



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 17, 2014 7:00 PM to 9:00 PM

1. Call to Order

The meeting was officially called to order at 7:02 PM by S Johnson.

2. Roll Call

The Board Coordinator called the roll. There were sufficient members for a quorum with seven members participating and two members excused.

A. Members Present: LeWayne Garrison R.Ph, Sam Johnson, PharmD, James 'Rick' Kant, RPh., Karen Weber D.O., Pam Reiter, PharmD, Edra Weiss, M.D., David Block (Industry Representative)

B. Medicaid Pharmacy Staff: Medicaid Pharmacy Department: Cathy Traugott, R.Ph, J.D., Gina Moore, PharmD, Robert Page, PharmD, Nila Mahyari, PharmD

C. Members Excused: Deborah Lehman, M.D., James R. Regan, M.D., Robert Lodge, PharmD

3. 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 L Garrison. R Kant seconded the motion. The minutes were approved.

4. Department Updates

Cathy Traugott, HCPF Pharmacy Clinical Supervisor, made an announcement regarding the Department's position on Hepatitis C and the need for interim criteria to allow immediate use of two new medications. Cathy also mentioned that, pursuant to Department rules, this class of medication was not up for review until August 2015; however, due to high demands and the unique situation with hepatitis C drugs, the DUR board will be reviewing Viekira Pak and Harvoni 6 months earlier than required. She

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outlined various HCPF efforts in helping infected beneficiaries as well as the constant effort to treat as many patients as possible. She explained that due to the heavy cost burden, safety concerns associated with newly released medications and the ever changing landscape of hepatitis C treatment, it is also important to consider the Department’s obligation to manage expenditures in a fiscally responsible way. Cathy stated that at this time, the Department will focus on patients who have disease that has progressed to a level that cannot wait any longer for treatment.

5. Open Comments

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: None preferred including vials and pens

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2014	November 2014	December 2014
Humalog Vial	37%	36%	36%
Humalog Pen	22%	25%	25%
Novolog Pen	21%	20%	20%
Novolog Vial	19%	19%	19%
Apidra Vial	<1%	<1%	<1%
Apidra Solstar	<1%	<1%	<1%

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2014	November 2014	December 2014
Humulin R Vial	97%	98%	99%
Novolin R Vial	<1%	1%	<1%
Relion Novolin R Vial	2%	<1%	<1%
Relion Humulin R Vial	<1%	0%	0%

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2014	November 2014	December 2014
Humulin N vial	89%	90%	87%
Humulin N Pen	8%	6%	11%
Novolin N Vial	2%	3%	1%
Relion Novolin N Vial	1%	<1%	<1%



Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2014	November 2014	December 2014
Levemir Flextouch	26%	43%	49%
Levemir Vial	41%	41%	38%
Levemir Flexpen	22%	5%	2%
Lantus Solostar	6%	5%	6%
Lantus Vial	5%	5%	5%

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2014	November 2014	December 2014
Novolin 70/30 Vial	37%	37%	35%
Humulin 70/30 Vial	23%	22%	25%
Novolog 70/30 Flexpen	17%	14%	16%
Novolog 70/30 Vial	6%	7%	7%
Humalog 75/25 Kwikpen	6%	8%	5%
Humalog 70/30 Kwikpen	6%	6%	7%
Novolog 70/30 Vial	6%	7%	7%
Humalog 50/50 Vial	<1%	<1%	<1%
Humalog Kwikpen	<1%	<1%	<1%

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 R Kant, seconded by K Weber, and the motion passed.

2. Alzheimer’s Agents

Preferred: Donepezil
Donepezil ODT

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Galantamine
Galantamine ER
Namenda IR

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2014	November 2014	December 2014
Donepezil	60%	63%	61%
Namenda	24%	22%	25%
Exelon Patch	6%	5%	3%
Namenda XR	5%	5%	3%
Donepezil ODT	1%	2%	2%
Aricept	1%	0%	<1%
Galantamine	<1%	2%	2%
Rivastigmine	<1%	<1%	<1%
Galantamine ER	0%	0%	<1%

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, seconded by L Garrison, and the motion passed.

3. Atypical Antipsychotics

- Preferred:
- Abilify®
 - Abilify ODT®
 - Clozaril®
 - Clozapine
 - Geodon®
 - Latuda®
 - Olanzapine



Risperdal®
 Risperidone
 Risperidone ODT
 Quetiapine
 Seroquel IR®
 Ziprasidone
 Zyprexa®

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2014	November 2014	December 2014
Abilify	25%	24%	25%
Quetiapine	23%	24%	24%
Risperidone	20%	20%	19%
Olanzapine	11%	12%	12%
Clozapine	4%	4%	4%
Ziprasidone	5%	5%	5%
Seroquel	3%	3%	3%
Latuda	2%	2%	3%
Invega ER	2%	2%	2%
Saphris	1%	1%	1%
Risperidone ODT	1%	1%	1%
Risperdal	<1%	<1%	<1%
Zyprexa	<1%	<1%	<1%
Olanzapine ODT	<1%	<1%	<1%
Invega Sustenna	<1%	<1%	<1%
Geodon	<1%	<1%	<1%
Fanapt	<1%	<1%	<1%
Fazaclo	<1%	<1%	<1%
Clozaril	<1%	<1%	<1%
Zyprexa Zydis	<1%	<1%	<1%

Prior Authorization Criteria:

Non-preferred products will only be approved for their FDA approved indications and age limits and only if the 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 Nonpreferred 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	6-17 years	15mg/day
	Bipolar Disorder/Mixed	10-17 years	30mg/day
	Mania	13-17 years	30mg/day
	Schizophrenia	6-17 years	20 mg/day



	Gilles de la Tourette's syndrome		
Clozapine (Fazaclo®, Clozaril®)	NOT APPROVED		
Iloperidone (Fanapt®)			
Lurasidone (Latuda®)			
Olanzapine (Zyprexa®)	Schizophrenia Bipolar Disorder/Mixed Mania	13-17 years	10mg/day
Olanzapine (Zyprexa Zydis®)		13-17 years	10mg/day
Paliperidone (Invega ER®)	Schizophrenia	12-17 years	12mg/day
Risperidone (Risperdal®)	Autism/Psychomotor Agitation Bipolar Disorder/Mixed Mania Schizophrenia	5-16 years	3mg/day
		10-17 years	6mg/day
		13-17 years	6mg/day
Quetiapine Fumarate (Seroquel®)	Schizophrenia Bipolar Disorder/Mixed Mania	13-17 years	800 mg/day
		10-17 years	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:

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

4. Growth Hormones

Preferred: Genotropin®

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2014	November 2014	December 2014
Norditropin Flexpro	88%	85%	88%
Saizen	5%	6%	5%
Omnitrope	5%	6%	4%
Norditropin Nordiflex	1%	3%	2%
Humatrope	1%	<1%	<1%

Prior Authorization Criteria:

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

- Member failed treatment with Genotropin 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:

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

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- Michelle Fazio, US Bioservices, Growth Hormone
- Jignesh Patel, Novonodisk, Growth Hormone
- Marybel Good, Parent Advocate, Growth Hormone

E Weiss made a motion to grandfather those that are currently on the medication. R Kant asks the reason for covering the current users. K Weber inquires about the product differences among Norditropin and Genotropin. C Traugott addressed this question with details regarding the storage and handling as well as device differences among the products. L Garrison inquired about the length of time that members will be asked to change. E Weiss commented regarding the storage differences as well as dose accuracy concerns for those under 30 kg. P Reiter suggested that we have a weight cutoff to address the issues of dose accuracy and K Weber requested more time for this change to occur.

A motion to approve the criteria above including highlighted amendments was made by R Kant, seconded by L Garrison, opposed by K Weber and abstained by E Weiss. The motion passed.

5. Intranasal Steroids

Preferred: Fluticasone Propionate
Nasonex®

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2014	November 2014	December 2014
Fluticasone Spray	81%	82%	82%
Nasonex	10%	9%	9%
Budesonide	7%	7%	8%
Dymista	<1%	<1%	<1%
Qnasl	<1%	<1%	<1%
Veramyst	<1%	<1%	<1%
Zetonna	<1%	<1%	<1%
Omnaris	<1%	<1%	<1%
Rhinocort AQ	<1%	<1%	<1%
Flunisolide	<1%	<1%	<1%
Beconase AQ	<1%	<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.



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

Discussion:

A motion to approve the above criteria was made by E Weiss and seconded by P Reiter, and the motion passed.

6. Leukotriene Modifiers

Preferred: Montelukast®

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2014	November 2014	December 2014
Montelukast	99%	99%	99%
Singulair	<1%	<1%	<1%
Zafirlukast	<1%	<1%	<1%
Zyflo CR	<1%	<1%	<1%

Prior Authorization Criteria:

Non-preferred leukotriene modifiers will be approved if **both** of the _____

_____ following criteria are met:

- 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 P Reiter seconded by K Weber, 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 2014	November 2014	December 2014



Copaxone	26%	27%	30%
Tecfidera	26%	23%	24%
Rebif	11%	11%	11%
Ampyra	13%	13%	12%
Avonex	11%	13%	12%
Gilenya	7%	7%	6%
Betaseron	2%	2%	2%
Aubagio	3%	4%	4%
Extavia	<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).

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 a 20% 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 (3 month trial), drug-drug interaction, or lack of efficacy (6 month trial) OR
 - In members with a contraindication to GILENYA, has failed COPAXONE or a preferred interferon product. Failure will be defined as intolerable side Effects (3 month trial), drug-drug interaction, or lack of efficacy (6 month trial). 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 (3 month trial), drug-drug interaction, or lack of efficacy (6 month trial) OR
 - In members with a contraindication to GILENYA, has failed COPAXONE or a preferred interferon product. Failure will be defined as intolerable side Effects (3 month trial), drug-drug interaction, or lack of efficacy (6 month trial). 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 (3 month trial), drug-drug interaction, or lack of efficacy (6 month trial). 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 within 3-4 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 individuals provided comment to the Board on the above topic:

- Dr. Corboy, University of Colorado, MS Products
- Leila kackson, Teva, Copaxone
- Rae Ann Maxwell, Biogen, MS Products

After discussion surrounding the T25FW assessment appropriateness, a motion was made by P Reiter to modify this requirement to state member has improvements in ADL. Seconded by R Kant, the motion passed. There was further discussion regarding changing T1, T2 lesions to state "any new lesion" and the 6 month trial to a 3 month trial.

A motion to approve the criteria above including highlighted amendments was made by R Kant, seconded by K Weber. The motion passed.



8. Sedative Hypnotics

Preferred: Eszopiclone
 Zaleplon
 Zolpidem

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2014	November 2014	December 2014
Zolpidem	97%	97%	97%
Zaleplon	2%	2%	21%
Rozerem	1%	1%	1%
Lunesta	<1%	<1%	<1%
Ambien	<1%	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 for narcolepsy AND

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:

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

- Ralph Gualtieri, Merck, Belsomra

There was discussion surrounding the absence of drug interactions with Belsomra and moderate CYP3A4 inhibitors and drug interactions only existing with strong CYP3A4 inhibitors.

A motion to approve the criteria above including highlighted amendments was made by P Reiter, seconded by R Kant. 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 2014	November 2014	December 2014
Atorvastatin	44%	45%	45%
Simvastatin	29%	28%	28%
Crestor	13%	15%	14%
Pravastatin	13%	13%	13%
Fluvastatin	<1%	<1%	<1%
Lipitor	<1%	<1%	<1%
Lovastatin	<1%	<1%	<1%
Livalo	<1%	<1%	<1%
Simcor	<1%	<1%	<1%
Vytorin	<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 R Kant, seconded by E Weiss, and the motion passed.

10. Ophthalmic Allergy

Preferred: Cromolyn
 Patanol®
 Pataday®

Medication	Percentage of Market Share Based on Number of Claims for Therapeutic Class		
	October 2014	November 2014	December 2014
Pataday	52%	51%	52%
Patanol	27%	26%	25%
Cromolyn	3%	3%	4%
Ketotifen	<1%	<1%	<1%
Epinastine	<1%	0%	<1%
Bepreve	<1%	<1%	<1%

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 R Kant seconded by K Weber, and the motion passed.

11. Harvoni (Ledipasvir and Sofosbuvir)-Interim Criteria

Will be approved on a case by case basis

Will be evaluated based on the following interim criteria:

1. Physician attests that the member’s health will be significantly impacted if treatment is delayed until October 2015 AND



2. Physician attests to the member's readiness for adherence AND
3. Must have chronic Hepatitis C (HCV) genotype 1a or 1b AND
4. Member is 18 years of age and older AND
5. Member does not have hepatitis B or human immunodeficiency virus (HIV) AND
6. Women of childbearing potential and their male partners must use two forms of effective (non-hormonal) contraception during treatment. Initial pregnancy test must be performed prior to beginning therapy AND
7. Harvoni is prescribed by or in conjunction with an infectious disease specialist, gastroenterologist, or hepatologist AND
8. Meets one of the following categories based on liver biopsy or other accepted test:
 - 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 compensated cirrhosis defined by one of the following: Child-Turcotte Pugh class A or B (Score 5-9 ascites), hepatic encephalopathy, or variceal bleeding.
 - Transplant members with fibrosing cholestatic HCV or recipient who have cirrhosis from recurrent HCV and have been approved for re-transplantation.
 - Member is listed on the transplant list with a projected time to transplant of < 1 year.
 - Member has a Metavir fibrosis score of 3-4, or equivalent using a widely recognized test.
9. Members may be treatment naïve or treatment experienced, except with a direct-acting antiviral (DAA) AND
10. The member does not have severe renal impairment (eGFR<30 ml/min/1.73m²), end state renal disease, on hemodialysis AND
11. Member must be 6 months free of: alcohol; and Schedule I controlled substance (including marijuana), and cocaine, opiate, benzodiazepine, and barbiturate misuse/abuse as documented by appropriate drug screens and counseled about the importance of refraining from drug and/or alcohol abuse. Routine substance/alcohol/opioid screens must be conducted monthly for members that have a history (within the past 2 years) of drug or alcohol abuse AND
12. The member is not taking a p-glycoprotein inducer (e.g., rifampin, St. John's wort, digoxin, carbamazepine, antacid, H₂ receptor antagonist, proton pump inhibitor, rosuvastatin, simeprevir, or tenofovir or ritonavir-containing regimens) AND
13. Member must have a baseline HCV RNA level within 30 days of anticipated start date AND



14. All approvals will initially be for an 8 week time period, with further approvals dependent on the submission of the HCV RNA level at 4, at week 12, and week 24 to rational drug therapy (see discontinuation criteria) AND
15. If the week 4 HCV RNA is detectable (≥ 25 copies) while on Harvoni therapy, HCV RNA will be reassessed in 2 weeks. If the repeated HCV RNA level has increased (i.e., $>1 \log_{10}$ IU/ml from nadir), all treatment will be discontinued unless documentation is provided to support continuation of therapy AND
16. Must be in accordance to approved regimens and duration (see Table 1) AND
17. **Must** be adherent to treatment regimen (see discontinuation criteria) AND
18. Must have received or planning to receive full courses of both Hepatitis A and Hepatitis B vaccinations.

Note: Once treated, the Department will only cover a once per lifetime treatment with any DAA.

Discontinuation Criteria:

- Members receiving a Sofosbuvir-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 documents non-adherence to filling their Harvoni prescription (e.g. within 7 days), 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 to continue receiving treatment for HCV.

Quantity and Refill Limits:

Quantity Limit: one ledipasvir 90 mg/sofosbuvir 400 mg tablet per day (28 tablets/28days)

Length of authorization: Based on HCV subtype

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.

Table 1. Recommended Regimens and Treatment Duration for Harvoni

HCV Genotype and Comorbidities	Treatment	Duration
Treatment naïve with or without compensated cirrhosis	Harvoni	12 weeks



Treatment-experienced without compensated cirrhosis	Harvoni	12 weeks
Treatment-experienced with compensated cirrhosis	Harvoni	24 weeks

Discussion:

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

- Michelle Puyear, Gilead HepC
- Jacob Langness, University of Colorado, HepC
- Nancy Steinfurth, HepC Connection, HepC

A motion to approve the above criteria was made by R Kant seconded by K Weber, and the motion passed.

12. Viekira Pak (Ombitasvir, Paritaprevir, Ritonavir, and Dasabuvir) -Interim Criteria

Will be approved on a case by case basis until final criteria are effective

Will be evaluated based on the following interim criteria:

19. Physician attests that the member’s health will be significantly impacted if treatment is delayed until October 2015 AND
20. Physician attests to the member’s readiness for adherence AND
21. Must have chronic Hepatitis C (HCV) genotype 1a or 1b AND
22. Member is 18 years of age and older AND
23. Women of childbearing potential and their male partners must use two forms of effective (non-hormonal) contraception during treatment. Initial pregnancy test must be performed prior to beginning therapy AND
24. Viekira Pak is prescribed by or in conjunction with an infectious disease specialist, gastroenterologist, or hepatologist AND
25. Meets one of the following categories based on liver biopsy or other accepted test:
 - 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 compensated cirrhosis defined by one of the following: Child-Turcotte Pugh class A or B (Score 5-9 ascites), hepatic encephalopathy, or variceal bleeding
 - Transplant members with fibrosing cholestatic HCV or recipient who have cirrhosis from recurrent HCV and have been approved for re-transplantation



- Member is listed on the transplant list with a projected time to transplant of < 1 year (genotype: 1 naïve or 1 experienced)
 - Member has a Metavir fibrosis score of 3-4, or equivalent using a widely recognized test.
26. Members may be treatment naïve or treatment experienced, except with a direct-acting antiviral (DAA) AND
 27. Members may be HIV positive AND
 28. The member does not have severe hepatic impairment, decompensated liver disease, end-stage renal disease requiring hemodialysis, or will be taking strong CYP3A4 and CYP2C8 inducers, estradiol-containing agents, including contraceptives, or strong CYP2C8 inhibitor medications concurrently AND
 29. Member must be 6 months free of: alcohol; and Schedule I controlled substance (including marijuana); and cocaine, opiate, benzodiazepine, and barbiturate misuse/abuse as documented by appropriate drug screens and counseled about the importance of refraining from drug and/or alcohol abuse. Routine substance/alcohol/opioid screens must be conducted monthly for members that have a history (within the past 2 years) of drug or alcohol abuse AND
 30. Member must have baseline HCV RNA and ALT levels within 30 days of anticipated start date AND
 31. All approvals will initially be for a 8 week time period, with further approvals dependent on the submission of the HCV RNA level at 4, at week 12, and week 24 to rational drug therapy (see discontinuation criteria) AND
 32. If the week 4 HCV RNA is detectable while on Viekira Pak therapy, HCV RNA will be reassessed in 2 weeks. If the repeated HCV RNA level has increased (i.e., >1 log₁₀ IU/ml from nadir) all treatment will be discontinued unless documentation is provided to support continuation of therapy AND
 33. Must be in accordance to approved regimens and duration (see Table 1) AND
 34. Must be adherent to treatment regimen **AND** prescriber to consider enrolling member in the proCeed program (by phone: 1-844-2proCeed or online at: <https://www.viekira.com/proceed-program>) to re-enforce adherence AND
 35. Must have received or planning to receive full courses of both Hepatitis A and Hepatitis B vaccinations.

Note: Once treated, the Department will only cover a once per lifetime treatment with any DAA.

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 documents non-adherence to filling their Viekira Pak prescription (e.g. within 7 days), 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 to continue receiving treatment for HCV.

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

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.

Table 1. Recommended Regimens and Treatment Duration for Viekira Pak

HCV Genotype and Comorbidities (Mono-infected and HCV/HIV-1 Co-infected)	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

Discussion:

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

- Moira Hagen, Abbvie, HepC

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



6. Rules

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.

7. The meeting was adjourned at 9:38 p.m.

The meeting adjourned at 9:38 PM.

I, Sam Johnson, PharmD, 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.

