



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

February 16, 2016 7:00 PM to 9:00 PM

1. Call to Order

The meeting was officially called to order at 7:03 PM by K Weber.

2. Roll Call

The Board Coordinator called the roll. There were sufficient members for a quorum with nine members participating and one member excused.

A. Members Present: James 'Rick' Kant, RPh , Edra Weiss, MD, Mark Boesen, PharmD, JD (Industry Representative), Sheila Botts, PharmD, Pam Reiter, PharmD, Karen Weber, DO, Kerstin Froyd, MD, LeWayne Garrison, RPH, James Regan, MD

B. Medicaid Pharmacy Staff: Nila Mahyari, PharmD, Robert Page, PharmD,
Medicaid Pharmacy Department: Robert Lodge, PharmD

C. Members Excused: Edra Weiss, MD

3. Approval of Minutes

After an introduction of DUR Board members, K Weber asked if there were any changes or needed discussion of the minutes from the last meeting. A motion to amend the Antiplatelet Agents section with inclusion of recommendation from the DUR Board to ensure availability of 7 days supply of Effient ®. A motion to approve the minutes with amendments was made by K Froyd, and seconded by P Reiter. The minutes were approved.

4. Department Updates

R Lodge announced updates with respect to the PDL criteria for the agents reviewed at the last meeting.

R Lodge introduced the letter from the University of Colorado Hospital Department of Hepatology to the DUR Board Members. Dr. G Everson and Dr. J Langness were present

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to give testimony regarding the focus areas highlighted within the body of the letter. Dr. G Everson asked if the process can be simplified utilizing an electronic record. R Lodge responded that at this point, the Department does not have technological capabilities to systematically organize the approval of Hepatitis C Prior Authorization Requests via electronic records. He described the Department’s current capacity and outlined the changes made to the criteria. The criteria for Hepatitis C was the first to be reviewed.

5. Rules

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

R Lodge 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.

6. Open Comments

Proposed Criteria

1. Insulin Products

Preferred: Rapid acting: Novolog Vials and Pens
 Short acting: Humulin R Vials and Pens
 Intermediate acting: Humulin N Vials and Pens
 Long acting: Levemir Vials and Pens
 Mixtures: Humulin 70/30 vial/pen, Humalog Mix 50/50 vial/pen,
 Humalog Mix 75/25 vial/pen, Novolog Mix 70/30 vial/pen

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2015	November 2015	December 2015

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Novolog Pen	50%	50%	51%
Novolog Vial	45%	44%	43%
Humalog Vial	3%	4%	4%
Humalog Pen	2%	2%	2%
Apidra Vial	<1%	<1%	<1%
Apidra Solostar	<1%	<1%	<1%
Afrezza	0%	<1%	<1%

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2015	November 2015	December 2015
Humulin R Vial	99%	99%	99.5%
Novolin R Vial	1%	1%	<1%

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2015	November 2015	December 2015
Humulin N vial	88%	89%	86%
Humulin N Pen	9%	9%	9%
Novolin N Vial	1%	1%	2%
Relion Novolin N Vial	1%	1%	2%

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2015	November 2015	December 2015
Levemir Flextouch	59%	60%	58%
Levemir Vial	30%	28%	30%
Lantus Solostar	6%	6%	6%
Lantus Vial	4%	5%	5%
Toujeo	1%	1%	1%
Levemir Flexpen	<1%	<1%	<1%

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2015	November 2015	December 2015
Relion Novolin 70/30 Vial	30%	29%	34%
Humulin 70/30 Vial	37%	34%	29%
Relion Novolin Vial	14%	15%	16%
Humilin 70/30 Kwikpen	10%	12%	10%
Humalog 75/25 Kwikpen	9%	9%	10%
Novolog 70/30 Vial	0%	0%	0%

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Humalog 50/50 Vial	0%	0%	0%
Humalog 50/50 Kwikpen	0%	1%	<1%
Humalog Kwikpen	0%	0%	0%
Novolog 70/30 Flexpen	0%	0%	0%
Novolog 70/30 Vial	0%	0%	0%

Prior Authorization Criteria:

Non-preferred products will be approved if the member has failed treatment with one of the preferred products in the last month. (Failure is defined as: allergy or intolerable side effects)

AFREZZA (human insulin) will be approved for members with the following criteria:

- Member is 18 years or older AND
- Member has intolerable side effects or severe allergic reactions to Novolog AND
- Member must not have chronic lung disease such as asthma and COPD AND
- If member is a type 1 diabetic, must use in conjunction with long-acting insulin AND
- Member must not be a smoker

Discussion:

A motion to approve the above criteria was made by K Froyd and seconded by P Reiter and the motion passed.

2. Alzheimer’s Agents

- Preferred:
- Donepezil
 - Donepezil ODT
 - Galantamine
 - Galantamine ER
 - Memantine**

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2015	November 2015	December 2015



Donepezil	65%	61%	59%
Memantine	25%	24%	27%
Namenda XR	5%	8%	6%
Rivastigmine Patch	3%	4%	4%
Rivastigmine Tablet	2%	2%	2%
Namenda (memantine)	1%	1%	1%
Exelon Patch (rivastigmine)	0%	0%	0%
Donepezil ODT	0%	0%	0%
Aricept (donepezil)	0%	0%	0%
Galantamine	<1%	<1%	<1%
Galantamine ER	0%	0%	0%

Prior Authorization Criteria:

Non-preferred products will be approved if the member 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)

Members 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 member has a diagnosis of dementia which can be verified by SMART PA.

Discussion:

A motion to approve the above criteria was made by P Reiter and seconded by L Garrison and the motion passed.

3. Atypical Antipsychotics

Preferred: Abilify®
 Abilify ODT®
 Aripiprazole oral solution
 Clozaril®
 Clozapine
 Geodon®
 Latuda®
 Olanzapine
 Risperdal®
 Risperidone
 Risperidone ODT
 Risperdal M-tab
 Quetiapine IR
 Seroquel IR®



Ziprasidone
Zyprexa®

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2015	November 2015	December 2015
Abilify (aripiprazole)	24%	24%	25%
Quetiapine	23%	23%	23%
Risperidone	19%	19%	19%
Olanzapine	12%	12%	12%
Latuda (lurasidone)	7%	7%	7%
Clozapine	4%	4%	4%
Ziprasidone	5%	4%	5%
Seroquel XR (quetiapine)	3%	3%	3%
Seroquel (quetiapine)	<1%	<1%	<1%
Invega ER (paliperidone)	<1%	<1%	<1%
Saphris (asenapine)	1%	1%	1%
Risperdal M-Tab (risperidone)	<1%	0%	0%
Risperidone ODT	1%	1%	1%
Risperdal (risperidone)	<1%	<1%	<1%
Zyprexa (olanzapine)	<1%	<1%	<1%
Olanzapine ODT	<1%	<1%	<1%
Invega Trinza (paliperidone palmitate)	<1%	0%	<1%
Invega Sustenna (paliperidone palmitate)	<1%	<1%	<1%
Geodon (ziprasidone)	<1%	<1%	<1%
Fanapt (iloperidone)	<1%	<1%	<1%
Fazaclo (clozapine)	<1%	<1%	<1%
Clozaril (clozapine)	<1%	<1%	<1%
Zyprexa Zydis (olanzapine)	<1%	<1%	<1%
Symbax (fluoxetine / olanzapine)	<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 member 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). See Table 1.

Table 1. FDA Approved Indications for Non-preferred Products

Drug	Indication
Fanapt®	<ul style="list-style-type: none"> Acute treatment of schizophrenia in adults



Fazaclo®	<ul style="list-style-type: none"> • Treatment-resistant schizophrenia • Reducing the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder
Invega®	<ul style="list-style-type: none"> • Acute and maintenance of schizophrenia • Acute treatment of schizophrenia (monotherapy) • Acute treatment of schizophrenia (adjunct to mood stabilizers and/or antidepressants)
Saphris®	<ul style="list-style-type: none"> • Acute and maintenance of schizophrenia • Bipolar mania, monotherapy • Maintenance treatment of bipolar I disorder as an adjunct to lithium or divalproex
Seroquel XR®	<ul style="list-style-type: none"> • 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 members younger than the FDA approved age for the agent. Members younger than the FDA approved age for the agent who are currently stabilized on an atypical antipsychotic will be eligible for grandfathering. See Table 2.

New Atypical Antipsychotic prescriptions for members under 5 years of age will be reviewed on an individual basis by a clinical health care 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. Members under the age of 5 will be reviewed annually for appropriateness of therapy and proper monitoring.

Table 2. FDA Approved Dosing for Members Under 18 years of Age.

Drug	FDA Approved Indication	FDA Approved Age	Maximal FDA Approved Dose
Asenapine (Saphris®)	NOT APPROVED		
Aripiprazole (Abilify®)	Autism/Psychomotor Agitation Bipolar Disorder/Mixed Mania Schizophrenia Gilles de la Tourette's syndrome	6-17 years 10-17 years 13-17 years 6-17 years	15mg/day 30mg/day 30mg/day 20 mg/day
Clozapine (Fazaclo®, Clozaril®)	NOT APPROVED		
Iloperidone (Fanapt®)			
Lurasidone (Latuda®)			
Olanzapine (Zyprexa®)	Schizophrenia Bipolar Disorder/Mixed Mania	13-17 years	10mg/day
Olanzapine (Zyprexa Zydys®)		13-17 years	10mg/day
Paliperidone (Invega ER®)	Schizophrenia	12-17 years	12mg/day
Risperidone (Risperdal®)	Autism/Psychomotor Agitation Bipolar Disorder/Mixed Mania	5-16 years 10-17 years	3mg/day 6mg/day

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	Schizophrenia	13-17 years	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		

Grandfathering: Members currently stabilized on a non-preferred atypical antipsychotic can receive approval to continue on that agent for two years even if the member 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 member must have an FDA approved indication and must have tried and failed on the FDA approved dosing regimen. See Table 3.

Table 3. 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
	Risperidone	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

FAZACLO will be approved for the treatment of schizophrenia if the member is 18 years of age or older and has tried and failed treatment with three preferred products (one of which must be generic clozapine) in the last 5 years.

INVEGA will be approved for the treatment of schizophrenia or schizoaffective disorder if the member is 18 years of age or older (12 years or older for schizophrenia) and has tried and failed treatment with / has had adherence issues with three preferred products in the last 5 years. A maximum of one tablet per day will be approved



SEROQUEL XR will be approved if the member 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 FDA approved indications (see Table 1):

If a member has been stabilized on QUETIAPINE 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.

IR QUETIAPINE when given at subtherapeutic doses may be restricted for therapy exceeding 30 days. Low-dose quetiapine (<150mg/day) is only FDA approved as part of a drug titration schedule to aid patients in getting to the target quetiapine dose. PA will be required for quetiapine < 150mg per day for longer than 30 days, except for utilization (when appropriate) in members age 65 years or older.

ZYPREXA ZYDIS will be approved for the treatment of schizophrenia or bipolar 1 disorder if the member 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 members 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

Discussion:

There was discussion about changes to criteria with respect to the use of low-dose quetiapine currently restricted for all members. The Board discussed restricting use only for members < 18 years of age after two board members agreed that the use of low-dose quetiapine is associated with less abuse potential than the use of sedative hypnotics for adults.

A motion to approve the above criteria was made by K Froyd and seconded by P Reiter and the motion passed.

4. Growth Hormones

Preferred: Genotropin®
 Norditropin®

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2015	November 2015	December 2015
Genotropin	93%	93%	93%
Norditropin Flexpro	1%	2%	2%
Genotropin Miniquick	3%	3%	3%
Saizen	<1%	<1%	<1%
Omnitrope	2%	2%	1%
Norditropin Nordiflex	0%	0%	0%
Humatrope	1%	<1%	1%
Nutropin AQ Nuspin	<1%	0%	<1%



Prior Authorization Criteria:

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

- Member failed treatment with Genotropin or Norditropin within the last 12months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)
- Member 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
- Grandfathering: If the member has a diagnosis for short bowel syndrome OR cachexia associated with AIDS, member will be grandfathered and receive approval for a non-preferred agent due to medical necessity.
- Grandfathering: If the member is < 30 kg, the member will be grandfathered on Norditropin due to ease of dose accuracy on Norditropin device.

Discussion:

A motion to approve the above criteria with the highlighted amendments was made by L Garrison and seconded by K Froyd and the motion passed.

5. Intranasal Steroids

Preferred: Fluticasone Propionate
Nasonex®

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2015	November 2015	December 2015



Fluticasone Spray	62%	59%	60%
Nasonex (mometasone)	7%	7%	7%
Budesonide	6%	6%	6%
Flonase (fluticasone)	<1%	0%	0%
Dymista (azelastine HCl / fluticasone)	<1%	<1%	<1%
Qnasl (beclomethasone)	<1%	<1%	<1%
Veramyst (fluticasone)	<1%	<1%	<1%
Zetonna (ciclesonide)	<1%	<1%	<1%
Omnaris (ciclesonide)	<1%	0%	<1%
Rhinocort AQ (budesonide)	0%	<1%	0%
Flunisolide	<1%	<1%	0%
Beconase AQ (beclomethasone)	0%	<1%	0%

Prior Authorization Criteria:

Non-preferred Intranasal Corticosteroids will be approved _____

_____ if the member 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 members without failure of Preferred products.

Discussion:

A motion to approve the above criteria was made by K Froyd and seconded by P Reiter and the motion passed.

6. Leukotriene Modifiers

Preferred: Montelukast® tab and chewable tab

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2015	November 2015	December 2015
Montelukast	99%	99%	99%
Singulair (montelukast)	<1%	<1%	<1%
Zafirlukast	<1%	<1%	<1%
Zyflo CR (zileuton)	0%	<1%	<1%
Zyflo (zileuton)	<1%	<1%	<1%

Prior Authorization Criteria:

Non-preferred leukotriene modifiers will be approved if **both** of the following criteria are met:

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- Member 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)
- Member has a diagnosis of Asthma

Discussion:

A motion to approve the above criteria was made by S Botts and seconded by P Reiter and the motion passed.

7. Agents for Multiple Sclerosis

- Preferred: Avonex®
 Betaseron®
 Rebif®
 Copaxone® 20 mg injection

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2015	November 2015	December 2015
Copaxone 20 (glatiramer acetate)	22%	22%	19%
Tecfidera (dimethyl fumarate)	20%	18%	21%
Ampyra (4-aminopyridine)	13%	11%	11%
Copaxone 40 (glatiramer acetate)	11%	13%	11%
Rebif (interferon beta-1a)	12%	12%	12%
Gilenya (fingolimod)	10%	11%	14%
Aubagio (teriflunomide)	5%	5%	6%
Avonex (interferon beta-1a)	4%	5%	4%
Betaseron (interferon beta-1a)	2%	2%	2%
Plegridy (peginterferon beta-1a)	1%	<1%	<1%
Extavia (interferon beta-1a)	<1%	<1%	<1%

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).

For treatment of EARLY disease, Gilenya will be approved for members that meet the following criteria:

- Documented, diagnosis of multiple sclerosis made by neurologist in the last 3 years AND
- Documentation provided by prescribing neurologist for marked functional decline as demonstrated by *two* of the following:



➤ MRI, EDSS scale OR medical chart notes that specify increased burden of disease AND

- Provider attests to shared decision making with respect to risks versus benefits of medical treatment AND
- Does not have a recent history of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or New York Heart Association Class III-IV heart failure within six months of initiating therapy AND
- Does not have a history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome unless patient has a pacemaker AND
- Has a baseline QTc interval < 500 ms prior to starting therapy AND
- Is not receiving treatment with a Class Ia or Class III anti-arrhythmic medication AND
- Has no active infections AND
- Had an ophthalmologic evaluation (ocular coherence test) prior to starting therapy and within 3-4 months follow-up after starting therapy AND
- Had baseline complete blood count with differential and liver function tests.

For the treatment of AGGRESSIVE, EARLY disease, Tecfidera and Aubagio may be approved for members that meet the following criteria:

- Member has failed Gilenya. Failure will be defined as intolerable side effects, drug-drug interaction, contraindication to, or lack of efficacy AND
- Documented, diagnosis of multiple sclerosis made by neurologist in the last 3 years AND
- Documentation provided by prescribing neurologist for marked functional decline as demonstrated by *two* of the following: AND

➤ MRI, EDSS scale OR medical chart notes that specify increased burden of disease

- Provider attests to shared decision making with respect to risks versus benefits of medical treatment AND
- Appropriate safety criteria for Tecfidera and Aubagio are met below:

Safety Criteria



Tecfidera	Aubagio
<ul style="list-style-type: none"> • Has no active infections AND • Had a complete blood count with differential within the six months prior to initiating therapy 	<ul style="list-style-type: none"> • Has no active infections AND • If a female patient of child bearing age, has a negative pregnancy test at baseline and is using a form of highly effective contraceptive AND • Had transaminase and bilirubin levels with ALT < 2 times the upper limit of normal within the 6 months prior to initiating therapy AND • Had a complete blood count with differential within the six months prior to initiating therapy AND • Has a documented baseline blood pressure AND • Has been evaluated for active or latent tuberculosis infection by documented test results (purified protein derivative test) or blood test.

COPAXONE® 40mg will be approved for members who have a severe intolerable injection site reactions (e.g., pain requiring local anesthetic, oozing, lipoatrophy, swelling, or ulceration) to COPAXONE 20mg

AMPYRA – A 90 day supply of AMPYRA will be approved if all of the following criteria are met:

- Member has a diagnosis of MS;
- Member is ambulatory and has established a baseline which is defined as ambulating between 8-45 seconds Timed 25-foot Walk (T25FW) assessment OR has established a baseline activities of daily living (ADL);
- Member is currently receiving a disease modifying agent (if indicated);
- Member has no history of seizure disorder;
- Member has no history of moderate to severe renal dysfunction (CrCl > 50 ml/min);
- Prescriber is a neurologist;
- The prescribed dose does not exceed 10 mg twice daily.

Extended coverage of AMPYRA (up to 1 year) will be approved if documentation shows improvement in ambulation (measured by T25FW assessment) or improvement in ADLs after three months of therapy.

AUBAGIO will be approved if the member has met all the following criteria:

- In members without a contraindication to GILENYA, member has failed COPAXONE or a preferred interferon product and GILENYA. Failure will be defined as intolerable side effects drug-drug interaction, or lack of efficacy OR
- In members with a contraindication to GILENYA, has failed COPAXONE or a preferred interferon product. Failure will be defined as intolerable side effects, drug-drug interaction, or lack of efficacy.



lack of efficacy will be defined as one of the following:

- On MRI: presence of any new spinal lesions, cerebellar or brain stem lesions, or change in brain atrophy.
- On clinical exam, signs and symptoms consistent with functional limitations that last one month or longer.

AND

- Has a diagnosis of a relapsing form of MS AND
- Is being prescribed by a neurologist AND
- Has no active infections AND
- If a female patient of child bearing age, has a negative pregnancy test at baseline and is using a form of highly effective contraceptive AND
- Had transaminase and bilirubin levels with ALT < 2 times the upper limit of normal within the 6 months prior to initiating therapy AND
- Had a complete blood count with differential within the six months prior to initiating therapy AND
- Has a documented baseline blood pressure AND
- Has been evaluated for active or latent tuberculosis infection by documented test results (purified protein derivative test) or blood test.

TECFIDERA will be approved if the member has met all the following criteria:

- In members without a contraindication to GILENYA, member has failed COPAXONE or a preferred interferon product and GILENYA. **Failure** will be defined as intolerable side effects drug-drug interaction, or lack of efficacy OR
 - In members with a contraindication to GILENYA, has failed COPAXONE or a preferred interferon product. Failure will be defined as intolerable side Effects, drug-drug interaction, or lack of efficacy. Lack of efficacy will be defined as one of the following:
 - One of the following on MRI: presence of any new spinal lesions, cerebellar or brain stem lesions, or change in brain atrophy
 - On clinical exam, signs and symptoms consistent with functional limitations that last one month or longer.
- AND
- Has a diagnosis of relapsing form of MS AND
 - Is being prescribed by a neurologist AND
 - Has no active infections AND
 - Had a complete blood count with differential within the six months prior to initiating therapy

GILENYA will be approved if the member has met all the following criteria:

- Has failed COPAXONE or a preferred interferon product. **Failure** will be defined as intolerable side effects, drug-drug interaction, or lack of efficacy. Lack of efficacy will be defined Lack of efficacy will be defined one of the following:
 - One of the following on MRI: presence of any new spinal lesions, cerebellar or brain stem lesions, or change in brain atrophy
 - On clinical exam, signs and symptoms consistent with functional limitations



that last one month or longer.
AND

- Has a diagnosis of relapsing form of MS AND
- Is being prescribed by a neurologist AND
- Does not a recent history of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or New York Heart Association Class III-IV heart failure within six months of initiating therapy AND
- Does not have a history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome unless patient has a pacemaker AND
- Has a baseline QTc interval < 500 ms prior to starting therapy AND
- Is not receiving treatment with a Class Ia or Class III anti-arrhythmic medication AND
- Has no active infections AND
- Had an ophthalmologic evaluation (ocular coherence test) prior to starting therapy and within 3-4 months follow-up after starting therapy AND
- Had baseline complete blood count with differential and liver function tests.

Grandfathering: Members currently stabilized GILENYA, TECFIDERA, and AUBAGIO can receive approval to continue on that agent.

Discussion:

The following speakers gave an oral presentation on the above topic:

Dr. John Corboy: University of Colorado

Ben Skoog: Biogen

Dr. Corboy highlighted that treatment decisions are unique to individual patients. There was discussion about the use of the word 'aggressive' in the newly written criteria and definitions that limit the use of agents for patients in which a drug is indicated.

A motion to approve the above criteria with highlighted amendments was made by L Garrison and seconded by K Froyd and the motion passed.

8. Sedative Hypnotics

Preferred: Eszopiclone
Zaleplon
Zolpidem

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2015	November 2015	December 2015



Zolpidem	93%	93%	93%
Zolpidem ER	2%	2%	2%
Zaleplon	2%	2%	2%
Zaleplon ER	2%	2%	2%
Rozerem (ramelteon)	1%	1%	1%
Belsomra (suvorexant)	1%	1%	1%
Ambien CR (zolpidem)	<1%	<1%	<1%
Lunesta (eszopiclone)	<1%	<1%	<1%
Ambien (zolpidem)	<1%	<1%	0%
Edular (zolpidem)	0%	0%	0%

Prior Authorization Criteria:

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

Sedative hypnotics will require prior authorization for members ≥65 years of age exceeding 90 days of therapy.

BELSOMRA (suvorexant) will be approved for members that meet the following criteria:

- Members who have failed treatment with two preferred agents in the last 12 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) AND
- Member is not receiving strong inhibitors (e.g., erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, delavirdine, and milk thistle) or inducers (e.g., carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifabutin, rifapentine, dexamethasone, efavirenz, etravirine, nevirapine, darunavir/ritonavir, ritonavir, and St Johns Wort) of CYP3A4 AND
- Member does not have a diagnosis of narcolepsy

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 members 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 members currently taking a long-acting benzodiazepine such as clonazepam or temazepam.

Discussion:

There was discussion about guidelines for the treatment of insomnia as related to the duration of therapy. A limit for duration was considered for implementation. R Lodge and others agreed that due to limitations in resources to evaluate and review PARs at this time, a limit is not feasible.



A motion to approve the above criteria was made by K Froyd and seconded by L Garrison and the motion passed.

9. Statin and Combinations

Preferred: Atorvastatin
Crestor®
Pravastatin
Simvastatin

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2015	November 2015	December 2015
Atorvastatin	51%	51%	52%
Simvastatin	25%	25%	24%
Crestor (rosuvastatin)	12%	13%	12%
Pravastatin	11%	11%	11%
Fluvastatin	0%	0%	0%
Lipitor (atorvastatin)	<1%	<1%	<1%
Lovastatin	<1%	<1%	<1%
Livalo (pitavastatin)	<1%	<1%	<1%
Simcor (niacin / simvastatin)	0%	0%	0%
Vytorin (ezetimibe / simvastatin)	<1%	<1%	<1%

Non-preferred Statin/Statin combinations will be approved if the member 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 members 18 years of age and older.
Caduet, fluvastatin and lovastatin will be approved for clients 10 years of age and older.

Simvastatin 80mg dose products will only be covered for members who have been stable for more than 12 months at that dose. Providers should consider alternate preferred statins in members 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.



Discussion:

A motion to approve the above criteria was made by S Botts and seconded by K Froyd and the motion passed.

10. Ophthalmic Allergy

- Preferred: Cromolyn
 olopatadine 0.1 %
 Pataday®
 Pazeo (olaptadine) ®
 Zaditor (ketotifen) ®

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2015	November 2015	December 2015
Pataday (olopatadine)	56%	53%	51%
Patanol (olopatadine)	22%	22%	12%
Azelastine	16%	20%	21%
Cromolyn (cromoglicic acid)	6%	5%	7%
Olapatadine	0%	0%	9%
Ketotifen	<1%	0%	<1%
Lastacaft (alcaftadine)	<1%	<1%	<1%
Epinastine	<1%	0%	<1%
Bepreve (bepostatine)	0%	<1%	0%

Prior Authorization Criteria:

Non-preferred Ophthalmic Allergy medications will be approved if the member has failed treatment with two preferred products in the last 12 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)

Discussion:

A motion to approve the above criteria was made by K Froyd and seconded by S Botts and the motion passed.

11. Xerese (acyclovir / hydrocortisone)

Xerese will be approved for members that meet the following criteria:

- Documented diagnosis of recurrent herpes labialis AND
- Member is immunocompetent AND
- Member has failed treatment of at least 10 days with acyclovir (please refer to the Anti-Herpetic Agents segment of the PDL for dose recommendations). Failure will be defined as



significant drug-drug interaction, lack of efficacy, contraindication to or intolerable side effects) AND

- Member has failed treatment of at least one day with famciclovir 1500 mg OR valacyclovir 2 GM twice daily (Failure is defined as significant drug-drug interaction, lack of efficacy, contraindication to or intolerable side effects)

Discussion:

A motion to approve the above criteria was made by P Reiter and seconded by S Botts and the motion passed.

12. Viberzi (eluxadoline)

Viberzi will be approved for members that meet the following criteria:

- Documented diagnosis of Irritable Bowel Syndrome (IBS) with diarrhea AND
- Member does not have severe (Child-Pugh C) hepatic impairment, history of severe constipation, known mechanical gastrointestinal obstruction, biliary duct obstruction, history of pancreatitis or structural disease of the pancreas AND
- Member does not drink more than 3 alcoholic drinks per day AND
- Member has tried and failed a 10 day treatment with both loperamide AND dicyclomine OR hyoscamine

Discussion:

A motion to approve the above criteria was made by R Kant and seconded by P Reiter and the motion passed.

12. Veltassa (patiromer)

Veltassa will be approved for members that meet the following criteria:

- Documented diagnosis of hyperkalemia (serum potassium > 5 mEq/L) AND
- Veltassa is not being used for emergent hyperkalemia AND
- Member does not have severe gastrointestinal motility dysfunction AND
- Member does not have hypomagnesemia (serum magnesium < 1.4 mg/dL)

Discussion:

The following speakers gave an oral presentation on the above topic:

Candice Barber: Relypsa

A motion to approve the above criteria was made by K Froyd and seconded by S Botts and the motion passed.

13. Hepatitis C Agents

Preferred agent criteria:

Requests for **Viekira Pak® (ombitasvir/paritaprevir/ritonavir/dasabuvir)** will be granted prior authorization if the following criteria are met:

- Physician attests to the member's readiness for adherence **AND**
- Physician attests to provide SVR12 and SVR24 timely **AND**
- Must have chronic Hepatitis C (HCV) genotype 1a or 1b **AND**
- Member is not co-infected with Hepatitis B **AND**
- Member is 18 years of age and older **AND**



- Member is not a pregnant female or a male with a pregnant female partner (**ribavirin contraindication**). Initial pregnancy test must be performed not more than 30 days prior to beginning therapy **AND**
- Women of childbearing potential and their male partners must use two forms of effective (non-hormonal) contraception during treatment (**for ribavirin containing regimens only**) **AND**
- Prescribed by or in conjunction with an infectious disease specialist, gastroenterologist, or hepatologist **AND**
- Meets one of the following categories:
 - Members with serious extra-hepatic manifestations of HCV such as leukocytoclastic vasculitis, hepatocellular carcinoma meeting Milan criteria, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia despite mild liver disease;
 - Members with fibrosing cholestatic HCV;
 - Members with compensated cirrhosis defined by Child-Turcotte-Pugh (CTP) class A(5-6) **AND**;
 - Member has cirrhosis (METAVIR F4) based on:
 - Biopsy not more than 5 years old; OR
 - FibroScan (≥ 9.6 kPa); OR
 - Imaging indicating definitive evidence of cirrhosis, or varices, or portal hypertension, or splenomegaly; OR
 - FibroMeter (>0.8 kPa); OR
 - FibroTest (> 0.74 kPa)
 - OR**
 - Member has a fibrosis score equivalent to METAVIR F3 based on:
 - Biopsy not more than 5 years old; OR
 - FibroScan (≥ 9.6 kPa); OR
 - Imaging indicating definitive fibrosis stage 3; OR
 - Concordance among one of the following FibroTest (>0.58 kPa) or FibroMeter (> 0.58 kPa) PLUS one of the following APRI (> 1) or FIB4 (> 2.2);
- Members may be treatment naïve or treatment experienced, except with a direct-acting antiviral (DAA) **AND**
- Liver post-transplant recipients approved despite any liver disease **AND**
- Members may be HIV positive **AND**
- Member does not have end stage renal disease requiring hemodialysis **AND**
- Member must have genotyping results within 1 year of anticipated therapy start date **AND**
- Member must have baseline levels within 90 days of anticipated start date for relevant labs such as: HCV RNA; CBC; CMP; INR; FibroTest; FibroMeter **AND**
- Member must have baseline alcohol/drug screen within 30 days of anticipated start date **AND**
- Member must be 6 months free of: alcohol and Schedule I controlled substances (including marijuana); and cocaine, opiate, benzodiazepine, and barbiturate misuse/abuse as documented by appropriate alcohol/drug screens. Member must also be counseled about the importance of refraining from alcohol use and drug misuse/abuse. Random alcohol/drug screens must be conducted monthly during treatment for clients that have a history (within the past 2 years) of alcohol/drug abuse **AND**
- Member is not taking agents highly dependent on CYP3A for clearance; strong inducers of CYP3A and strong inducers and inhibitors of CYP 2C8 **AND**
- Member is not taking agents that are contraindicated with ribavirin if ribavirin will be coadministered for treatment **AND**
- For drugs that decrease the effectiveness of Viekira, provider to supply plan as to how to manage these drug-drug interactions **AND**



- All approvals will initially be for an 8 week time period, with further approvals dependent on the submission of the HCV RNA level at week 4, week 12, and week 24 to justify continuing drug therapy (see discontinuation criteria) **AND**
- If the week 4 HCV RNA is detectable (>25 copies) while on Viekira Pak therapy, HCV RNA will be reassessed in 2 weeks. If the repeated HCV RNA level has not decreased (i.e., >1 log₁₀ IU/ml from nadir) all treatment will be discontinued unless documentation is provided to support continuation of therapy **AND**
- Must be in accordance with approved regimens and duration (see Table 1) **AND**
- Must be adherent to treatment regimen (see discontinuation criteria) **AND** prescriber must confirm member enrollment in the proCeed Nurse Connector program (by phone: 1-844-277-6233 or Fax: 1-866-299-1687 or online at: <https://www.viekira.com/proceed-program>) to reinforce adherence **AND**
- Must have received or in process of receiving full courses of both Hepatitis A and Hepatitis B vaccinations, or have immunity.

Note: The Department will only cover a once per lifetime treatment with any DAA.

Table 1. Recommended Regimens and Treatment Duration for Viekira Pak

Patient Population	Treatment	Duration
Members with genotype 1a, without compensated cirrhosis	Viekira Pak + ribavirin	12 weeks
Members with genotype 1a, with compensated cirrhosis	Viekira Pak + ribavirin	24 weeks
Members with genotype 1b, without compensated cirrhosis	Viekira Pak	12 weeks
Members with genotype 1b, with compensated cirrhosis	Viekira Pak + ribavirin	12 weeks
Post-transplant members	Viekira Pak + ribavirin	24 weeks

Quantity and Refill Limits:

- Quantity Limit: two ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg tablets once daily and one dasabuvir 250 mg tablet twice daily (112 tablets/28days)
- Length of authorization: Based on HCV subtype and comorbidities
- Refills: Should be reauthorized in order to continue the appropriate treatment plan. The member **MUST** receive refills within one week of completing the previous fill.

Discontinuation Criteria:

- Members receiving a Viekira Pak-based regimen should have HCV RNA levels assessed at weeks, 4, 6 (if applicable), and 12 (if applicable). If the HCV RNA is above the lower limit of quantification by a validated test at any of these time points, all treatment will be discontinued.
- Members receiving a Viekira Pak-based regimen should have ALT levels at baseline, 4 weeks, and again as clinically necessary. Members may need to discontinue if ALT levels remain over 10 times ULN, and will need to discontinue if ALT elevation is accompanied with signs or symptoms of liver inflammation, increased conjugated bilirubin, alkaline phosphatase, or INR.
- The department will prospectively evaluate medication adherence based on prescription fills. If a member is non-adherent in filling their Viekira Pak prescription (e.g. not filled within 7 days of the end of the previous fill), all treatment will be discontinued.
- Members with a history of drug or alcohol abuse/misuse within the last 2 years must provide random monthly drug and alcohol screens during treatment to continue receiving treatment for HCV.



Requests for **Harvoni® (sofosbuvir/ledipasvir)** for genotype 1 will be considered if Viekira Pak® is contraindicated or cannot be used due to documented resistance to protease inhibitors for the treatment of Hepatitis C virus (e.g. Olysio, Victrelis, Incivek), **significant drug-drug interactions exist between member's drug regimen and Viekira, or increased risk of adverse events associated with the change in CTP class status.** Other genotypes (4, 5, 6) will not require a contraindication to Viekira®. Prior authorization may be granted if the following criteria are met:

- Physician attests to the member's readiness for adherence **AND**
- Physician attests to provide SVR12 and SVR24 timely **AND**
- Must have chronic Hepatitis C (HCV) genotypes 1a, 1b, 4, 5, or 6 **AND**
- Member is not co-infected with Hepatitis B **AND**
- Member is 18 years of age and older **AND**
- Member is not a pregnant female or a male with a pregnant female partner (ribavirin contraindication). Initial pregnancy test must be performed not more than 30 days prior to beginning therapy **AND**
- Women of childbearing potential and their male partners must use two forms of effective (non-hormonal) contraception during treatment (for ribavirin containing regimens only) **AND**
- Prescribed by or in conjunction with an infectious disease specialist, gastroenterologist, or hepatologist **AND**
- Meets one of the following categories:
 - Members with serious extra-hepatic manifestations of HCV such as leukocytoclastic vasculitis, hepatocellular carcinoma meeting Milan criteria, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia despite mild liver disease;
 - Members with fibrosing cholestatic HCV
 - **Members with compensated cirrhosis defined by Child-Turcotte-Pugh (CTP) class A or decompensated cirrhosis CTP > 6 AND;**
 - Member has cirrhosis (METAVIR F4) based on:
 - Biopsy not more than 5 years old; OR
 - FibroScan (≥ 9.6 kPa); OR
 - Imaging indicating definitive evidence of cirrhosis, or varices, or pulmonary hypertension, or splenomegaly; OR
 - FibroMeter (>0.8 kPa); OR
 - FibroTest (> 0.74 kPa)
 - OR**
 - Member has a fibrosis score equivalent to METAVIR F3 based on:
 - Biopsy not more than 5 years old; OR
 - FibroScan (≥ 9.6 kPa); OR
 - Imaging indicating definitive fibrosis stage 3; OR
 - Concordance among one of the following FibroTest (>0.58 kPa) or FibroMeter (> 0.58 kPa) PLUS one of the following APRI (> 1) or FIB4 (> 2.2);
 - Members may be treatment naïve or treatment experienced, except with a direct-acting antiviral (DAA) **AND**
 - Liver post-transplant recipients approved despite any liver disease **AND**
 - Members may be HIV positive **AND**
 - Member does not have severe renal impairment (eGFR <30), end stage renal disease, on hemodialysis **AND**
 - Member must have genotyping results within 1 year of anticipated therapy start date **AND**
 - Member must have baseline levels within 90 days of anticipated start date for relevant labs such as: HCV RNA; CBC; CMP; INR; FibroTest; FibroMeter **AND**
 - Member must have baseline alcohol/drug screen within 30 days of anticipated start date **AND**



- Member must be 6 months free of: alcohol; and Schedule I controlled substances (including marijuana), and cocaine, opiate, benzodiazepine, and barbiturate misuse/abuse as documented by appropriate alcohol/drug screens. Member must also be counseled about the importance of refraining from alcohol use and drug misuse/abuse. Random alcohol/drug screens must be conducted monthly during treatment for members that have a history (within the past 2 years) of alcohol/drug abuse **AND**
- Member is not taking potent P-gp inducers or amiodarone **AND**
- Member is not taking agents that are contraindicated with ribavirin if ribavirin will be coadministered for treatment **AND**
- For drugs that decrease the effectiveness of Harvoni, provider to supply plan as to how to manage these drug-drug interactions **AND**
- All approvals will initially be for an 8 week time period, with further approvals dependent on the submission of the HCV RNA level at week 4, week 12, and week 24 to justify continuing drug therapy (see discontinuation criteria) **AND**
- If the week 4 HCV RNA is detectable (>25 copies) while on sofosbuvir/ledipasvir therapy, HCV RNA will be reassessed in 2 weeks. If the repeated HCV RNA level has not decreased (i.e., >1 log₁₀ IU/ml from nadir), all treatment will be discontinued unless documentation is provided to support continuation of therapy **AND**
- Must be in accordance with approved regimens and duration (see Table 1) **AND**
- Must be adherent to treatment regimen (see discontinuation criteria) **AND**
- Must have received or in progress of receiving full courses of both Hepatitis A and Hepatitis B vaccinations, or have immunity.

Note: The Department will only cover a once per lifetime treatment with any DAA.

Table 1. Recommended Regimens and Treatment Duration for Harvoni

Patient Population	Treatment	Duration
GT1: Treatment naïve with or without compensated cirrhosis	Harvoni	12 weeks
GT:1 Treatment experienced without compensated cirrhosis	Harvoni	12 weeks
GT1: Treatment experienced with compensated cirrhosis	Harvoni + ribavirin	12 weeks
GT1: Treatment-naïve or -experienced with decompensated cirrhosis	Harvoni + ribavirin	12 weeks
GT4, 5, 6: Treatment-naïve or -experienced with or without compensated cirrhosis	Harvoni	12 weeks

Quantity and Refill Limits:

- Quantity Limit: one ledipasvir 90 mg/sofosbuvir 400 mg tablet per day (28 tablets/28days)
- Length of authorization: Based on comorbidities and treatment status
- Refills: Should be reauthorized in order to continue the appropriate treatment plan. The member **MUST** receive refills within one week of completing the previous fill.

Discontinuation Criteria:

- Members receiving a sofosbuvir/ledipasvir-based regimen should have HCV RNA levels assessed at weeks 4, 6 (if applicable), and 12 (if applicable); if the HCV RNA is above the lower limit of quantification by a validated test at any of these time points, all treatment will be discontinued.
- The department will prospectively evaluate medication adherence based on prescription fills. If a member is non-adherent in filling their Harvoni prescription (e.g. not filled within 7 days of the end of the previous fill), all treatment will be discontinued.
- Members with a history of drug or alcohol abuse/misuse within the last 2 years must provide random monthly drug and alcohol screens during treatment to continue receiving treatment for HCV.



Discussion:

The following speakers gave an oral presentation on the above topic:

Jacob Langness, PharmD: University of Colorado

Gregory Everson, MD: University of Colorado

Nancy Steinforth: HepC Connection

Dr. G Everson asked if the process can be simplified utilizing an electronic record. R Lodge responded that at this point, the Department does not have technological capabilities to systematically organize the approval of Hepatitis C Prior Authorization Requests via electronic records. He described the Department's current capacity. The criteria for Hepatitis C was the first to be reviewed. R Lodge announced that based on the recommendations enclosed in the letter received from the University of Colorado, amendments were made to the criteria. The DUR Board made a recommendation to simplify the process when possible.

A motion to approve the above criteria with the highlighted amendments was made by P Reiter and seconded by R Kant and the motion passed.

7. The meeting was adjourned at 9:18 PM

There being no further business, P Reiter made a motion to adjourn. R Kant seconded. The meeting adjourned at 9:18 PM.

I, Karen Weber, DO, 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: _____
Karen Weber, DO, Committee Chair

Date: _____

By: _____

Reasonable accommodations will be provided upon request for persons with disabilities. Please notify the DUR Coordinator Robert Lodge at 303- 866-3105 or or email him at Robert.lodge@state.co.us at least one week prior to the meeting.

