



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

May 24, 2015 7:00 PM to 9:00 PM

1. Call to Order

The meeting was officially called to order at 7:02 PM by K Weber.

2. Roll Call

The Board Coordinator called the roll. There were sufficient members for a quorum with 1 member excused and one open, unfilled position.

A. Members Present: LeWayne Garrison, RPh, Laura Borgelt, PharmD, Pam Reiter, PharmD, Karen Weber, DO, Sheila Botts, PharmD, Kerstin Froyd, MD

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

C. Members Excused: James Regan, MD

3. Approval of Minutes

After an introduction of DUR Board members, R Page asked if there were any changes or needed discussion of the minutes from the last meeting. A motion was passed to approved the minutes by K Froyd and seconded by S Botts. The motion passed with one abstention from L Borgelt.

4. Department Updates

R Lodge introduced new member present at meeting, Laura Borgelt, and announced the remaining open positions on the DUR Board: one physician and one industry representative position.

R Lodge stated that the HCPF Department software system was undergoing changes in vendor from Xerox to Magellan.

R Lodge gave updates on Hepatitis C drugs as well as Multiple Sclerosis agents. P Reiter inquired about the possibility to review hepatitis C agents during a separate meeting for



the August review of these agents. R Lodge informed the board that he would explore this option.

5. Rules

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

R Page 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

1. Newer Generation Antihistamines/Antihistamine Combinations

Preferred: Loratadine
Cetirizine

Utilization:

Medication	Percentage of Market Share for Therapeutic Class: Antihistamines		
	Brand / Generic	Total Claims	Total Days Supplied
fexofenadine	Generic	0.52%	0.58%
fexofenadine children’s	Generic	0.04%	0.06%
loratadine children’s	Generic	3.54%	4.25%
desloratadine	Generic	0.05%	0.05%
loratadine	Generic	23.07%	21.96%
loratadine ODT	Generic	0.01%	0.01%
levocetirizine	Generic	0.95%	1.01%
XYZAL (levocetirizine)	Brand	0.01%	0.01%



cetirizine	Generic	71.80%	72.07%
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Medication	Percentage of Market Share for Therapeutic Class: Antihistamine Combinations		
	Brand / Generic	Total Claims	Total Days Supplied
fexofenadine/PSE	Generic	16.95%	16.67%
loratadine/PSE	Generic	76.27%	75.00%
cetirizine/PSE	Generic	6.78%	8.33%

PSE: pseudoephedrine

Prior Authorization Criteria:

Non-preferred antihistamines and antihistamine/decongestant combinations will be approved for members who have failed treatment with two preferred products in the last 6 months. For members with respiratory allergies, an additional trial of intranasal corticosteroid will be required in the last 6 months.

Discussion:

Recommendation from DUR Board Committee: List agents in utilization tables based on market share. A motion to approve the above criteria with the highlighted amendments was made by P Reiter and seconded by L Borgelt and the motion passed.

2. Angiotensin Receptor Blockers/ARB Combinations

- Preferred:
- Irbesartan
 - Benicar® (olmesartan)
 - Valsartan
 - Losartan
 - Benicar -HCT® (olmesartan/HCTZ)
 - Diovan-HCT® (valsartan/HCTZ)
 - Losartan-HCTZ

Utilization:

Medication	Percentage of Market Share for Therapeutic Class: ARBs		
	Brand / Generic	Total Claims	Total Days Supplied
candesartan	Generic	0.14%	0.15%
irbesartan	Generic	4.33%	4.22%
AVAPRO (irbesartan)	Brand	0.06%	0.05%
BENICAR (olmesartan)	Brand	5.61%	6.15%
losartan	Generic	81.23%	79.85%
DIOVAN (valsartan)	Brand	8.38%	9.25%
valsartan	Generic	0.16%	0.21%
EDARBI (azilsartan)	Brand	0.01%	0.02%



telmisartan	Generic	0.05%	0.06%
MICARDIS (telmisartan)	Brand	0.02%	0.03%
eprosartan	Generic	0.02%	0.03%

Medication	Percentage of Market Share for Therapeutic Class: ARB Combinations		
	Brand / Generic	Total Claims	Total Days Supplied
BENICAR HCT (omesartan/hctz)	Brand	10.67%	11.37%
DIOVAN HCT (valsartan/hctz)	Brand	13.19%	15.25%
valsartan/hctz	Generic	0.17%	0.11%
EDARBYCLOR (azilsartan/chlorthalidone)	Brand	0.20%	0.28%
amlodipine/valsartan	Generic	0.11%	0.17%
EXFORGE (amlodipine/valsartan)	Brand	0.07%	0.04%
amlodipine/valsartan/hctz	Generic	0.12%	0.13%
EXFORGE HCT (amlodipine/valsartan/hctz)	Brand	0.07%	0.11%
losartan/hctz	Generic	74.35%	71.36%
telmisartan/hctz	Generic	0.31%	0.26%
TRIBENZOR (olmesartan/amlodipine/hctz)	Brand	0.32%	0.44%
amlodipine/telmisartan	Generic	0.05%	0.04%

HCTZ: hydrochlorothiazide

Medication	Percentage of Market Share for Therapeutic Class: Renin Inhibitors and Combinations		
	Brand / Generic	Total Claims	Total Days Supplied
TEKTURNA (aliskiren)	Brand	100%	100%

HCTZ: hydrochlorothiazide

Prior Authorization Criteria:

Non-preferred ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products will be approved for members who have failed treatment with three preferred products in the last 12 months (Failure is defined as lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction.).

Renin inhibitors and combinations will not be approved in patients with diabetes. Renin inhibitors are contraindicated when used in combination with an ACE-inhibitor, ACE-inhibitor combination, ARB, or ARB-combination.

Grandfathering: Members currently stabilized on non-preferred agents



can receive approval to continue on that agent for one year if medically necessary. Verification may be provided from the prescriber or pharmacy

Discussion:

After discussion regarding the rewording of the statement above to eliminate confusion, a motion to approve the above criteria with highlighted amendments was made by K Froyd and seconded by P Reiter and the motion passed.

3. Fibromyalgia Agents

Preferred: Lyrica® (Pregabalin)
Duloxetine

Utilization:

Medication	Percentage of Market Share for Therapeutic Class: Fibromyalgia Agents		
	Brand / Generic	Total Claims	Total Days Supplied
duloxetine	Generic	43.86%	41.61%
CYMBALTA (duloxetine)	Brand	1.08%	1.00%
LYRICA (pregabalin)	Brand	53.38%	55.75%
SAVELLA (milnacipran)	Brand	1.68%	1.64%

Prior Authorization Criteria:

Non-preferred agents will be approved for fibromyalgia if member has failed an adequate trial (8 weeks) of both Lyrica and duloxetine OR the member has contraindication to Lyrica and duloxetine

For members with no epilepsy diagnosis in the last two years (as confirmed by SMART PA), PA will be required for LYRICA prescriptions requiring more than 3 capsules per day or for prescriptions requiring doses greater than 600mg per day.

GENERIC DULOXETINE will be approved if the member has diagnosis for fibromyalgia

Discussion:

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

4. Long Acting Opiates

Preferred: Methadone
Morphine ER
Fentanyl Patches
Tramadol ER



One-step: Butrans

Utilization:

Medication	Percentage of Market Share for Therapeutic Class: Long-Acting Opioids		
	Brand / Generic	Total Claims	Total Days Supplied
morphine (Avinza)	Generic	0.09%	0.09%
AVINZA (morphine)	Brand	0.01%	0.01%
BUTRANS (buprenorphine)	Brand	1.49%	1.50%
CONZIP (tramadol)	Brand	0.01%	0.01%
fentanyl	Generic	20.32%	20.16%
DURAGESIC (fentanyl)	Brand	0.02%	0.02%
EMBEDA (morphine/naltrexone)	Brand	0.07%	0.07%
hydromorphone ER	Generic	0.48%	0.45%
HYSINGLA (hydrocodone ER)	Brand	0.36%	0.33%
morphine ER	Generic	0.27%	0.27%
KADIAN (morphine ER)	Brand	0.03%	0.03%
methadone	Generic	12.24%	12.62%
morphine sulfate ER	Generic	45.71%	46.17%
MS ER (morphine sulfate ER)	Brand	0.01%	0.02%
NUCYNTA ER (tapentadol)	Brand	0.58%	0.55%
oxymorphone ER	Generic	0.66%	0.63%
OPANA ER (oxymorphone ER)	Brand	0.60%	0.60%
OXYCONTIN (oxycodone ER)	Brand	13.52%	13.10%
oxycodone ER	Generic	1.74%	1.63%
tramadol ER	Generic	1.64%	1.60%
XARTEMIS (oxycodone/APAP)	Brand	0.03%	0.03%
ZOXYDRO (hydrocodone ER)	Brand	0.09%	0.09%

APAP: Acetaminophen

Prior Authorization Criteria:

Non-preferred, long-acting oral opioids will be approved for members who have failed treatment with two preferred agents in the last six months. (Failure is defined as lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction.)

Fentanyl patches will require a PA for doses of more than 1 patch/2 days.

BUTRANS will be approved for members who have failed treatment with ONE preferred agent in the last six months. (Failure is defined as lack of efficacy, allergy, intolerable side effects, contraindication



to, or significant drug-drug interaction.)

ZOHYDRO ER® and HYSINGLA ER ®and OXYCONTIN (new starts) will be approved for members who have failed treatment with two preferred products, AND at least one other long acting opiate in the past year.

OXYCONTIN®, OPANA ER®, NUCYNTA ER®, and ZOHYDRO ER® will only be approved for twice daily dosing.

No more than one long acting opioid will be approved at one time.

Medicaid is not mandating that a patient switch from a non-preferred drug to methadone. Methadone requires special training due to its complex pharmacokinetic profile. However, if a patient has tried methadone in the past, then it may be considered one trial of one preferred drug.

Use of opioid analgesics during pregnancy has been associated with neonatal abstinence syndrome. Providers MUST counsel women of childbearing age regarding the risks of becoming pregnant while receiving opioids, including the risk of neonatal abstinence syndrome. Providers should offer access to contraceptive services when necessary.

For all prior authorization requests for opiate agents, provider must attest to counseling provided to women of childbearing age.

The total daily limit of milligrams of morphine equivalents will be 300mg effective 2/17/2016. This includes opioid-containing products where conversion calculations are applied. Prescriptions that cause the member's drug regimen to exceed the maximum daily limit of 300 milligrams of morphine equivalents (MME) will be denied. This does not currently include methadone prescriptions.

Prior authorizations will be granted to allow for tapering.

- Diagnosis of sickle cell anemia will receive a preemptive PA for lifetime.
- A one year PA will be granted for admission to or diagnosis of hospice or end of life care.
- A one year PA will be granted for pain associated with cancer.
- Medicaid provides guidance on the treatment of pain, including tapering, on our website Pain Management Resources and Opioid Use at www.Colorado.gov/hcpf then search Pain Management.
- Only one long-acting oral opioid agent (including different strengths) and one short-acting opioid agent (including different strengths) will be considered for a prior authorization.

Discussion:

The following speakers provided testimony:

Alex Reish, DO

There was discussion surrounding the increase in utilization of Butrans patches. K Froyd pointed out the need for inclusion of Oxycontin in the category of Zohydro ER and Hysingla ER above. K Weber made a recommendation to include a statement about members of child bearing age and the risks associated with pregnancy. K Froyd inquired about the lack of restrictions placed on sickle cell patients and stated



the high risk of overdose. The group agreed that this group’s exclusion from being prompted to decrease opioids is inappropriate.

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

5. Inhaled Anticholinergics/Anticholinergic Combinations

- Preferred: Albuterol/Ipratropium
 Ipratropium
 Atrovent HFA®(ipratropium)
 Combivent Respimat ® (albuterol/Ipratropium)
 Spiriva Handihaler® (tiotropium)

Utilization:

Medication	Percentage of Market Share for Therapeutic Class: Inhaled Anticholinergics		
	Brand / Generic	Total Claims	Total Days supplied
Ipratropium bromide	Generic	2.75%	5.16%
ATROVENT INHALER (ipratropium bromide)	Brand	8.59%	9.81%
INCRUSE ELLIPTA (umeclidinium)	Brand	0.14%	0.12%
SPIRIVA HANDIHALER (tiotropium)	Brand	85.46%	81.54%
SPIRIVA RESPIMAT (tiotropium)	Brand	1.81%	1.92%
TUDORZA (aclidinium bromide)	Brand	1.26%	1.45%

Medication	Percentage of Market Share for Therapeutic Class: Inhaled Inhaled Anticholinergic Combinations		
	Brand / Generic	Total Claims	Total Days Supplied
ANORO ELLIPTA (umeclidinium/vilanterol)	Brand	1.93%	1.53%
COMBIVENT (ipratropium bromide/albuterol)	Brand	61.79%	48.62%
Ipratropium bromide/albuterol	Generic	36.28%	49.85%

Prior Authorization Criteria:

Non-preferred anticholinergic inhalants and anticholinergic combination inhalants will require a brand-name PA stating medical necessity



ATROVENT® and DUONEB ® will require a brand-name prior Authorization stating medical necessity.

SPIRIVA RESPIMAT ® will be approved for members with a diagnosis of asthma requiring the use of this drug for maintenance therapy

Non-preferred anticholinergic agents will be approved for members with a diagnosis of COPD including chronic bronchitis and/or emphysema who have failed treatment with Spiriva Handihaler® (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction), or who have a contraindication to Spiriva Handihaler.

Non-preferred combination anticholinergic agents will be approved for members with a diagnosis of COPD including chronic bronchitis and/or emphysema AND has failed treatment with Combivent Respimat® (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction), OR who have a contraindication to Combivent Respimat®.

Discussion:

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

6. Short Acting Inhaled Beta-2 Agonists

Preferred: Albuterol solution
Proair HFA® (albuterol)

Utilization:

Medication	Percentage of Market Share for Therapeutic Class: Short-Acting Inhaled Beta-2 Agonists		
	Brand / Generic	Total Claims	Total Days Supplied
albuterol (AccuNeb)	Generic	0.61%	1.15%
albuterol	Generic	8.84%	14.23%
PROAIR HFA INHALER (albuterol)	Brand	88.88%	83.03%
PROAIR RESPICLICK (albuterol)	Brand	0.01%	0.01%
PROVENTIL HFA INHALER (albuterol)	Brand	0.14%	0.13%
VENTOLIN HFA INHALER (albuterol)	Brand	0.75%	0.65%
levalbuterol	Generic	0.18%	0.25%



XOPENEX INHALER (levalbuterol)	Brand	0.61%	0.55%
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Prior Authorization Criteria:

Non-preferred, short acting beta2 agonists will be approved for members who have failed treatment with one preferred agent. (Failure is defined as: lack of efficacy, allergy, contraindication to, intolerable side effects, or significant drug-drug interaction).

Proair HFA, Proventil HFA, Ventolin HFA:

Quantity limits: 2 inhalers / 30 days

Discussion:

K Froyd inquired about the date that Proair will be removed from market and P Reiter suggested a step to address this change preemptively. R Lodge commented that the Department does not yet have a timeline but will address this with provider communication when we have a definitive date for market withdrawal. A motion to approve the above criteria was made by P Reiter and seconded by K Froyd and the motion passed.

7. Long Acting Inhaled Beta-2 Agonists

Preferred: **Serevent*® (salmeterol)**

Utilization:

Medication	Percentage of Market Share for Therapeutic Class: Long-Acting Inhaled Beta-2 Agonists		
	Brand / Generic	Total Claims	Total Days Supplied
ARCAPTA (indacaterol)	Brand	1.22%	1.48%
BROVANA solution (arformoterol)	Brand	14.61%	16.86%
FORADIL (formoterol)	Brand	23.47%	19.23%
PERFOROMIST (formoterol)	Brand	23.94%	26.33%
SEREVENT (salmeterol)	Brand	35.55%	34.62%
STRIVERDI RESPIMAT (olodaterol)	Brand	1.22%	1.48%

Prior Authorization Criteria:

SEREVENT ® will be approved for members with for members with moderate to very severe COPD.

Non-preferred agents will be approved for members with moderate to severe COPD, AND members must have failed a trial of SEREVENT (Failure is defined as: lack of efficacy, allergy, contraindication to, intolerable side effects, or significant drug-drug interaction).



****For treatment of members with diagnosis of asthma needing add-on therapy, please refer to preferred agents in combination Long-Acting Beta Agonist/Inhaled Corticosteroid. SEREVENT will not be approved for treatment of asthma in members needing add-on therapy due to safety risks associated with monotherapy.**

Discussion:

K Froyd made a motion to remove the indication of asthma for this drug category and insert language addressing the asthma population as outlined above. A motion to approve the above criteria with highlighted amendments was made by P Reiter and seconded by L Garrison and the motion passed.

8. Inhaled Corticosteroids

Preferred: Asmanex® (mometasone)
 Budesonide nebulas 0.25 mg and 0.5 mg
 Pulmicort (budesonide) nebulas 1 mg
 Flovent HFA® (fluticasone)
 Flovent diskus®(fluticasone)
 QVAR®(beclomethasone)

Utilization:

Medication	Percentage of Market Share for Therapeutic Class: Inhaled Corticosteroids		
	Brand / Generic	Total Claims	Total Days Supplied
ALVESCO (ciclesonide)	Brand	0.38%	0.49%
ARNUITY ELLIPTA	No Util	0.00%	0.00%
ASMANEX HFA INHALER (mometasone furoate)	Brand	0.02%	0.03%
ASMANEX TWISTHALER (mometasone furoate)	Brand	3.07%	3.14%
FLOVENT DISKUS (fluticasone)	Brand	2.63%	2.83%
FLOVENT HFA INHALER (fluticasone)	Brand	54.22%	54.38%
PULMICORT FLEXHALER (budesonide)	Brand	0.41%	0.42%
Budesonide respule	Generic	8.58%	11.06%
PULMICORT RESPULE	Brand	0.25%	0.31%
QVAR (beclomethasone dipropionate)	Brand	30.44%	27.36%

Prior Authorization Criteria:

Non-preferred inhaled corticosteroids will be approved in members with asthma who have failed



an adequate trial of two preferred agents
 An adequate trial is defined as at least 6 weeks.
 (Failure is defined as: lack of efficacy, allergy, contraindication to, intolerable side effects, or significant drug-drug interactions.)

PULMICORT FLEXHALER® will be approved for female members with asthma who have a new diagnosis of pregnancy.

BUDESONIDE NEBULIZER will only be approved for a maximal dose of 2mg/day.

Discussion:

N Mahyari presented the NHLBI 2007 guidelines for Management of Asthma via a focused summary on pharmacotherapy recommendations during pregnancy. A motion to approve the above criteria was made by L Garrison and seconded by K Froyd and the motion passed.

9. Inhaled Corticosteroid Combinations

Preferred: Advair Diskus ® (fluticasone/salmeterol)
 Dulera® (mometasone/formoterol)
 Advair HFA removed

Utilization:

Medication	Percentage of Market Share for Therapeutic Class: Inhaled Corticosteroid Combinations		
	Brand / Generic	Total Claims	Total Days Supplied
ADVAIR DISKUS (fluticasone/salmeterol)	Brand	53.70%	53.98%
ADVAIR HFA INHALER (fluticasone/salmeterol)	Brand	19.86%	20.27%
BREO ELLIPTA (fluticasone furoate/vilanterol)	Brand	0.23%	0.25%
DULERA (formoterol/mometasone)	Brand	21.73%	21.13%
SYMBICORT (budesonide/formoterol)	Brand	4.47%	4.37%

Prior Authorization Criteria:

Non-preferred inhaled corticosteroid combinations will be approved for members meeting both of the following criteria:

- Member has a qualifying diagnosis of asthma or COPD; and
- Member with a diagnosis of asthma has failed two preferred agents due to lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction.

Members with a diagnosis of COPD will only have to fail one preferred agent due to lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction.



Discussion:

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

10. Skeletal Muscle Relaxants

Preferred: Baclofen
Cyclobenzaprine
Tizanidine Tabs

Utilization:

Medication	Percentage of Market Share for Therapeutic Class: Skeletal Muscle Relaxants		
	Brand / Generic	Total Claims	Total Days Supplied
AMRIX (cyclobenzaprine)	Brand	0.07%	0.05%
dantrolene	Generic	0.15%	0.10%
cyclobenzaprine	Generic	55.80%	62.69%
baclofen	Generic	22.52%	18.02%
orphenadrine	Generic	0.15%	0.12%
chlorzoxazone	Generic	0.04%	0.04%
methocarbamol	Generic	1.08%	0.99%
metaxalone	Generic	0.47%	0.40%
carisoprodol	Generic	0.18%	0.17%
tizanidine	Generic	19.55%	17.43%

Prior Authorization Criteria:

All agents in this class will require a prior authorization for members 65 years of age and older. Approval will only be given if the member has had at least a 7-day trial with an opiate or has a diagnosis of spasticity. The maximum allowable approval will be for a 7-day supply.

Non-preferred skeletal muscle relaxants will be approved for members who have failed two preferred agents in the last 6-months.(Failure is defined as: lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions.)

Authorization for any CARISOPRODOL product will be given for a maximum 3-week one-time authorization for members with acute, painful musculoskeletal conditions who have failed treatment with three preferred products.



Discussion:

After discussion to remove the section addressing the tapering of carisoprodol, a motion to approve the above criteria was made by K Froyd and seconded by P Reiter and the motion passed.

11. Testosterone Products

- Preferred: Angrogel 1.62%®(Testosterone topical)
 Androderm® (Testosterone topical)
 Depo Testosterone® (Testosterone injection)
 Generic Depo® Testosterone (Testosterone injection)

Medication	Percentage of Market Share for Therapeutic Class: Testosterone Products		
	Brand / Generic	Total Claims	Total Days Supplied
ANDRODERM (testosterone)	Brand	5.06%	5.35%
ANDRODERM testosterone	Generic	4.61%	5.16%
ANDROGEL 1% (testosterone)	Brand	0.49%	0.60%
ANDROGEL 1.62% (testosterone)	Brand	27.28%	30.95%
AXIRON (testosterone)	Brand	2.41%	2.56%
DELATESTRYL testosterone	Generic	0.88%	1.17%
Depo-testosterone	Generic	55.15%	49.45%
DEPO-TESTOSTERONE	Brand	1.28%	1.28%
FORTESTA testosterone	Generic	0.46%	0.53%
TESTIM testosterone	Generic	2.23%	2.75%
TESTIM (testosterone)	Brand	0.15%	0.19%

Prior Authorization Criteria:

Hypogonadotropic or Primary Hypogonadism

Preferred androgenic drugs will be approved for members meeting the following:

1. Male patient \geq 18 years of age AND
2. Has a documented diagnosis of hypogonadotropic or primary hypogonadism (Patients with other diagnoses will require a manual review by a state pharmacist) AND
3. Has two documented low serum testosterone levels below the lower limit of normal range for testing laboratory prior to initiation of therapy AND
4. Does not have a diagnosis of breast or prostate cancer AND
5. Does not have a palpable prostate nodule or prostate-specific antigen (PSA) > 4ng/mL AND
6. Has normal liver function tests prior to initiation of therapy

Gender Transition

Preferred androgenic drugs will be approved for members meeting the following:

1. Biologically born female patient \geq 18 years of age* AND
2. Is undergoing female to male transition AND
3. Has a negative pregnancy test prior to initiation AND
4. Has normal liver function tests prior to initiation of therapy



*For members < 18 years of age, a manual review will be required.

Non-preferred androgenic drugs will be approved for patients meeting the above criteria with documented failure with an 8 week trial of a preferred androgenic drug (Failure is defined as lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction)

Grandfathering: Members may be grandfathered on preferred agents without requirement of updated low serum testosterone laboratory testing that meet the following criteria:

- Male patient \geq 18 years of age AND
- Has at least one past documented low serum testosterone levels below the lower limit of normal range for testing laboratory prior to initiation of therapy AND
- Has documented diagnosis of hypogonadotropic or primary hypogonadism AND
- Does not have a diagnosis of breast or prostate cancer AND
- Does not have a palpable prostate nodule or prostate-specific antigen (PSA) > 4ng/mL AND
- Has normal liver function tests prior to initiation of therapy

Discussion:

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

12. Topical Immunomodulators

Preferred: Elidel® (pimecrolimus)

Utilization:

Medication	Percentage of Market Share for Therapeutic Class: Topical Immunomodulators		
	Brand / Generic	Total Claims	Total Days Supplied
ELIDEL (pimecrolimus)	Brand	81.73%	80.64%
tacrolimus	Generic	18.27%	19.36%

Prior Authorization Criteria:

Manual review will be required for members needing \geq 6 weeks of therapy.

ELIDEL® will only be approved for a member who had an adequate trial (e.g, one month or longer) of a topical steroid and failed treatment. (Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions.)

Tacrolimus will only be approved for a member who had an adequate trial (e.g, one month or longer) of a topical steroid and ELIDEL® and failed treatment. (Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions.)



For members under 18 years of age, must be prescribed by or in conjunction with a pediatric dermatologist

Discussion:

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

13. Onfi (clobazam) [PI Enclosed]

ONFI® will be approved for members who meet the following criteria:

Member is > 2 years of age AND

Has a documented diagnosis of seizure AND

Is being prescribed by or in conjunction with a neurologist AND

Has failed a one month trial with three anticonvulsants (Failure is defined as: lack of efficacy, allergy, intolerable side effects contraindication to, or significant drug-drug interactions)

Discussion:

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

14. Taltz (ixekizumab)

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

Approval will be given for an initial 12 weeks and further authorization will be provided based on clinical response

Discussion:

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

15. Fentanyl Preparations:

**Short-acting: Actiq ® Fentora ® Onsolis ® Subsys ®
Long-acting: Duragesic ®**

Actiq, Fentora, Onsolis and Subsys: Approval will be granted for members experiencing breakthrough cancer pain and those that have already received and are tolerant to opioid drugs for the cancer pain AND are currently being treated with a long-acting opioid drug. The PA may be granted for up to 4 doses per day

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Duragesic Transdermal System: A PA is required for doses of more than 1 Patch/2 Days.

For all Fentanyl preparations: If the patient is in hospice or palliative care, the PA will be automatically granted regardless of the number of doses prescribed.

Discussion:

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

5. The meeting was adjourned at 9:12 p.m.

The meeting adjourned at 9:12 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: _____
K Weber, DO, 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.

