

**COLORADO MEDICAID DUR BOARD OPEN MEETING
M I N U T E S
August 20, 2013**

Members Present

LeWayne Garrison, RPh (phone)
Sam Johnson, PharmD
James 'Rick' Kant, RPh
Pam Reiter, PharmD
Tim Hartman, PharmD (Industry Representative)

Members Absent

Karen Weber, DO
James Regan, MD
Deborah Lehman, MD
Edra Weiss, MD
Gina Moore, PharmD (CO DUR)

Medicaid Pharmacy Department

Robert Lodge, PharmD
Robert L Page, PharmD, MSPH (CO DUR)
Jon Campbell, Ph.D (CO DUR)

UNFINISHED BUSINESS, GENERAL ORDERS, and NEW BUSINESS

The quarterly meeting of the Medicaid DUR Board was held on August 20th, 2013 at 225 16th Avenue, 1st floor conference room, Denver. A quorum being present, the meeting was officially called to order at 7:00 PM by S Johnson.

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 L Garrison. 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.

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

Proposed Criteria

1. **Oral Anticoagulants**
Preferred: Warfarin

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	April 2013	May 2013	June 2013
Coumadin	93%	88%	87%
Eliquis®	3%	3%	4%
Pradaxa®	2%	2%	2%
Xarelto®	5%	7%	7%

Prior Authorization Criteria:

Eliquis or Pradaxa will be approved if all the following criteria have been met:

- The client has a diagnosis of nonvalvular atrial fibrillation **AND**
- The client does not have a mechanical prosthetic heart valve **AND**
- The client does not have an active pathological bleed **AND**
- The client has a labile INR for reasons other than noncompliance (e.g, client has an INR outside of 2-3 > 60% of the time for a period of two months) **OR**
- The client has significant difficulty with complying with anticoagulation monitoring **OR**
- The client has an allergy or intolerance to warfarin

Xarelto will be approved if all the following criteria have been met:

- The client has a diagnosis of nonvalvular atrial fibrillation **OR**
- The client has a diagnosis of deep vein thrombosis (DVT), pulmonary embolism (PE) **OR**
- The client is in need of a prophylaxis of DVT following knee or hip replacement surgery **AND**
- The client does not have a mechanical prosthetic heart valve **AND**
- The client does not have an active pathological bleed **AND**
- The client has a labile INR for reasons other than noncompliance (e.g, client has an INR outside of 2-3 > 60% of the time for a period of two months) **OR**
- The client has significant difficulty with complying with anticoagulation monitoring **OR**
- The client has an allergy or intolerance to warfarin

Discussion:

Presentations were made by Darrell Smith from Johnson and Johnson (Xarelto), Julie McDavid from Boehringer Ingelheim (Pradaxa), Laura Litenberger from Janssen Scientific Affairs Diana Dills from Pfizer (Apixaban), and Eric Johnson, a community pharmacist. Discussion was had by the committee regarding issues if a patient was discharged from the hospital with a prescription for a new generation oral anticoagulant and could not get it filled at the pharmacy that this would delay therapy. In turn, a pharmacist may not know which provider to contact (e.g, the discharging physician or the patient's primary care provider). A motion was made by K Weber to add the following criteria: "For patients being discharged with Eliquis, Pradaxa, or Xarelto, a seven day supply will be approved without prior authorization." The motion was seconded by L Garrison. The motion passed unanimously. S Johnson highlighted the issues with dosing these agents in patients with renal dysfunction. The committee discussed that it may be hard to provide an exact creatinine clearance. Therefore, S Johnson made the motion that the following criteria be added

to Eliquis, Pradaxa, and Xarelto: "The client is NOT on dialysis." The motion was seconded by L Garrison and the motion unanimously passed.

2. Oral Bisphosphonates

Preferred: Alendronate

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	April 2013	May 2013	June 2013
Actonel®	2%	2%	2%
Actonel with Calcicum®	0%	0%	0%
Alendronate	89%	89%	88%
Atelvia®	1%	<1%	1%
Binosto®	0%	0%	0%
Boniva®	0%	0%	0%
Didronel®	0%	0%	0%
Etidronate	<1%	<1%	0%
Evista	5%	5%	5%
Fosamax®	0%	0%	0%
Fosamax Plus Vitamin D®	0%	0%	0%
Ibandronate	3%	3%	4%
Skelid®	0%	0%	0%

Prior Authorization Criteria:

Non-preferred products will be approved for clients who have failed treatment with at least one strength of alendronate. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.)

Prior authorization will be approved for etidronate in clients with heterotopic ossification without treatment failure.

Discussion:

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

3. Biguanides

Preferred: Metformin
Metformin XR 500mg tablets

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	April 2013	May 2013	June 2013
Fortamet ER®	<1%	<1%	<1%
Glucophage®	<1%	<1%	<1%

Glucophage XR®	0%	0%	0%
Glumetza ®	<1%	<1%	<1%
Metformin	90%	90%	89%
Metformin ER	10%	10%	11%
Riomet®	<1%	<1%	<1%

Prior Authorization Criteria:

Non-preferred products will be approved for clients who have failed treatment with two Preferred Products.

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

Liquid metformin will be approved for clients who meet one of the following:

- under the age of 12
- with a feeding tube
- who have difficulty swallowing

Discussion:

S Johnson asked the committee why the current criteria is a fail two when both products are metformin . A motion was made by S Johnson to amend the criteria from “failed treatment with two preferred product” to “one preferred product.” This was seconded by R Kant. The motion passed unanimously.

4. Hypoglycemic Combinations

Preferred: None

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	April 2013	May 2013	June 2013
Actoplus Met	<1%	<1%	<1%
Actoplus Met XR	0%	4%	0%
Avandamet	0%	4%	0%
Avandaryl	0%	4%	0%
Duetact	0%	4%	0%
Glipizide/Metformin	0%	4%	0%
Glucovance	0%	4%	0%
Glyburide/Metformin	6%	7%	0%
Janumet	77%	76%	77%
Janumet XR	0%	4%	0%
Jentadueto	3%	4%	0%
Juvisync	<1%	<1%	<1%
Kazano	0%	4%	0%
Kombiglyze XR	15%	10%	23%
Metaglip	0%	4%	0%
Oseni	0%	4%	0%
Prandimet	0%	4%	0%

Prior Authorization Criteria:

Hypoglycemic combinations will be approved for clients who have been stable on the two individual ingredients for 3 months and have an adherence issue.

Discussion:

A motion was made by P Reiter to approve criteria as written. This was seconded by D Lehman. The motion passed unanimously.

5. Metglitinides

Preferred: None

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	April 2013	May 2013	June 2013
Prandin®	50%	25%%	50%
Nateglinide	50%	75%%	50%
Starlix®	0%	0%	0%

Prior Authorization Criteria:

Metglitinides will be approved for clients who have failed treatment with one sulfonylurea (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.)

Discussion:

A motion was made by P Reiter to approve criteria as written. This was seconded by D Lehman. The motion passed unanimously.

6. Thiazolidinediones

Preferred: None

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	April 2013	May 2013	June 2013
Actos®	2%	2%	3%
Avandia®	0%	0%	0%
Pioglitazone	98%	98%	97%

Prior Authorization Criteria:

Rosiglitazone will not be approved due to the associated cardiovascular risk.

Clients currently stabilized on and compliant with pioglitazone therapy will be allowed to continue therapy. Prior authorization will be required for new starts or when no claims have been filled in the last 120 days.

Pioglitazone will be approved upon documentation that the following criteria have been met:

- The client has been counseled that TZD's may cause or exacerbate heart failure and has been given examples of signs and symptoms of heart failure;
- The client does not currently have NYHA Class III-IV heart failure;
- The client does not have active bladder cancer or prior history of bladder cancer.
- The prescriber agrees to monitor for signs and symptoms of heart failure at all follow-up appointments;
- Liver tests are obtained prior to initiation of therapy.

Discussion:

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

7. Newer Diabetic Agents

Preferred: Byetta®
 Januvia®
 Tradjenta®

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	April 2013	May 2013	June 2013
Bydureon®	1%	1%	2%
Byetta®	12%	12%	14%
Invokana®	0%	<1%	<1%
Januvia®	67%	67%	63%
Nesina®	0%	0%	0%
Onglyza®	1%	2%	1%
Symlin®	<1%	<1%	<1%
Tradjenta®	10%	9%	11%
Victoza®	9%	9%	9%

Prior Authorization Criteria:

Approval for selected preferred products require a 3 month trial of (or documented contraindication to) metformin therapy prior to initiation of therapy.

For all products, dosing will be limited to FDA approved dosing. Prior Authorization will be required for doses in excess of FDA approved dosing.

Non-preferred products will be approved for clients who have failed treatment with one preferred product in the last year. (Failure is defined as: lack of efficacy [e.g., hemoglobin A1c \geq 7%], allergy, intolerable side effects, or significant drug-drug interaction.)

Prior authorization will be approved for Symlin® products for clients with Diabetes Mellitus Type 1 without failed treatment. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.)

Discussion:

A presentation was provided by Julie McDavid from Boehringer Ingelheim (Tradjenta). A motion was made by P Reiter to approve criteria as written. This was seconded by R Kant. The motion passed unanimously.

8. Overactive Bladder Agents

Preferred: oxybutynin
oxybutynin ER
Toviaz®

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	April 2013	May 2013	June 2013
Detrol®	2%	2%	1%
Detrol LA®	0%	0%	0%
Ditropan®	0%	0%	0%
Ditropan XL®	<1%	<1%	<1%
Enablex®	<1%	<1%	1%
Gelnique®	0%	0%	0%
Oxytrol®	<1%	<1%	<1%
Oxybutynin	45%	44%	43%
Oxybutynin ER	38%	39%	40%
Sanctura®	0%	0%	0%
Sanctura XR®	0%	0%	0%
Toviaz®	13%	13%	14%
Vesicare®	1%	2%	2%

Prior Authorization Criteria:

Non-preferred products will be approved for clients who have failed treatment with two preferred products.

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

Clients with hepatic failure can receive approval to receive trospium or trospium extended release (Sanctura XR®) products without a trial on a Preferred product.

Discussion:

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

9. Protease Inhibitors for Hepatitis C

Preferred: Victrelis®

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	April 2013	May 2013	June 2013
Incivek®	6%	17%	33%
Victrelis®	94%	83%	67%

Prior Authorization Criteria:

Requests for Victrelis® will be prior authorized if the following criteria are met:

- A documented diagnosis of Hepatitis C Genotype 1 with no HIV co-infection AND concurrent therapy with ribavirin and pegylated interferon.
- The patient has been on a treatment regimen of ribavirin and pegylated interferon for three (3) weeks.
- The patient is eighteen (18) years or older.
- The patient is not receiving strong CYP3A4 inducer (e.g., rifampin, rifabutin, phenytoin).
- The patient has been screened and counseled about the importance of refraining from drug and/or alcohol abuse.
- The patient's previous treatment history and weight are presented at the time of initial request
- The patient's Child-Pugh score is <6 (compensated cirrhotic liver disease).
- The patient has not previously tried/failed therapy with a hepatitis C protease inhibitor (e.g. Incivek® or Victrelis®).
- The patient is not a pregnant female or a male with a pregnant female partner (ribavirin contraindication).
- A sensitive RT-PCR assay HCV-RNA test with a lower limit of quantification of ≤ 25 IU/ml and a limit of detection of approximately 10 to 15 IU/ml is required to be submitted before the start of therapy. Further testing must be scheduled for the end of weeks eight (8), twelve (12) and twenty-four (24). Initial test results and the scheduled testing dates for the indicated weeks must be submitted before prior authorization will be issued.
- The dispensing pharmacy agrees to dispense an initial six-week supply. The prescriber should ensure that viral levels are done at treatment weeks eight (8), twelve (12) and twenty-four (24). (Initial approval of Victrelis® will be for six (6) weeks, providing four (4) weeks for initial treatment and 2 weeks for administrative review.)
- Viral levels are submitted at the end of treatment weeks eight (8), twelve (12) and twenty-four (24) of the treatment course. (Further prior approvals will not be issued without submission of viral levels performed with the sensitive RT-PCR assay HCV-RNA test with a lower limit of quantification of ≤ 25 IU/ml and a limit of detection of approximately 10-15 IU/ml.)
- Continuation of therapy will be approved in accordance with the manufacturer's guidelines according to viral levels at the established treatment timelines.

Requests for Incivek® will be prior authorized if the following criteria are met:

- A documented diagnosis of Hepatitis C Genotype 1 with no HIV co-infection AND concurrent therapy with ribavirin and pegylated interferon.
- The patient is eighteen (18) years or older.
- The patient's previous treatment history and weight are presented at the time of initial request.
- The patient has been screened and counseled about the importance of refraining from drug and/or alcohol abuse.
- The patient's Child-Pugh score is <6 (compensated cirrhotic liver disease).

- The patient is not receiving strong CYP3A4 inducer (e.g., rifampin, rifabutin, phenytoin) or drug dependent on CYP3A4 clearance (e.g., alfuzosin, cisparide, dihydroergotamine, ergonovine, ergotamine, lovastatin, sildenafil, tadalafil, simvastatin, triazolam).
- The patient has not previously tried/failed therapy with a hepatitis C protease inhibitor (e.g. Incivek® or Victrelis®).
- The patient is not a pregnant female or a male with a pregnant female partner (ribavirin contraindication).
- A sensitive RT-PCR assay HCV-RNA test with a lower limit of quantification of ≤ 25 IU/ml and a limit of detection of approximately 10 to 15 IU/ml is required to be submitted before the start of therapy. Further testing must be scheduled for the end of weeks four (4), twelve (12) and twenty-four (24). Initial test results and the scheduled testing dates for the indicated weeks must be submitted before prior authorization will be issued.
- The dispensing pharmacy agrees to dispense an initial six-week supply. The prescriber should ensure that viral levels are done at weeks four (4), twelve (12) and twenty-four (24) of therapy. (Initial approval of Incivek® will be for six (6) weeks, providing 4 weeks for initial treatment and 2 weeks for administrative review)
- Viral levels are to be submitted at the end of weeks four (4), twelve (12) and twenty-four (24) of the treatment course. (Further prior approvals will not be issued without submission of viral levels performed with the sensitive RT-PCR assay HCV-RNA test with a lower limit of quantification of ≤ 25 IU/ml and a limit of detection of approximately 10-15 IU/ml.)

Prior authorization for Incivek® will be determined on a case by case basis. Providers must provide the Department with full documentation regarding the rationale for treatment with Incivek®.

Discussion:

A presentation was made by Lisa Boreland with Vertex (Incivek). R Lodge discussed that difficulty to enforce the criteria as written and the recommendation for a more streamlined criteria. For Victrelis, the committee discussed removing “has been on a treatment regimen” to “will be on.” Additionally, on that same line edit, a recommendation was made to change “for three weeks” to “four weeks prior to initiation of Victrelis.” It was also recommended to strike from “Further testing must be scheduled for the end of eight weeks” ... through “continuation of therapy will be approved in accordance...” A motion was made by L Garrison to approve criteria with the recommended changes to the Victrelis PA. This was seconded by K Weber. The motion passed unanimously.

For Incivek, the committee in turn discussed striking from “Further testing must be scheduled for the end of four weeks...” through...”Viral levels are to be submitted...” A motion was made by P Reiter to approve criteria with the recommended changes to the Incivek PA. This was seconded by S Johnson. The motion passed unanimously.

10. Erythropoiesis Stimulating Agents

Preferred: Procrit®
Aransep®

Utilization:

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class
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	April 2013	May 2013	June 2013
Aranesp®	0%	0%	0%
Epogen®	25%	11%	30%
Omontys®	0%	0%	0%
Procrit®	75%	89%	70%

Prior Authorization Criteria:

Clients must meet all criteria in one of the following four areas:

- A diagnosis of cancer, currently receiving chemotherapy, with chemotherapy-induced anemia, and hemoglobin of 10g/dL or lower.
- A diagnosis of chronic renal failure, and hemoglobin below 10g/dL
- A diagnosis of hepatitis C, currently taking Ribavirin and failed response to a reduction of Ribavirin dose, and hemoglobin less than 10g/dL (or less than 11g/dL if symptomatic).
- A diagnosis of HIV, currently taking Zidovudine, hemoglobin less than 10g/dL, and serum erythropoietin level of 500mUnits/mL or less.

Hemoglobin results must be from the last 30 days. Medication must be administered in the client's home or long-term care facility.

Non-preferred products:

- Same as above; and
- Failed treatment with Procrit. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.)

Note: The FDA has announced a risk evaluation mitigation strategy for the use of Erythropoiesis Stimulating Agents (ESAs) in patients with cancer, who are currently receiving chemotherapy, and who are experiencing chemotherapy induced anemia. Patients must receive a medication guide outlining the risks and benefits of treatment, and patient consent must be obtained before therapy. Prescribers are required to enroll and register in the ESA APPRISE Oncology program and complete training prior to prescribing ESAs to patients with cancer. For non-cancer indications, the distribution of a medication guide to the patient is the only requirement currently.

Discussion:

A motion was made by P Reiter to approve criteria as written. This was seconded by E Weiss. The motion passed unanimously.

11. Stimulants and Non-Stimulant Agents

Preferred: Mixed Amphetamine salts
 Adderall XR®
 Concerta®
 Dextmethylphenidate
 Focalin XR®

Methylphenidate
Methylphenidate SR
Methylphenidate ER
Strattera®
Vyvanse®

Utilization:

	Percentage of Market Share Based on Number of Claims for Medication Therapeutic Class		
	April 2013	May 2013	June 2013
Adderall®	<1%	<1%	<1%
Adderall XR®	14%	15%	15%
Mixed amphetamine salts	12%	12%	13%
Mixed amphetamine salts ER	<1%	<1%	<1%
Concerta®	5%	5%	4%
Daytrana®	<1%	<1%	<1%
Desoxyn®	0%	0%	0%
Focalin®	0%	0%	0%
Focailin XR®	7%	7%	7%
Intuniv®	6%	7%	7%
Kapvay®	<1%	<1%	<1%
Metadate CD®	<1%	<1%	<1%
Metadate ER®	0%	0%	0%
Methylin Suspension®	0%	0%	0%
Methylphenidate	9%	8%	9%
Methylphenidate CD	<1%	<1%	<1%
Methylphenidate ER	23%	22%	21%
Methylphenidate SR	<1%	<1%	<1%
Nuvigil®	<1%	<1%	<1%
Provigil®	<1%	<1%	<1%
Quillivant XR®	<1%	<1%	<1%
Ritalin®	<1%	<1%	<1%
Ritalin LA®	<1%	<1%	<1%
Strattera®	7%	7%	7%
Vyvanse®	14%	14%	14%

Prior Authorization Criteria:

For beneficiaries with ADD/ADHD or narcolepsy warranting treatment with a stimulant or non-stimulant, a diagnosis of ADD/ADHD or narcolepsy must be documented in the beneficiaries medical record at the time of diagnosis and annually.

For patients with ADD/ADHD, prior to receiving pharmacotherapy, the beneficiary must have additional documentation through a validated ADHD/ADD instrument.

For beneficiaries with ADD/ADHD who are currently receiving a stimulant or non-stimulant but does not have an official diagnosis of ADD/ADHD, the beneficiary will have six months to obtain a diagnosis otherwise the medication will be discontinued.

Non-preferred agents will be approved for clients who have documented failure with two Preferred products in the last 12 months (age six years or older) or documented failure with one Preferred products in the last 12 months if ages 3 –5 years (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.); however, certain exceptions exist for Daytrana®, Intuniv®, Methylin solution®, Nuvigil® and Provigil®. Please see the criteria below.

Non-preferred agents will only be approved for FDA and official compendium indications.

- Intuniv® will be approved for clients with a diagnosis of ADHD/ADD. Beneficiaries with ADD/ADHD must fail 4 week trial of generic guanfacine before the use of Intuniv® will be approved.
- Provigil® will be approved for Narcolepsy, Obstructive Sleep Apnea/Hypopnea Syndrome, Shift Work Sleep Disorder, Multiple Sclerosis related fatigue or ADHD. Beneficiaries with must fail a 4 week trial of an Preferred Stimulant before the use of Provigil® will be approved. Only one tablet per day will be approved
- Nuvigil® will be approved for obstructive sleep apnea/hypopnea syndrome, narcolepsy and shift work sleep disorder. Beneficiaries with must fail a 4 week trial of an Preferred Stimulant before the use of Nuvigil® will be approved. Only one tablet per day will be approved

All other Non-preferred products will be approved for clients with a diagnosis of ADD, ADHD, Narcolepsy, Multiple Sclerosis related fatigue, or traumatic brain injury.

And

Non-preferred agents will only be approved for FDA approved age limitations.

- Provigil® will be approved for clients 16 years of age and older.
- Nuvigil® will be approved for clients 17 years of age and older.
- Adderall IR®, Dexedrine® and Dextrostat® will be approved for clients 3 years of age and older.
- All other medications in this class will be approved for clients 6 years of age and older.
- Daytrana® and Methylin solution®: Clients with documented difficulty swallowing that are unable to utilize alternative dosing with Focalin XR®, Vyvanse® or Adderall XR® can receive approval without failure on preferred products. Provider must document contraindications.

Prior authorization will be required for patients who exceed the following maximum daily doses.

Drug	Maximum Daily Dose
Preferred	

Drug	Maximum Daily Dose
AMPHETAMINE SALTS	40 mg/day
CONCERTA ER [®]	54 mg/day or 72 mg/day \geq age 13
METHYLPHENIDATE ER	60 mg/day
VYVANSE [®]	70 mg/day
FOCALIN XR [®]	40 mg/day
ADDERALL XR [®]	40 mg/day
METHYLPHENIDATE	60 mg/day
METHYLIN	60 mg/day
METHYLPHENIDATE	60 mg/day
METHYLPHENIDATE SR	60 mg/day
Non preferred	
METADATE CD [®]	60 mg/day
KAPVAY ER [®]	0.1 mg/day
D-AMPHETAMINE ER	40 mg/day
DAYTRANA [®]	30 mg/day
PROVIGIL [®]	400 mg/day
RITALIN LA [®]	60 mg/day
INTUNIV ER [®]	4 mg/day
ADDERALL [®]	40 mg/day
NUVIGIL [®]	250 mg/day
METHYLIN ER [®]	60 mg/day
METHYLIN SUSPENSION [®]	60 mg/day
FOCALIN [®]	20 mg/day
QUILLIVANT XR	60 mg/day

Discussion:

A presentation was made by Michael Dutro with Pfizer (Quillivant XR). A motion was made by P Reiter to approve criteria as written. A discussion was had by the committee regarding the addition of traumatic brain injury be added to potential inclusion for Provigil. Additionally, within the PA criteria, where Methylin solution is mentioned, Quillivant XR should also be added since it is a solution. A motion was made to accept the criteria based on these changes by R Kant. This was seconded by E Weiss. The motion passed unanimously.

12. Zubsolv[®] (Buprenorphine and Naloxone sublingual tablet)

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

- The prescriber meets the qualification criteria under the Drug Additional Treatment Act (ACT) of 2000 and has been issued a unique DEA identification number by the DEA, indicating that he or she is qualified under the DATA to prescribe Subutex[®] or Suboxone[®] **AND**
- The client has a diagnosis of opioid dependence **AND**
- The patient is 16 years of age or older **AND**
- No claims data show concomitant use of opiates in the proceeding 30 days **AND**
- The client must have tried and failed, intolerant to, or has a contraindication to generic buprenorphine/naloxone SL tablets.

Discussion:

A motion was made to accept the criteria as written by P Reiter. This was seconded by L Garrison. The motion passed unanimously.

13. Procysbi® (cysteamine bitartrate)

Procysbi® will be approved if all the following criteria are met:

- The client is 6 years of age and older **AND**
- Has a diagnosis of nephropathic cystinosis **AND**
- Documentation is provided to the Department that treatment with cysteamine IR (Cystagon®) was ineffective, not tolerated, or is contraindicated.

Discussion:

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

14. Diclegis (doxylamine and pyroxidine)

Diclegis® will be approved if all the following criteria are met:

- The client has a diagnosis of nausea and vomiting associated with pregnancy **AND**
- The client has failed a trial of doxylamine 10-12.5 mg and pyridoxine 25 mg QID for five days **OR**
- The client has failed a trial of oral ondansetron 4mg every 8 hours for five days **OR**
- The client has an intolerance or contraindication to ondansetron.

Discussion:

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

Upcoming Meeting

R Page stated that he would send an email to the Board regarding the upcoming November meeting to see which date was most convenient for the Board.

A motion was made by P Reiter to adjourn the meeting and was seconded by L Garrison. The meeting was adjourned at 9:35 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: _____