferred: Acyclovir (generic)

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	July 2014	August 2014	September 2014
ACYCLOVIR TABLET	80%	80%	82%
ACYCLOVIR CAPSULE	10%	10%	10%
VALACYCLOVIR TABLET	5%	5%	5%
ACYCLOVIR SUSPENSION	3%	3%	3%
FAMCICLOVIR TABLET	<1%	<1%	<1%
VALTREX	<1%	<1%	<1%

Prior Authorization Criteria:

Non-preferred products will be approved for members who have failed an adequate trial (dose and duration) of acyclovir as deemed by approved compendium (see below)

(Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.)

Indication	Adult	Pediatric
Genital herpes simplex: Initial	400 mg orally 3 times daily for 7 to 10 days or 200 mg orally 5 times daily (guideline dosing) for 10 days.	12 years or older, 1000 to 1200 mg/day orally in 3 to 5 divided doses for 7 to 10 days.
Genital herpes simplex: episodic	400 mg orally 3 times daily for 5 days or 800 mg orally twice daily for 5 days or 800 mg orally 3 times daily for 2 days (guideline dosing); or 200 mg orally every 4 hours, 5 times daily for 5 days; initiate at earliest sign or symptom of recurrence.	12 years or older, 1000 to 1200 mg/day orally in 3 divided doses for 3 to 5 days
Genital herpes simplex: Suppressive	400 mg orally twice daily for up to 12 months; alternative dosing, 200 mg orally 3 to 5 times daily.	12 years or older, 800 to 1200 mg/day orally in 2 divided doses for up to 12. .months
Genital Herpes Simplex with HIV infection: Initial or Recurrent	400 mg ORALLY 3 times daily for 5 to 14 days	< 45 kg: 20 mg/kg (MAX, 800 mg) ORALLY 4 times daily for 7 to 10 days or until no new lesions appear for 48 hours. Adolescents: 400 mg ORALLY twice daily for 5 to 14 days.
Genital Herpes Simplex with HIV infection: Chronic suppression	400 mg orally twice daily	
Herpes labialis	400 mg orally 3 times daily for 5 to 10 days	
Herpes zoster, Shingles	800 mg orally every 4 hours 5 times a day for 7 to 10 days	
Herpes Zoster, Shingles with HIV infection	800 mg orally 5 times daily for 7 to 10 days	
Varicella	800 mg orally 4 times a day for 5 days	2 years or older: 20 mg/kg ORALLY 4 times a day for 5 days; over 40 kg, 800 mg ORALLY 4 times a day for 5 days
Varicella with HIV infection	20 mg/kg (MAX, 800 mg) ORALLY 5 times daily for 5 to 7 days	20 mg/kg (MAX, 800 mg) ORALLY 4 times daily for 7 to 10 days or until no new lesions appear for 48 hours [

Discussion:

K Weber commented on further definition of time frame for the suspension dosage form. R Page stated that will not be necessary and may complicate cases. A motion to approve the above criteria was made by P Reiter, seconded by K Weber, and passed.

3. Pancreatic Enzymes

Preferred: Creon®

Zenpep®

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	July 2014	August 2014	September 2014
CREON	65%	67%	69%
ZENPEP	31%	28%	27%
PANCREAZE	2%	2%	1%
PERTZYE	1%	<1%	<1%
PANCREALIPASE	1%	1%	1%
VIOKASE	0%	1%	<1%
ULTRESA	0%	0%	<1%

Prior Authorization Criteria:

Non-preferred products will be approved for members who have failed an adequate trial (4 weeks) with at least two preferred products. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.)

Grandfathering:
Members currently stabilized on a Non-preferred pancreatic enzyme can receive approval to continue on that agent for one year if medically necessary.

Discussion:
R Kant inquired about the term for grandfathering. R. Lodge stated one year for newly added class. S. Johnson commented to revisit the grandfathering if utilization becomes an issue. A motion to approve the criteria was made by R Kant and seconded by L Garrison. The motion passed.

4. Antiplatelet Agents

Preferred: Aggrenox®
Effient®
Clopidogrel
Ticlopidine

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	July 2014	August 2014	September 2014
CLOPIDOGREL	85%	87%	85%

EFFIENT	7%	7%	8%
AGGRENOX	4%	2%	2%
CILOSTAZOL	3%	3%	4%
BRILINTA	<1%	<1%	<1%
DIPRYIDAMOLE	<1%	<1%	<1%
PLAVIX	<1%	<1%	0%

Prior Authorization Criteria:

Effient 10mg should only be considered for patients < 75 years of age and patients weighing ≥ 60 kg without a diagnosis of TIA or ischemic stroke.

Brilinta will be approved for patients who have a contraindication to Effient (e.g., body weight < 60kg or age ≥ 75 years) OR who have had a hypersensitivity reaction to clopidogrel or prasugrel AND must be taking a maintenance dose of aspirin not exceeding 100 mg/day.

Zontivity will be approved for patients with a diagnosis of myocardial infarction or peripheral artery disease without a history of stroke, transient ischemic attack~~, gastrointestinal bleed, or peptic ulcer~~ intracranial bleeding, and active pathological bleeding
Patients must also be taking aspirin and/or clopidogrel concomitantly.

Ticlopidine should only be considered for patients who can be monitored for neutropenia and thrombocytopenia during the first four months of therapy.

Discussion
There was discussion to amend criteria as highlighted in blue above. A motion to approve the highlighted changes was made by R Kant and seconded by P Retier. The motion was passed.

5. Targeted Immune Modulators

Preferred: Enbrel®
Humira®

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	July 2014	August 2014	September 2014
HUMIRA PEN	50%	49%	51%
EMBREL SURECLICK	22%	24%	21%
EMBREL SYRINGE	15%	13%	14%
ORENCIA SYRINGE	3%	2%	4%

HUMIRA CROHNS/PSORIASIS	2%	2%	1%
ACTEMRA SYRINGE	2%	2%	2%
CIMZIA SYRINGE KIT	2%	2%	3%
SIMPONI PEN/SYRINGE	1%	2%	2%
STELARA SYRINGE	1%	2%	2%
XELJANZ	1%	1%	0%
CIMZIA STARTER KIT	<1%	<1%	<1%
KINERET SYRINGE	<1%	<1%	0%

Prior Authorization Criteria:
Cimzia (all dosage forms) will be approved for treatment of Crohn's disease in members who have had treatment failure with Humira (Failure is defined as: lack of efficacy of a three month trial, allergy, intolerable side effects, or significant drug-drug interaction.)

Cimizia will be approved for treatment of RA in members who have had treatment failure with Enbrel and Humira (Failure is defined as: lack of efficacy of a three month trial, allergy, intolerable side effects, or significant drug-drug interaction.)

Cimizia will be approved for treatment of Ankylosing Spondylitis or Psoriatic Arthritis in members who have had treatment failure with Enbrel and Humira (Failure is defined as: lack of efficacy of a three month trial, allergy, intolerable side effects, or significant drug-drug interaction.)

Kineret will be approved for treatment of RA in members who have had treatment failure with Enbrel and Humira (Failure is defined as: lack of efficacy of a three month trial, allergy, Intolerable side effects, or significant drug-drug interaction.)

Kineret will be approved without prior authorization for members With documented neonatal-onset multisystem inflammatory disease (NOMID).

Orencia will be approved for the treatment of RA in members who have tried and failed Enbrel and Humira (Failure is defined as: lack of efficacy of a three month trial, allergy, intolerable side effects, or significant drug-drug interaction).

Orencia will be approved for the treatment juvenile idiopathic arthritis who have tried and failed Enbrel and Humira (Failure is defined as: lack of efficacy of a three month trial, allergy, intolerable side effects, or significant drug-drug interaction).

Simponi will be approved (in combination with methotrexate) for treatment of RA in members who have tried and failed Enbrel

and Humira (Failure is defined as: lack of efficacy of a three month trial, allergy, intolerable side effects, or significant drug-drug interaction).

Simponi will be approved with or without methotrexate for the treatment of Ankylosing Spondylitis or Psoriatic Arthritis in members who have tried and failed Enbrel and Humira (Failure is defined as: lack of efficacy of a three month trial, allergy, intolerable side effects or significant drug-drug interaction).

Simponi will be approved for the treatment of ulcerative colitis in members who have tried and failed Humira (Failure is defined as: lack of efficacy of a three month trial, allergy, intolerable side effects or significant drug-drug interaction).

Stelara will be approved with or without methotrexate for the treatment of Psoriatic Arthritis in members who have tried and failed Enbrel and Humira (Failure is defined as: lack of efficacy of a three month trial, allergy, intolerable side effects or significant drug-drug interaction).

Stelara will be approved for moderate to severe plaque psoriasis in members who have tried and failed Enbrel and Humira (Failure is defined as: lack of efficacy of a three month trial, allergy, intolerable side effects or significant drug-drug interaction).

Xeljanz will be approved for the treatment of RA in members who have had treatment failure with methotrexate, Humira, and 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

Actemra (SQ) will be approved for treatment of RA in members who have had treatment failure with at least one conventional DMARD (e.g, methotrexate, leflmonide, and sulfasalazine), Enbrel and Humira (Failure is defined as: lack of efficacy of a three month trial, allergy, intolerable side effects or significant drug-drug interaction.)

Discussion:
There was discussion to amend criteria as highlighted in blue above. A motion to approve the highlighted changes was made by K Weber and seconded by L Garrison. The motion passed.

6. Newer Generation Antidepressants

Preferred: Bupropion IR, SR, XL
Citalopram
Escitalopram
Fluoxetine
Mirtazipine

Paroxetine
Sertraline
Venlafaxine IR tablets
Venlafaxine XR capsules

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	July 2014	August 2014	September 2014
SERTRALINE	21%	21%	21%
CITOLAPRAM	18%	18%	18%
FLUOXETINE	16%	16%	16%
VENLAFAXINE ER	9%	9%	9%
BUPROPRION XL	7%	7%	7%
PAROXETINE	6%	6%	6%
BUPROPION SR	6%	6%	6%
DULOXETINE DR	5%	5%	5%
MIRTAZAPINE	4%	4%	4%
ESCITALOPRAM	3%	3%	2%
BUPROPRION	2%	2%	2%
VENLAFAXINE	2%	2%	2%
FLUVOXAMINE	<1%	<1%	<1%
PRISTIQ ER	<1%	<1%	<1%
VIIBRYD	<1%	<1%	<1%
EFFEXOR XR	<1%	<1%	<1%
LEXAPRO	<1%	<1%	<1%
CELEXA	<1%	<1%	<1%
ZOLOFT	<1%	<1%	<1%
FETZIMA	<1%	<1%	<1%
WELLBUTRIN XL	<1%	<1%	<1%
WELLBUTRIN SR	<1%	<1%	<1%
WELLBUTRIN	<1%	<1%	<1%
PROZAC	<1%	<1%	<1%
PAXIL	<1%	<1%	<1%
PAROXETINE CR	<1%	<1%	<1%
PAROXETINE ER	<1%	<1%	<1%
BRINTELLIX	<1%	<1%	<1%
DESVENLAFAXINE ER	<1%	<1%	<1%
CYMBALTA	<1%	<1%	<1%
NEFAZADONE	<1%	<1%	<1%
SARAFEM	<1%	0%	<1%
OLEPTRO ER	<1%	0%	0%

Prior Authorization Criteria:
Non-preferred products will be approved for members who have failed treatment with three preferred products with exceptions for Cymbalta and duloxetine (see below). Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Cymbalta or duloxetine will be approved for members with

depression AND diabetic neuropathic pain without failure
of three preferred products

Grandfathering:
Members currently stabilized on a non-preferred newer generation Antidepressant can receive approval to continue on that agent for one year if medically necessary.
Verification may be provided from the prescriber or the pharmacy.

~~Cymbalta or duloxetine: Members will not need to fail on three preferred products if the diagnosis is diabetic peripheral neuropathi~~c pain. (Ammended and moved up right under PA criteria)

Cymbalta or duloxetine will also be approved for patients with chronic musculoskeletal pain (e.g. osteoarthritis or chronic lower back pain) who have failed a one-month consecutive trial of three non-narcotic analgesic agents (e.g. acetaminophen, NSAID, tramadol) at maximally tolerated doses.

Discussion:
The following individuals provided comment to the Board on the above topic:

- Pfizer Speaker

There was discussion regarding the confusing nature of Cymbalta criteria with multiple indications and the necessity to fail three agents not being appropriate. This discussion led to a motion to amend criteria as highlighted in blue above. A motion to approve the highlighted changes was made by K Weber and seconded by L Garrison. The motion was passed.

7. Phosphodiesterase Inhibitors

Preferred: Sildenafil (generic)

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	July 2014	August 2014	September 2014
SILDENAFIL	56%	54%	53%
ADCIRCA	43%	44%	45%
REVATIO	1%	2%	2%

Prior Authorization Criteria:
***Eligibility Criteria for all agents in the class**
Approval will be granted for a diagnosis of pulmonary hypertension

Grandfathering:
Members currently stabilized on Adcrica can receive approval

to continue on that agent for one year if medically necessary.

Discussion:
A motion to approve the criteria was made by R Kant and seconded by E Weiss. The motion passed.

8. Endothelin Antagonists

Preferred: Letairis®

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	July 2014	August 2014	September 2014
LETAIRIS	57%	48%	50%
TRACLEER	30%	30%	31%
OPSUMIT	13%	22%	19%

Prior Authorization Criteria:
Non-preferred products will be approved for members who have failed treatment with Letairis or for members requiring a dose preparation not available with a preferred product (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction)

Grandfathering:
Members who have been previously stabilized on a non-preferred product can receive approval to continue on the medication for one year if medically necessary.

Discussion:
A motion was made by P Reiter to approve the criteria. This was seconded by K Weber. The motion passed.

9. Prostanoids

Preferred: Epoprostenol

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	July 2014	August 2014	September 2014
FLOLAN	38%	42%	46%

TYVASO	30%	25 %	27%
REMODULIN	30%	25%	27%

Prior Authorization Criteria:

Non-preferred products will be approved for members who have failed treatment with a preferred product. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, contraindication to IV therapy or significant drug-drug interaction)

Discussion:
There was discussion about the grandfathering rule removal due to zero utilization on preferred products. A motion was made by R Kant to approve the criteria. This was seconded by K Weber. The motion passed.

10. Antiemetics

Preferred: Ondansetron tablets
Ondansetron ODT tablets
Ondansetron suspension

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	July 2013	August 2013	September 2013
ONDANSETRON TABLET and ODT	99%	99%	99%
EMEND CAPSULE	<1%	<1%	<1%
GRANISETRON HCL	<1%	<1%	<1%
SANCUSO PATCH	<1%	<1%	<1%
DICLEGIS	<1%	<1%	<1%

Prior Authorization Criteria:
Non-preferred products will be approved for members who have failed treatment with brand or generic ondansetron within the last year. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.)

Ondansetron suspension will be approved for members < 5 years and those members ≥ 5 years of age with a feeding tube.

Emend will be approved upon verification that the member is undergoing moderately emetogenic or highly emetogenic chemotherapy as part of a

regimen with a corticosteroid and a 5HT3 antagonist. **Verification may be provided from the prescriber or the pharmacy.**

Emend will be approved for prophylaxis of postoperative nausea and vomiting (one 40mg capsule will be approved). **Verification may be provided from the prescriber or the pharmacy.**

Approval for DICLEGIS will be granted if the member has nausea and vomiting associated with pregnancy **AND**
The member has failed a trial of doxylamine 10-12.5mg **OR**
The member has failed a trial of oral ondansetron 4mg every 8 hours for five days OR
The member has and intolerance or contraindication to ondansetron

Discussion:

A motion was made by R Kant to approve criteria as written. This was seconded by K Weber. The motion passed unanimously.

11. Proton Pump Inhibitors

Preferred: Lansoprazole capsules
Nexium (capsules and packets)
Omeprazole generic
Pantoprazole
Prevacid solutabs

Utilization:

Medication	**Percentage of Market Share Based on Number of Claims for** Medication **Therapeutic Class**		
	July 2014	August 2014	September 2014
OMEPRAZOLE DR	68%	68%	68%
NEXIUM DR/PACKETS	13%	14%	14%
RABEPRAZOLE	7%	7%	7%
LANSOPRAZOLE DR	3%	4%	3%
PREVACID SOLUTAB	3%	3%	3%
PREVACID 24HR DR	2%	2%	2%
DEXILANT DR	1%	1%	1%
PANTOPRAZOLE	1%	1%	1%
PRILOSEC OTC	<1%	<1%	<1%
PRILOSEC	<1%	<1%	<1%
PRILOSEC DR SUSPENSION	<1%	0%	<1%

Medication	**Percentage of Market Share Based on Number of Claims for** Medication **Therapeutic Class**		
	July 2014	August 2014	September 2014
PROTONIX DR SUSPENSION	<1%	<1%	<1%
OMEPRAZOLE-BICARB	<1%	<1%	<1%
ESOMPEPRAZOLE	<1%	<1%	<1%
ZEGRID	0%	<1%	0%

Prior Authorization Criteria:
Prior authorization will be required for therapy beyond 60 days of treatment per year for all agents. For members treated for GERD, once 60 days of therapy per year has been exceeded, members must fail an adequate trial of a histamine 2 receptor antagonist before PPI therapy can be reconsidered. An adequate trial is defined as 8 weeks of histamine 2 receptor antagonist.

Long-term therapy will be approved for members with Barrett's Esophagus; Erosive Esophagitis; GI Bleed; Hypersecretory Conditions (Zollinger Ellison); Recurrent Aspiration Syndrome; Chronic NSAID or prednisone therapy; Spinal Cord Injury members with an acid reflux diagnosis; or children (< 18 years of age) with Cystic Fibrosis, on mechanical ventilation, or have a feeding tube. In addition, members with continuing, symptomatic GERD or recurrent peptic ulcer disease who have documented failure on step-down therapy to an H2-receptor antagonist will be approved for up to one year of daily PPI therapy.

Non-preferred proton pump inhibitors will be approved if all of the following criteria are met:

- Member failed treatment with two Preferred Products within the last 24 months,
- Member has a qualifying diagnosis, and
- Member has been diagnosed by an appropriate diagnostic method.

The Qualifying Diagnoses are:
Barrett's Esophagus, Duodenal Ulcer, Erosive Esophagitis, Gastric Ulcer, GERD, GI Bleed, H. pylori, Hypersecretory Conditions (Zollinger-Ellison), NSAID-Induced Ulcer, Pediatric Esophagitis, Recurrent Aspiration Syndrome or Ulcerative GERD

The Appropriate Diagnostic Methods are:
GI Specialist, Endoscopy, X-Ray, Biopsy, Blood test, or Breath test

Quantity Limits:
Non-preferred agents will be limited to once daily dosing except for the following diagnoses: Barrett's Esophagus, GI Bleed, H. pylori, Hypersecretory Conditions, or Spinal Cord Injury patients with any acid reflux diagnosis.

Age Limits:

Aciphex, Protonix, and Zegerid will not be approved for members less than 18 years of age.

Prevacid Solutab will be approved for members < 2 years of age and for members ≥ 2 years of age with a feeding tube.

Discussion:
A motion was made by L Garrison to approve criteria as written. This was seconded by R Kant. The motion passed unanimously.

12 Triptan and Triptan Combinations

Preferred: Imitrex® (nasal spray, injection)
Naratriptan
Sumatriptan tablets
Relpax®
Rizatriptan MLT

Utilization:

Medication	**Percentage of Market Share Based on Number of Claims for** Medication **Therapeutic Class**		
	July 2014	August 2014	September 2014
SUMATRIPTAN TABLET	65%	68%	67%
RIZATRIPATAN	22%	22%	22%
NARATRIPTAN	2%	2%	3%
IMITREX SPRAY	3%	3%	2%
IMITREX CARTRIDGE/PEN	3%	3%	3%
RELPAX	2%	1%	2%
FROVA	<1%	<1%	<1%
MAXALT	<1%	<1%	<1%
TREXIMET	<1%	<1%	<1%
AXERT	<1%	<1%	<1%
SUMAVEL DOSEPRO	<1%	<1%	0%
IMITREX TABLET	<1%	<1%	<1%
ZOMIG	<1%	<1%	<1%
ZOMIG NASAL SPRAY	<1%	<1%	<1%
SUMATRIPTAN NASAL SPRAY	<1%	<1%	<1%

Prior Authorization Criteria:
Non-preferred products will be approved for members who have failed treatment with two Preferred Products within the last 6 months. (Failure is defined as: lack of efficacy, allergy, intolerable side

effects or significant drug-drug interactions)

Quantity Limits:
Amerge, Frova, Imitrex, Treximet and Zomig: Max 9 tabs / 30 days.
Axert and Relpax: Max 6 tabs / 30 days.
Maxalt: Max 12 tabs / 30 days.
Zomig nasal spray and Imitrex Nasal Spray: Max 6 inhalers / 30 days.
Imitrex injection: Max 4 injectors / 30 days

Discussion:
A motion was made by P Reiter to approve criteria as written. This was seconded by K Weber. The motion passed unanimously.

13. Ofev (Nintedanib)

Prior Authorization Criteria:
Ofev will be approved if all the following criteria are met:

- Member has been diagnosed with idiopathic pulmonary fibrosis AND
- Is being prescribed by or in conjunction with a pulmonologist AND
- Member is 18 years and older ~~AND~~ OR
- Member has baseline ALT, AST, and bilirubin prior to starting therapy AND
- Member does not have moderate (Child Pugh B) or severe (Child Pugh C) hepatic impairment AND
- Female members of reproductive potential must have been counseled regarding risk to the fetus and to avoid becoming pregnant while receiving treatment with Ofev and to use adequate contraception during
  treatment and at least 3 months after the last dose of Ofev AND
- Member is not taking a P-gp or CYP3A4 inducer (e.g, rifampin, carbamazepine, phenytoin, St. John's Wort)

Quantity Limits: 60 tablets/30 days

Discussion:
There was discussion to amend criteria as highlighted in blue above. A motion to approve the highlighted changes was made by P Reiter and seconded by R Kant and L Garrison.

14. Esbriet (Pirenidone)

Prior Authorization Criteria:
Esbriet will be approved if all the following criteria are met:

- Member has been diagnosed with idiopathic pulmonary fibrosis AND
- Is being prescribed by or in conjunction with a pulmonologist AND
- Member is 18 years and older ~~AND~~ OR
- Member has baseline ALT, AST, and bilirubin prior to starting therapy AND
- Member does not have severe (Child Pugh C) hepatic impairment, severe renal impairment (Crcl<30 ml/min), or end stage renal disease requiring dialysis AND

- Female members of reproductive potential must have been counseled regarding risk to the fetus
  AND
- Member is not receiving a strong CYP1A2 inducer (e.g, carbamazepine, phenytoin, rifampin)

Discussion:
There was discussion to amend criteria as highlighted in blue above. A motion to approve the highlighted changes was made by E Weiss and seconded by R Kant. The motion passed.

15. Otezla (apremilast)

Prior Authorization Criteria:
Otezla will be approved for treatment of psoriatic arthritis or plaque psoriasis in members who have had treatment failure with at least one conventional DMARD (e.g, methotrexate, leflunomide, and sulfasalazine), Enbrel and Humira
(Failure is defined as: lack of efficacy of a 3 month trial, allergy, intolerable side effects or significant drug-drug interaction.)

Discussion:
A motion was made to accept the criteria as written by L Garrison. This was seconded by K Weber. The motion passed unanimously.

16. Cerdelga (eligulstat)

Cerdela will be approved if all the following criteria are met:

- Member has a diagnosis of Gaucher disease type 1 AND
- Documentation has been provided to the Department that the member is a CYP2D6 extensive,
  intermediate, or poor metabolizer as detected by an FDA cleared test AND
- Members who are CYP2D6 intermediate or poor metabolizers are not taking a strong CYP3A4 inhibitor
  (e.g, indinavir, nelfinavir, ritonavir, saquinavir, suboxone, erythromycin, clarithromycin, telithromycin, posaconazole, itraconazole, ketoconazole, nefazodone) AND
- Members who are CYP2D6 extensive or intermediate metabolizers are not receiving strong or moderate CYP2D6 inhibitors (e.g, sertraline, duloxetine, quinidine, paroxetine, fluoxetine, buproprion, terbinafine) AND a strong or moderate CYP3A4 inhibitor (e.g, indinavir, nelfinavir, ritonavir, saquinavir, suboxone, erythromycin, clarithromycin, telithromycin, posaconazole, itraconazole, ketoconazole, fluconazole, nefazodone, verapamil, diltiazem)

Quantity Limits: Max 60 tablets/30 days

Discussion:
The following individuals provided comment to the Board on the above topic:

- Genzyme Speaker

A motion was made to accept the criteria as written by K Weber. This was seconded by S Johnson. The motion passed unanimously.

17. Phenobarbital

Phenobarbital will be approved for neonatal narcotic abstinence syndrome based on the following criteria:

- The member has a diagnosis of non-opiate or polysubstance abuse OR
- The member has first failed methadone for the diagnosis of opiate withdrawal AND
- Serum phenobarbital levels are being monitored.

Max duration: 3 months

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

18. Lupron

Lupron will be approved for Gender Identity Dysphoria based on the following criteria:

- The member has a diagnosis of Gender Identity Dysphoria which is made by a mental health professional with experience in treating gender dysphoria. Where available, the mental health professional should ideally have training in child and adolescent developmental psychology AND
- The member should have at least 6 months of counseling and psychometric testing for gender identity prior to initiation of Lupron AND
- The prescribing provider has training in puberty suppression using a gonadotropin releasing hormone agonist AND
- Lupron may not be started until girls and boys exhibit physical changes of puberty (confirmed by levels of estradiol and testosterone, respectively) and no earlier than Tanner stages 2-3 (bilateral breast budding or doubling to tripling testicular size to 4-8 cc).
- Duration of treatment: Lupron will be covered to a maximum of 16 years of age for Gender Identity Dysphoria.

Discussion:
The following individuals provided comment to the Board on the above topic:

- Dr. Daniel Reirden from University of Colorado Children's Hospital

A motion to approve the criteria as written was made by P Reiter and seconded by K Weber. The motion was passed.

~~**19. Xartemis**~~ This item was tabled for now for further review due to controversy surrounding second bullet point.

~~Members are NOT required to fail two long-acting Preferred Drugs as Xartemis is approved for acute pain only and NOT chronic pain. Xartemis will be approved for two weeks (14 days) if the following criteria are met:~~

- ~~Member has a diagnosis of acute pain severe enough to require opioid treatment and for which non-opioid alternatives are inadequate or not tolerated AND~~

- ~~Member must have current or history of substance abuse (e.g. alcohol, illegal drugs, prescription drugs).~~

Discussion:

The following individuals provided comment to the Board on the above topic:

- Mallincrodkt Speaker

A motion to table the criteria for this drug was made by R Kant due to insufficient data and studies related to the potential issues associated with this drug. The motion was seconded by K Weber. The motion was passed.

Upcoming Meeting

R Lodge noted the next meeting is tentatively scheduled on February 17th, 2015 at the CU Skaggs School of Pharmacy and Pharmaceutical Sciences

7. The meeting was adjourned at 7:07 p.m.

The meeting was adjourned at 9:12 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: _____

Reasonable accommodations will be provided upon request for persons with disabilities. Please notify the DUR Coordinator Robert Lodge at 303- 866-xxxx or or email him at Robert.lodge@state.co.us at least one week prior to the meeting.