# **Alaska Medical Assistance DUR Committee Meeting Minutes**

Friday, November 15th, 2019

Frontier Building, 3601 C Street; Room 896

1:00pm

## **Drug Utilization Review Committee Attendees**

Members Present	Non-Members Present
Erin Narus, PharmD (DHSS)	Umang Patel, PharmD (Magellan)
Charles Semling, PharmD (DHSS)	Marti Padilla, PharmD, (Magellan)
Ryan Ruggles, PharmD	
Keri McCutcheon, RPh	
Barb Piromalli, DO	
Robert Carlson, MD	

## **Review of minutes from September 2019**

- Minutes approved by Barb Piromalli Do 2<sup>nd</sup>: Keri McCutcheon RPh.
- No changes or issues with previous minutes.

## **Review of Agenda**

Dr. Semling went over the Agenda to the committee members.

# **Overview of Medicaid Prescription and Cost Trends**

Dr. Semling reviewed the Alaska Medicaid prescription costs and trends.

In table 1. Below, we see that there was an increase in about \$700,000 or 6% increase in total amount paid since last year. PMPM increased 6% from October of last year. Increase is due to new biologics to market over the last year.

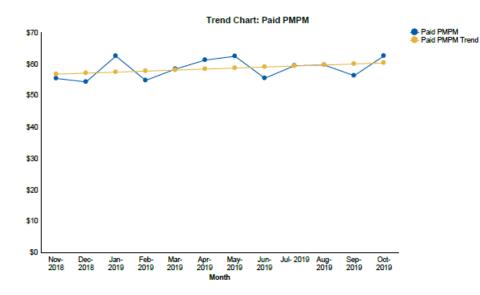
Data Source: ALASKA MEDICAID Service Date: Nov - 2018 to Oct - 2019

				Clinical Metrics - Annual Trend Repor	
Latest Month (Oot - 2019)	8MLY (Oot - 2018)	%SMLY*	Last 12 Months Average	Fiscal YTD++ (Jul - 2019 -> Oot - 2019)	
\$13,858,389.83	\$13,101,827.04	6%	\$13,101,533.19	\$53,147,405.89	
123,058	121,235	2%	117,028	478,274	
\$112.62	\$108.07	4%	\$111.95	\$111.59	
\$82.50	\$59.20	6%	\$58.58	\$59.53	
\$353.05	\$341.92	3%	\$343.43	\$347.50	
3.1	3.2	(1%)	3.1	3.1	
85.08%	82.12%	4%	84.48%	85.30%	
92.94%	91.76%	1%	92.58%	93.07%	
\$0.60	\$0.64	(7%)	\$0.61	\$0.60	
221,413	221,312	0%	223,845	802,840	
30,253	38,318	2%	38,140	152,944	
17.73%	17.31%	2%	17.08%	17.13%	
8.90%	10.96%	(18%)	9.37%	8.84%	
	(Oct - 2019) \$13,658,399.83 123,058 \$112.62 \$82.59 \$353.05 3.1 85.08% 92.04% \$0.80 221,413 39,253 17.73%	(Oof - 2018)         (Oof - 2018)           \$13,658,380,83         \$13,101,627.04           123,058         \$121,235           \$112,62         \$108,07           \$82,59         \$59,20           \$353,05         \$341,92           3.1         3.2           \$50,8%         \$2,12%           \$2,94%         91,76%           \$0,80         \$0,84           \$21,413         \$21,312           \$0,253         \$8,316           \$17,73%         \$17,31%	(Oot - 2018) (Oot - 2018)  \$13,658,380.83 \$13,101,627.04 694  123,058 \$12,235 294  \$112.62 \$108.07 4494  \$82.50 \$59.20 694  \$353.05 \$341.92 394  3.1 3.2 (1194)  85.0894 82.1294 4494  92.9494 91.7894 1194  \$0.60 \$0.84 (794)  221,413 221,312 094  30,253 38,318 294  17.3194 294	(Oof - 2018)         (Oof - 2018)         Average           \$13,658,380.83         \$13,101,627.04         6%         \$13,101,533.19           123,058         \$121,235         2%         \$17,028           \$112.62         \$108.07         4%         \$111.95           \$82.50         \$50.20         6%         \$58.58           \$353.05         \$341.92         3%         \$343.43           3.1         3.2         (1%)         3.1           \$5.06%         \$2.12%         4%         \$4.48%           \$0.29%         91.76%         1%         \$0.56%           \$0.60         \$0.64         (7%)         \$0.61           \$21,413         \$21,312         0%         \$23,645           \$0,253         \$8,316         2%         \$8,140           \$17,73%         \$17,31%         2%         \$17,06%	

Table 1.

Line graphs 1 and 2 below demonstrate that the PMPM/PUPM trend is flat.

Data Source : ALASKA MEDICAID Service Date: Nov - 2018 to Oct - 2019

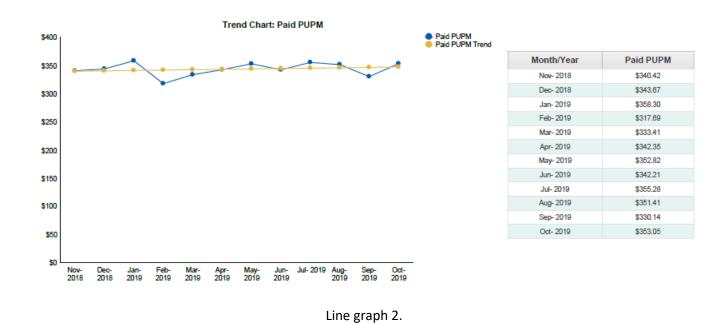


Month/Year	Paid PMPM
Nov- 2018	\$55.43
Dec- 2018	\$54.33
Jan- 2019	\$62.57
Feb- 2019	\$54.81
Mar- 2019	\$58.42
Apr- 2019	\$61.28
May- 2019	\$62.49
Jun- 2019	\$55.51
Jul- 2019	\$59.50
Aug- 2019	\$59.71
Sep- 2019	\$56.32
Oct- 2019	\$62.59

Line graph 1.

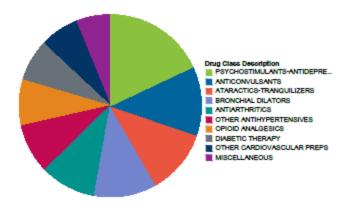
<sup>\* %</sup>SMLY = % Change between Latest Month and Same Month Last Year \*\* Fiscal YTD = Client Specific Fiscal Year

Data Source : ALASKA MEDICAID
Service Date : Nov - 2018 to Oct - 2019



Dr. Semling went over the top 10 therapeutic classes by volume and cost. See Pie Charts 1 and 2 below.

Data Source : ALASKA MEDICAID Service Date : Oct-2019

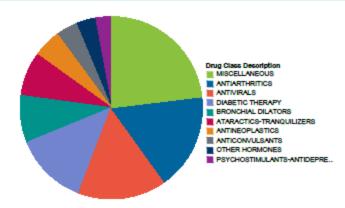


Claims Coun

Drug Class	Drug Class Description	Claims Count
11	PSYCHOSTIMULANTS-ANTIDEPRESSANTS	11,642
48	ANTICONVULSANTS	7,908
07	ATARACTICS-TRANQUILIZERS	7,401
15	BRONCHIAL DILATORS	7,211
42	ANTIARTHRITICS	6,378
71	OTHER ANTIHYPERTENSIVES	5,686
40	OPIOID ANALGESICS	5,244
58	DIABETIC THERAPY	4,767
76	OTHER CARDIOVASCULAR PREPS	4,453
99	MISCELLANEOUS	3,992
Total		64,682

Pie Chart 1.

Data Source : ALASKA MEDICAID Service Date : Oct-2019



Total Amt Paid

Drug Class	Drug Class Description	Total Amt Paid
99	MISCELLANEOUS	\$2,250,069.97
42	ANTIARTHRITICS	\$1,658,196.37
33	ANTIVIRALS	\$1,535,086.31
58	DIABETIC THERAPY	\$1,264,255.58
15	BRONCHIAL DILATORS	\$816,490.70
07	ATARACTICS-TRANQUILIZERS	\$756,167.65
30	ANTINEOPLASTICS	\$485,607.55
48	ANTICONVULSANTS	\$369,824.59
64	OTHER HORMONES	\$329,574.71
11	PSYCHOSTIMULANTS-ANTIDEPRESSANTS	\$284,797.93
Total		\$9,750,071.36

Pie chart 2.

Dr. Semling went over the top 25 drug classes and drugs by total amount paid in Table 2 and Table 3, respectively.

Data Source : ALASKA MEDICAID Service Date : 1 Month (Oct-2019)

Rank	Drug Class	Drug Class Desc	Total Amt Paid	% of Total Amt Paid
1	90	MISCELLANEOUS	\$2,250,089.97	17.92%
2	42	ANTIARTHRITICS	\$1,658,196.37	13.21%
3	33	ANTIVIRALS	\$1,535,086.31	12.23%
4	58	DIABETIC THERAPY	\$1,264,255.58	10.07%
5	15	BRONCHIAL DILATORS	\$816,490.70	6.50%
6	07	ATARACTICS-TRANQUILIZERS	\$756,167.65	6.02%
7	30	ANTINEOPLASTICS	\$485,607.55	3.87%
8	48	ANTICONVULSANTS	\$360,824.50	2.95%
9	64	OTHER HORMONES	\$329,574.71	2.63%
10	11	PSYCHOSTIMULANTS-ANTIDEPRESSANTS	\$284,797.93	2.27%
11	87	ELECTROLYTES & MISCELLANEOUS NUTRIENTS	\$275,907.92	2.20%
12	90	BIOLOGICALS	\$261,312.94	2.08%
13	51	GLUCOCORTICOIDS	\$250,474.87	2.00%
14	10	CNS STIMULANTS	\$243,824.67	1.94%
15	71	OTHER ANTIHYPERTENSIVES	\$240,009.66	1.91%
16	77	ANTICOAGULANTS	\$233,042.64	1.88%
17	95	ALL OTHER DERMATOLOGICALS	\$200,714.34	1.67%
18	12	AMPHETAMINE PREPARATIONS	\$197,956.14	1.58%
19	40	OPIOID ANALGESICS	\$194,680.33	1.55%
20	76	OTHER CARDIOVASCULAR PREPS	\$158,024.83	1.28%
21	27	OTHER ANTIBIOTICS	\$122,088.12	0.97%
22	20	OPHTHALMIC PREPARATIONS	\$118,273.65	0.94%
23	41	NON-OPIOID ANALGESICS	\$104,006.52	0.83%
24	69	ENZYMES	\$99,098.21	0.79%
25	01	ANTI-ULCER PREPS/GASTROINTESTINAL PREPS	\$95,793.24	0.78%
otal			\$12,554,279.44	100.00%

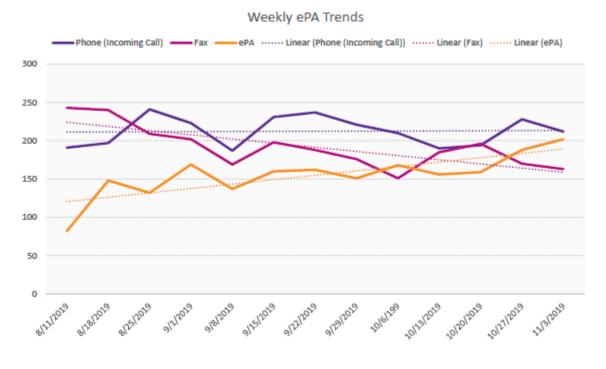
Table 2.

Data Source : ALASKA MEDICAID Service Date : 1 Month (Oct-2019)

Rank	Drug Name	Total Amt Paid	% of Total Amt Paid
1	MAVYRET 100-40 MG TABLET	\$791,913.41	17.98%
2	HUMIRA(CF) PEN 40 MG/0.4 ML	\$448,886.86	10.19%
3	HUMIRA PEN 40 MG/0.8 ML	\$311,625.68	7.08%
4	BIKTARVY 50-200-25 MG TABLET	\$245,401.55	5.57%
5	STELARA 90 MG/ML SYRINGE	\$237,851.48	5.40%
6	VIVITROL 380 MG VIAL + DILUENT	\$236,110.00	5.36%
7	LANTUS SOLOSTAR 100 UNIT/ML	\$203,323.63	4.62%
8	BUPRENORP-NALOX 8-2 MG SL FILM	\$184,344.14	4.19%
9	HUMIRA(CF) 40 MG/0.4 ML SYRING	\$150,340.38	3.41%
10	ENBREL 50 MG/ML SYRINGE	\$144,306.98	3.28%
11	VICTOZA 3-PAK 18 MG/3 ML PEN	\$132,055.25	3.00%
12	SUBOXONE 8 MG-2 MG SL FILM	\$127,018.82	2.88%
13	TECFIDERA DR 240 MG CAPSULE	\$107,084.62	2.43%
14	ORKAMBI 200 MG-125 MG TABLET	\$105,638.60	2.40%
15	ELIQUIS 5 MG TABLET	\$99,936.61	2.27%
16	ALBUTEROL HFA 90 MCG INHALER	807,134.99	2.21%
17	TRIUMEQ 600-50-300 MG TABLET	\$95,689.48	2.17%
18	NOVOLOG 100 UNIT/ML FLEXPEN	\$94,582.11	2.15%
19	SPIRIVA 18 MCG CP-HANDIHALER	\$93,061.31	2.11%
20	SYMBICORT 160-4.5 MCG INHALER	\$92,987.08	2.11%
21	SUBLOCADE 300 MG/1.5 ML SYRING	\$89,190.08	2.02%
22	DUPIXENT 300 MG/2 ML SYRINGE	\$80,831.60	1.84%
23	JANUVIA 100 MG TABLET	\$70,270.88	1.80%
24	COMBIVENT RESPIMAT 20-100 MCG	\$78,975.94	1.79%
25	ICATIBANT 30 Mg/3 ML SYRINGE	\$76,998.90	1.75%
al		\$4,404,569.34	100.00%

Table 3.

Dr. Semling went over the Electronic Prior Authorization (ePA) trends. Electronic Prior Authorization is increasing in utilization and the phone calls and faxes are decreasing. See Line Graph 3 below.



Line Graph 3.

## **Prospective Drug Utilization Review/Clinical Topic Areas**

# New Prescription Medications (Interim (Suspend) PA List – 6-month review)

The DUR Committee members reviewed new medications to market. Newer drugs to market are reviewed each meeting. The committee reviewed a subset of drugs, recommended by the state, that were place on the Interim Prior Authorization list. These new to market medications will remain on the list for a period of no less than 6 months. Medications added to the Suspend List require prior authorization or step through therapy unless there are specific criteria the DUR committee determines necessary to be set and recommended.

## New Prior Authorizations, Quantity Limits, Edits

Dr. Semling reviewed new medication criteria for prior authorizations. The below drugs will be approved if criteria below are met.

## Firdapse®, Ruzurgi® (amifampridine)

## FDA INDICATIONS AND USAGE 1,2

FIRDAPSE® and Ruzurgi® are a potassium channel blocker indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS). Ruzurgi® is only indicated for patients age 6 to 17 years of age and FIRDAPSE® is only indicated for adult patients.

#### APPROVAL CRITERIA<sup>1,2,3</sup>

- For Ruzurgi® the patient is between 6 and 17 years of age or for FIRDAPSE® the patient is 18 years of age or older <u>AND</u>;
- 2. Patient has the diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) AND;
- Prescribed by or in consultation of a neurologist or neuromuscular specialist AND;
- Patient does not have a history of seizures AND;
- Prescriber agrees to monitor for use with acetylcholinesterase inhibitors or other medication that can lower seizure threshold AND;
- 6. Patient has moderate to severe weakness that that interferes with daily functions.

#### DENIAL CRITERIA<sup>1,2,3</sup>

- For Ruzurgi® the patient is not between 6 and 17years of age or for FIRDAPSE® the
  patient is less than 18 years of age <u>OR</u>;
- Patient does not have the diagnosis of Lambert-Eaton myasthenic syndrome (LEMS)
   OR:
- Medications are not being prescribed by or in consultation of a neurologist or neuromuscular specialist <u>OR</u>;
- 4. Patient has a history of seizures OR;
- Prescriber does not agree to monitor for use with acetylcholinesterase inhibitors or other medication that can lower seizure threshold <u>OR</u>;
- 6. Patient does not have moderate to severe weakness that interferes with daily functions.

## CAUTIONS<sup>1,2</sup>

- Can cause paresthesia/dysesthesia, abdominal pain, dyspepsia, dizziness, and nausea.
- Consider discontinuation or dose reduction for patients that have a seizure while on treatment.
- The concomitant use of drugs that lower seizure threshold may lead to an increased risk of seizures.
- Concomitant use of drugs with cholinergic effects can increase the risk of adverse reactions.

Motion to approve: Dr. Ryan Ruggles, PharmD 2<sup>nd</sup>: Dr. Barb Piromalli, DO

## Vyndaqel®, Vyndamax™ (tafamidis meglumine, tafamidis)

#### FDA INDICATIONS AND USAGE<sup>1</sup>

Vyndaqel® and Vyndamax™ are transthyretin (TTR) stabilizers. Tafamidis meglumine and tafamidis are indicated for the treatment of the cardiomyopathy of the wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce the cardiovascular mortality and cardiovascular-related hospitalization.

#### APPROVAL CRITERIA<sup>1,2,3</sup>

- Patient is 18 years of age or older AND;
- 2. Prescribed by or in consultation with a cardiologist AND;
- Patient has a diagnosis of transthyretin (ATTR)- mediated amyloidosis with cardiomyopathy confirmed by:
  - a. Presence of amyloid deposits identified on a cardiac biopsy OR;
  - Confirmation of a TTR mutation by genetic testing or wild type amyloidosis AND;
- 4. Patient has clinical symptoms of cardiomyopathy and heart failure AND;
- 5. Patient has not had a liver or heart transplant.

#### DENIAL CRITERIA 1,2,3

- Patient is less than 18 years of age OR;
- 2. Has not been prescribed by or in consultation with a cardiologist OR;
- Patient does not have a diagnosis of transthyretin (ATTR)- mediated amyloidosis with cardiomyopathy confirmed by:
  - Presence of amyloid deposits identified on a cardiac biopsy OR;
  - b. Confirmation of a TTR mutation by genetic testing or wild type amyloidosis OR;
- 4. Patient does not have clinical symptoms of cardiomyopathy and heart failure OR;
- 5. Patient has had a liver or heart transplant OR;
- 6. Patient has New York Heart Association class IV heart failure.

### CAUTIONS1

- Tafamidis may cause fetal harm, therefore it is recommend that females use some form of contraception.
- Breastfeeding is not recommended during treatment due to potential serious adverse reactions in a breastfed infant.

## DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months

### QUANTITY LIMIT

- · 120 20mg capsules (80mg per day) Vyndaqel
- 30 61mg capsules Vyndamax

Motion to approve: 1st: Dr. Ryan Ruggles, 2nd: Dr. Barb Piromalli, DO

#### Corlanor® (ivabradine)

#### FDA INDICATIONS AND USAGE<sup>1</sup>

 $Corlanor\Phi$  is indicated to reduce the risk of hospitalization for worsening heart failure in adult patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction  $\leq 35\%$ , who are in simus rhythm with resting heart rate ≥ 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use. Corlanor® is also indicated for the treatment of stable symptomatic heart failure due to dilated cardiomyopathy (DCM) in pediatric patients aged 6 months and older, who are in sinus rhythm with an elevated heart rate.

#### APPROVAL CRITERIA<sup>1,2</sup>

- 1. Patient has a worsening heart failure diagnosis of stable, symptomatic heart failure AND;
- 2. Medication is being prescribed by or in consultation with a cardiologist AND;
- If the patient is 18 years of age or older, all the following criteria must be met:
  - a. Patient has a left ejection fraction ≤35 % AND;
  - b. Patient is in normal sinus rhythm AND;
  - Patient's heart rate is > 70 beats per minute AND;
  - d. Patient has tried and failed or has a contraindication to beta blockers at maximally tolerated dose.
- If the patient is 6 months to 17 years of age, all the following criteria must be met:
   a. Patient has stable symptomatic heart failure due to dilated cardiomyopathy AND;

  - b. Patient is in normal sinus rhythm with an elevated heart rate.

## DENIAL CRITERIA<sup>1,2</sup>

- Patient has clinically significant hypotension <u>OR</u>;
- 2. Patient has sick sinus syndrome, sino-atrial block, or third degree atrioventricular block, unless a functioning demand pacemaker is present OR;
- Demand pacemakers set to rates ≥ 60 beats per minute <u>OR</u>;
- Severe hepatic impairment OR;
- 5. Acute decompensated heart failure.

#### CAUTIONS1

- · Females should use effective contraception due to fetal toxicity.
- Patients should be monitored for atrial fibrillation.
- Not recommended in patients with second degree AV block.
- Heart rate should be monitored throughout therapy.

#### DURATION OF APPROVAL

Initial Approval: 3 months

## QUANTITY LIMITS

- 60 5mg tablets
- 60 7.5mg tablets
- 450ml 5mg/5ml oral solution

Motion to Approve with changes: Keri McCutcheon, RPh, 2<sup>nd</sup>: Dr. Barb Piromalli, DO

#### Xiaflex®

#### (collagenase clostridium histolyticum)

#### FDA INDICATIONS AND USAGE<sup>1</sup>

Xiaflex® is indicated for the treatment of adult patients with Dupuytren's Contracture (DC) with a palpable cord and for the treatment of adult men with Peyronie's Disease (PD) with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy

#### APPROVAL CRITERIA<sup>1,2,3</sup>

#### For Dupuytren's Contracture:

- 1. Patient is 18 years of age or older AND;
- 2. Patient has a confirmed diagnosis of Dupuytren's Contracture with a palpable cord AND;
- Prescribe by or in consultation with a healthcare provider experienced in injection procedures of the hand and in the treatment of DC AND;
- Patient has not received surgical treatment (e.g., fasciotomy) on the selected primary joint within the last 90 days <u>AND</u>;
- 5. If two injections (two vials) are requested, they are for one of the following (a or b):
  - a. One cord affecting two joints in the same finger OR;
  - b. Two cords affecting two joints in the same hand AND;
- 6. Documentation that the flexion deformity is causing functional limitations.

#### For Peyronie's Disease:

- 1. Patient is 18 years of age or older AND;
- Patient has a confirmed diagnosis of Peyronie's Disease (PD) with a palpable plaque and curvature deformity of at least 30 degrees and less than 90 degrees at the start of therapy AND;
- Prescribed by or in consultation with a healthcare provider experienced in the treatment of male urological diseases <u>AND</u>;
- Documentation that the patient has had stable disease defined by symptoms (I.E. penial curvature and pain) for at least 6 months <u>AND</u>;
- Xiaflex in not being used for sexual or erectile dysfunction associated with Peyronie's Disease AND;
- 6. Must be used in conjunction with penile modeling.

#### DENIAL CRITERIA

1. Failure to meet approval criteria.

#### CAUTIONS1

- · Tendon rupture or serious injury to the injected finger/hand may occur.
- · Corporal rupture (penile fracture) or other serious injury to the penis may occur.
- Xiaflex® is contraindicated for Peyronie's plaques that involve the penile urethra.
- Use caution in patients with abnormal anticoagulation.

## DURATION OF APPROVAL

- Initial Approval: One treatment cycle
- Re-approval: up to 2 more cycles at 4-week intervals for Dupuytren's Contracture (3 total) and must have> 15 degrees of deformity for Peyronie's Disease (4 total)

## QUANTITY LIMITS

· 2 vials (injections) per treatment cycle

Motion to Approve with updates: Dr. Barb Piromalli, DO 2<sup>nd</sup>: Keri McCutcheon, RPh

## Review of Existing Prior Authorizations, Quantity Limits, Edits

The committee reviewed the utilization for Oxycodone liquid IR and then reviewed the existing prior authorizations of Oxycodone IR and Hydromorphone IR criteria. Below are the criteria for Oxycodone IR and Hydromorphone IR. Oxycodone liquid will bypass the PA edit only when patients are less than 14 years of age and had a post-surgical procedure and the quantity must be equal or less than 90mL.

#### Oxycodone Hydrochloride Immediate Release (Various Brand Names)

Tablets: 5mg, 7.5mg, 10mg, 15mg, 20mg, 30mg, Capsules: 5mg, Oral Soln: 5mg/5mL. Concentrated Soln: 20mg/mL

#### FDA INDICATIONS AND USAGE

Oxycodone Immediate Release is indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Due to the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve oxycodone IR for use in patients for whom alternative treatment options (i.e., non-opioid analgesics or physical therapy) are not tolerated or adequate analgesia cannot be achieved.

### CRITERIA 1,2,3

The following criteria must be met for the approval of coverage:

- Every request for Oxycodone Immediate Release will reject at the pharmacy, unless a PA is already on file or the patient is less than 14 years of age filling oxycodone solution 10mg/10ml post procedure in a quantity no greater than 90ml.
- The dispensing pharmacy may override PA for patients in hospice, or who have cancer, or are in LTC facilities.
- Must have failed or was intolerant to at least 2 non-opioid therapies such as: APAP/NSAIDs/Cox-2 agent, Anticonvulsants, Muscle relaxants, Antidepressants, Corticosteroids, Topical analgesics; <u>AND</u>
- The patient cannot be either safely or effectively treated with a combination opioid analgesic that is combined with either acetaminophen, aspirin, or ibuprofen; AND
- If used as a single agent, the total daily Oxycodone dose does not exceed 90mg; OR
- The patient has an active prior authorization for Oxycontin

   (extended release); AND
- 7. The immediate release Oxycodone is used for breakthrough pain; AND
- 8. The total daily dose of all forms of Oxycodone does not exceed 160mg; AND
- 9. Breakthrough dosing is on an as needed basis, (PRN), and not a scheduled basis; AND
- 10. Patient is not exhibiting addictive behaviors and is not being treated for substance use.

#### Oxycodone 10mg / 10 mL Oral Solution:

- Patient meets criteria for oxycodone immediate release, but is unable to utilize a solid dosage form; <u>OR</u>
- The patient is less than 14 years of age filling oxycodone solution 10mg/10ml post procedure in a quantity no greater than 90ml.

## Oxycodone Concentrated 20mg / mL Oral Solution:

- 1. Patient meets criteria for Oxycodone 10mg/10mL Oral Solution; AND
- Patient has a documented medical condition that necessitates the use of an oral solution that is more concentrated than 10mg/10mL.

### DENIAL CRITERIA<sup>1,3</sup>

 Concomitant use with benzodiazepines above the established quantity limits. Refer to the Maximum Units Med List

http://dhss.alaska.gov/dhcs/Pages/pharmacy/medpriorauthoriz.aspx

#### DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Re-authorization: up to 12 months with clinically meaningful chart notes showing the patient is responding positively to therapy.

## QUANTITY LIMITS

 Refer to the Maximum Units Med List http://dhss.alaska.gov/dhcs/Pages/pharmacy/medpriorauthoriz.aspx

### Dilaudid® (Hydromorphone Hydrochloride)

Tablets: 2mg, 4mg, 8mg. Oral Solution: 1mg / 1mL. Suppositories: 3mg

#### FDA INDICATIONS AND USAGE

Hydromorphone Immediate Release is indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Due to the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve hydromorphone IR for use in patients for whom alternative treatment options (i.e., non-opioid analgesics or physical therapy) are not tolerated or adequate analgesia cannot be achieved.

#### APPROVAL CRITERIA<sup>1,2</sup>

- The dispensing pharmacy may override PA for patients in hospice, or who have cancer, or are in LTC facilities.
- 2. The prescriber attests to checking the PDMP; AND
- Treatment with at least three different analgesic medications that have been less than
  optimal, or is inappropriate (I.E. post-surgery); AND
- The patient cannot be either safely or effectively treated with a combination opioid analgesic that also contains either acetaminophen, aspirin, or ibuprofen; AND
- If used as a single agent, the total daily hydromorphone immediate release dose does not exceed 24mg; <u>AND</u>
- If used in conjunction with a long acting opioid, the total daily dose of all opioids does not
  exceed an average daily morphine equivalent dose established by the State of Alaska Health and Social Services Drug Utilization Committee; AND
- Breakthrough dosing is on an as needed basis, (PRN), and not a scheduled basis; AND
- Patient has been screened and is not exhibiting addictive behaviors and is not being treated for substance use.

### DENIAL CRITERIA

- Hydromorphone has been prescribed for something other than the relief of moderate to severe pain such as that due to: Biliary Colic, Burns, Cancer, Myocardial Infarction, Renal Colic, Surgery, Trauma.; <u>OR</u>
- The patient has acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; <u>OR</u>
- 3. The patient has a known or suspected gastrointestinal obstruction.

#### CAUTIONS1

- · Monitor for addiction, abuse, and misuse.
- · Serious, life threatening or fatal respiratory depression may occur.
- Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death

## DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months, if the patient has shown positive clinical improvement.

#### QUANTITY LIMIT

Up to 30 day supply

Motion to Approve with updates: Keri McCutcheon, RPh 2<sup>nd</sup>: Dr. Barb Piromalli, DO

## Review of Opioid Utilization

The committee reviewed the quarterly Opioid report that shows opioid utilization alone and in combination with benzodiazepines and antipsychotics. Opioid utilization alone and in combination with benzodiazepines and antipsychotics continues to trend downward which is what is expected.

# **End of Public Meeting**

Adjournment 4:05 p.m.

Next meeting date January 17<sup>th</sup>, 2019.