Alaska Medical Assistance DUR Committee Meeting Minutes

Friday, September 20th, 2019

Frontier Building, 3601 C Street; Room 890 $\,$

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	

Review of minutes from April 2019

- Minutes approved.
- 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. Charles Semling reviewed the Alaska Medicaid prescription costs and trends.

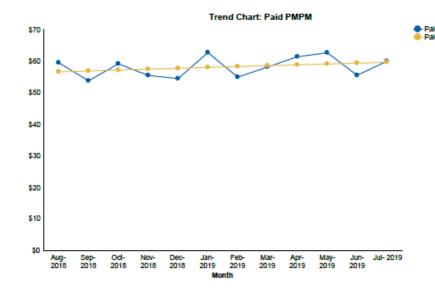
In table 1. Below, we see that there was an increase in about \$1,088,0960.00 or 9% increase in total amount paid since last year. PMPM increased 8%.

Clinical Metrics - Annual										
	Latest Month (Jul - 2019)	SMLY (Jul - 2018)	%SMLY*	Last 12 Months Average	Fiscal YTD** (Jul - 2019 → Jul - 2019)					
Total Amt Pald	\$13,296,363.30	\$12,207,403.34	9%	\$12,921,537.45	\$13,296,363.30					
Claims Count	118,447	112,156	6%	116,148	118,447					
Paid/Claim	\$112.26	\$108.84	3%	\$111.25	\$112.26					
Pald PMPM	\$60.02	\$55.76	8%	\$58.17	\$60.02					
Pald PUPM	\$354.77	\$341.97	4%	\$341.91	\$354.77					
Claims/User/Month	3.2	3.1	1%	3.1	3.2					
Generic Utilization	85.38%	83.40%	2%	83.71%	85.38%					
Seneric Substitution	93.36%	91.33%	2%	92.26%	93.36%					
o-Pay/Claim	\$0.61	\$0.65	(6%)	\$0.62	\$0.61					
Member-Months	221,548	218,909	1%	222,132	221,548					
Jaer-Months	37,479	35,697	5%	37,792	37,479					
% Users	16.92%	16.31%	4%	17.01%	16.92%					
% Single-Source	8.54%	8.68%	(2%)	9.27%	8.54%					

^{* %}SMLY = % Change between Latest Month and Same Month Last Year

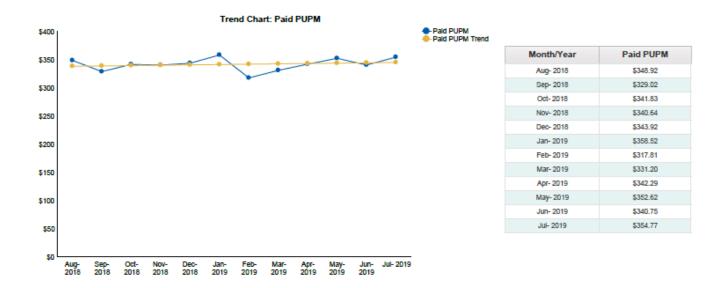
Table 1.

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



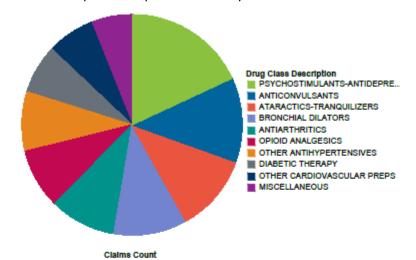
Month/Year	Paid PMPM
Aug- 2018	\$59.52
Sep- 2018	\$53.79
Oct- 2018	\$ 59.18
Nov- 2018	\$55.50
Dec- 2018	\$54.48
Jan- 2019	\$62.74
Feb- 2019	\$54.95
Mar- 2019	\$58.17
Apr- 2019	\$61.43
May- 2019	\$62.69
Jun- 2019	\$ 55.53
Jul- 2019	\$60.02

Line graph 1.



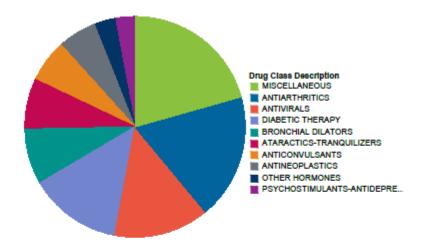
Line graph 2.

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



Drug Class Drug Class Description Claims Count PSYCHOSTIMULANTS-ANTIDEPRESSANTS 11 11,534 48 ANTICONVULSANTS 7,903 07 ATARACTICS-TRANQUILIZERS 7,286 15 **BRONCHIAL DILATORS** 6,879 42 ANTIARTHRITICS 6,192 OPIOID ANALGESICS 40 5,613 71 OTHER ANTIHYPERTENSIVES 5,562 58 DIABETIC THERAPY 4,584 76 OTHER CARDIOVASCULAR PREPS 4,399 99 MISCELLANEOUS 3,875 63,827

Pie Chart 1.



Total Amt Paid

Drug Class	Drug Class Description	Total Amt Paid
99	MISCELLANEOUS	\$1,960,735.73
42	ANTIARTHRITICS	\$1,745,088.14
33	ANTIVIRALS	\$1,327,610.11
58	DIABETIC THERAPY	\$1,291,805.66
15	BRONCHIAL DILATORS	\$775,946.57
07	ATARACTICS-TRANQUILIZERS	\$699,784.45
48	ANTICONVULSANTS	\$594,985.00
30	ANTINEOPLASTICS	\$537,646.06
64	OTHER HORMONES	\$292,113.33
11	PSYCHOSTIMULANTS-ANTIDEPRESSANTS	\$282,008.93
Total		\$9,507,723.98

Pie chart 2.

Dr. Semling went over the top 25 drug classes by total amount paid in Table 2. Below.

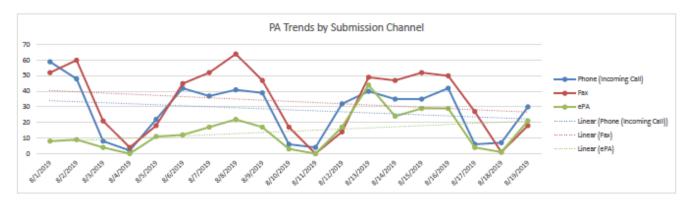
Rank	Drug Class	Drug Class Desc	Total Amt Paid	% of Total Amt Paid
1	99	MISCELLANEOUS	\$1,960,735.73	16.29%
2	42	ANTIARTHRITICS	\$1,745,088.14	14.50%
3	33	ANTIVIRALS	\$1,327,610.11	11.03%
4	58	DIABETIC THERAPY	\$1,291,805.66	10.73%
5	15	BRONCHIAL DILATORS	\$775,946.57	6.45%
6	07	ATARACTICS-TRANQUILIZERS	\$699,784.45	5.81%
7	48	ANTICONVULSANTS	\$594,985.00	4.94%
8	30	ANTINEOPLASTICS	\$537,646.06	4.47%
9	64	OTHER HORMONES	\$292,113.33	2.43%
10	11	PSYCHOSTIMULANTS-ANTIDEPRESSANTS	\$282,008.93	2.34%
11	87	ELECTROLYTES & MISCELLANEOUS NUTRIENTS	\$280,989.21	2.33%
12	51	GLUCOCORTICOIDS	\$228,974.61	1.90%
13	10	CNS STIMULANTS	\$227,541.00	1.89%
14	77	ANTICOAGULANTS	\$223,063.27	1.85%
15	71	OTHER ANTIHYPERTENSIVES	\$219,480.71	1.82%
16	40	OPIOID ANALGESICS	\$209,198.63	1.74%
17	12	AMPHETAMINE PREPARATIONS	\$177,497.42	1.47%
18	76	OTHER CARDIOVASCULAR PREPS	\$156,458.23	1.30%
19	95	ALL OTHER DERMATOLOGICALS	\$148,445.73	1.23%
20	27	OTHER ANTIBIOTICS	\$119,172.23	0.99%
21	20	OPHTHALMIC PREPARATIONS	\$114,165.53	0.95%
22	18	ADRENERGICS	\$114,027.31	0.95%
23	90	BIOLOGICALS	\$112,588.60	0.94%
24	41	NON-OPIOID ANALGESICS	\$103,428.64	0.86%
25	63	SYSTEMIC CONTRACEPTIVES	\$95,743.22	0.80%
otal			\$12,038,498.32	100.00%

Table 2.

Dr. Semling went over the e-PA stats. See table 3 and Line Graph 3 below.

Prior Authorization Submission Channel	8/1/2019	8/2/2019	8/3/2019	8/4/2019	8/5/2019	8/6/2019	8/7/2019	8/8/2019	8/9/2019	8/10/2019	8/11/2019	8/12/2019	8/13/2019	8/14/2019	8/15/2019	8/16/2019	8/17/2019	8/18/2019	8/19/2019
Phone (Incoming Call)	59	48	8	2	22	42	37	41	39	6	4	32	40	35	35	42	6	7	30
Fax	52	60	21	4	18	45	52	64	47	17	0	14	49	47	52	50	27	1	18
ePA	8	9	4	0	11	12	17	22	17	3	0	17	44	24	29	29	4	1	21
Auto-Approved	0	2	0	0	4	4	4	8	3	0	0	5	27	9	11	7	0	0	12
Queued for Manual Review	8	7	4	0	7	8	13	14	14	3	0	12	17	15	18	22	4	1	9
Total	119	117	33	6	51	99	106	127	103	26	4	63	133	106	116	121	37	9	69
Prior Authorization Submission Channel			Percent	of PA's															
Prior Authorization Submission Channel Phone (Incoming Call)	49.58%	41.03%	Percent 24.24%	of PA's 33.33%	43.14%	42.42%	34.91%	32.28%	37.86%	23.08%	100.00%	50.79%	30.08%	33.02%	30.17%	34.71%	16.22%	77.78%	43.48%
	49.58% 43.70%	41.03% 51.28%			43.14% 35.29%	42.42% 45.45%	34.91% 49.06%	32.28% 50.39%	37.86% 45.63%	23.08% 65.38%	100.00%	50.79% 22.22%	30.08% 36.84%	33.02% 44.34%	30.17% 44.83%	34.71% 41.32%	16.22% 72.97%	77.78% 11.11%	43.48% 26.09%
			24.24%	33.33%															
Phone (Incoming Call) Fax	43.70%	51.28%	24.24% 63.64%	33.33% 66.67%	35.29%	45.45%	49.06%	50.39%	45.63%	65.38%	0.00%	22.22%	36.84%	44.34%	44.83%	41.32%	72.97%	11.11%	26.09%
Phone (Incoming Call) Fax ePA	43.70% 6.72%	51.28% 7.69%	24.24% 63.64% 12.12%	33.33% 66.67% 0.00% 0.00%	35.29% 21.57%	45.45% 12.12% 33.33% 66.67%	49.06% 16.04%	50.39% 17.32%	45.63% 16.50%	65.38% 11.54%	0.00% 0.00%	22.22% 26.98%	36.84% 33.08%	44.34% 22.64%	44.83% 25.00%	41.32% 23.97% 24.14% 75.86%	72.97% 10.81%	11.11% 11.11%	26.09% 30.43%

Table 3.



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 will be reviewed each meeting after 6 months medications are new to the market and will be considered for placement on the Suspend List by the committee. The Suspend List requires prior authorization unless there is specific criteria the DUR committee determines necessary to be set and recommended.

New Prior Authorizations, Quantity Limits, Edits

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

Mavenclad® (cladribine)

FDA INDICATIONS AND USAGE¹

Mavenclad® is a purine antimetabolite indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, use of Mavenclad® is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternate drug indicated for the treatment of MS.

APPROVAL CRITERIA^{1,2}

- Patient is 18 years of age or older AND;
- Patient has a diagnosis of relapsing MS, including relapsing-remitting disease, and active secondary progressive disease AND;
- Is being prescribed by or in consultation with a neurologist or a prescriber that specializes in MS AND;
- The patient has had a complete blood cell count and liver function testing, showing results deemed appropriate for treatment AND;
- The prescriber has counseled patients of reproductive potential to use effective contraception during and for 6 months after the last dose in each treatment course AND;
- The patient has had an adequate trial and failure of at least one drug indicated for MS.

DENIAL CRITERIA12

- Patient has the diagnosis of clinically isolated syndrome <u>OR</u>;
- Patient has the presence of current malignancy <u>OR</u>;
- The patient has HIV or an active chronic infection <u>OR</u>;
- Mavenclad® is being administered with other disease modifying agents OR;
- Patient is pregnant

CAUTIONS^{1,2}

- Mavenclad® may increase the risk of malignancy.
- Mavenclad® may cause fetal harm if administered to pregnant women.
- A reduction in the body's immune defense, may increase the chances that an infection may occur.
- Immunizations should be administered at least 4-6 weeks before initiating treatment

DURATION OF APPROVAL

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

Motion to approve: Dr. Barb Piromalli, DO 2nd: Keri McCutcheon, RPh

Mayzent® (siponimod)

FDA INDICATIONS AND USAGE¹

MAYZENT® is a sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

APPROVAL CRITERIA^{1,2}

- Patient is 18 years of age or older AND;
- Patient has a diagnosis of relapsing MS, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease AND;
- Is being prescribed by or in consultation with a neurologist or a provider that specializes in MS AND;
- The patient has had an electrocardiogram, complete blood cell count, liver enzyme testing, and an ophthalmic evaluation, showing results deemed appropriate for treatment AND;
- The Patient has not had a myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure with in the last 6 months AND;
- The patient has no presence or history of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker AND;
- The prescriber has performed genetic testing to rule out CYP2C9*3/*3 AND;
- 8. The patient has had an adequate trial and failure of at least one drug indicated for MS.

DENIAL CRITERIA

- Patient is not 18 years of age or older OR;
- Patient does not have a diagnosis of relapsing MS, including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease OR;
- Is not being prescribed by or in consultation with a neurologist or a physician that specializes in MS OR;
- The patient has not had an electrocardiogram, complete blood cell count, liver enzyme testing, and an ophthalmic evaluation, showing results deemed appropriate for treatment <u>OR</u>;
- The Patient has had a myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure with in the last 6 months OR;
- The patient has a presence or history of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome OR;
- The prescriber has not performed genetic testing to rule out CYP2C9*3/*3 OR;
- The patient has not had an adequate trial and failure of at least one drug indicated for MS OR;

Mayzent® will concurrently be used with other MS disease modifying agents.

CAUTIONS1,2

- Mayzent® may increase the risk of infection.
- Patients with a history of uveitis and patients with diabetes mellitus are at increased risk of macular edema when taking MAyzent®.
- · Mayzent® may cause Bradyarrhythmia and Atrioventricular Conduction Delays
- · Live attenuated vaccines should be avoided for up to 4 weeks after treatment.
- Concomitant use of moderate CYP2C9 and moderate to strong CYP3A4 inhibitors and inducers is not recommended.

DURATION OF APPROVAL

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

OUANTITY LIMIT

- · 120 0.25mg tablets per month
- 30 2mg tablets per month

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

SunosiTM (solriamfetol)

FDA INDICATIONS AND USAGE¹

SunosiTM is a dopamine and norepinephrine reuptake inhibitor (DNRI) indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA). SunosiTM is not indicated for the treatment of underlying airway obstruction. SunosiTM has the potential for abuse and is listed as a controlled substance (Schedule IV).

APPROVAL CRITERIA^{1,2}

- Patient is 18 years of age or older AND;
- Patient has a diagnosis of excessive daytime sleepiness associated with narcolepsy or excessive daytime sleepiness associated with obstructive sleep apnea (OSA) AND;
- Is being prescribed by or in consultation with a neurologist, psychiatrist, or sleep specialist <u>AND</u>;
- If the patient has underlying airway obstruction it must be treated with a continuous
 positive airway pressure (CPAP) or similar device for a minimum of 90 days and for the
 duration of treatment with SunosiTM AND;
- The patient has tried and failed armodafinil or modafinil for a period of at least 30 days or has an allergy to both agents <u>AND</u>;
- The patient's blood pressure is well controlled.

DENIAL CRITERIA

- Patient is not 18 years of age or older <u>OR</u>;
- Patient does not have a diagnosis of excessive daytime sleepiness associated with narcolepsy or excessive daytime sleepiness associated with obstructive sleep apnea (OSA) OR;
- Is not being prescribed by or in consultation with a neurologist, psychiatrist, or sleep specialist <u>OR</u>;
- The patient has not tried and failed armodafinil or modafinil for a period of at least 30 days or does not have an allergy to both agents <u>OR</u>;
- The patient's blood pressure is not well controlled.

CAUTIONS1

- SunosiTM is contraindicated when used with in 14 days of monoamine oxidase inhibitors.
- Patients should be monitored for an increased heart rate and blood pressure
 prior to and throughout therapy. Use should be avoided in patients with serious
 heart problems.

 Doses may need to be reduced or discontinued for patients with a history of psychosis or bipolar disorder if psychiatric symptoms arise.

DURATION OF APPROVAL

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

OUANTITY LIMIT

- 30 75mg tablets per month
- 30 150mg tablets per month

Motion: send criteria to subject matter expert.

Emflaza® (deflazacort)

FDA INDICATIONS AND USAGE¹

Emflaza® (delazacort) is a corticosteroid indicated for the treatment of patients 2 years of age and older with the diagnosis of Duchenne muscular dystrophy (DMD). DMD is an X-linked recessive disease affecting male infants, which leads to the loss a structural protein of muscle cells called dystrophin.

APPROVAL CRITERIA^{1,2,3}

- 1. Patient is 2 years of age or older AND;
- Patient has a diagnosis of Duchenne muscular dystrophy (DMD) documented by the mutation or absence of the dystrophin gene <u>AND</u>;
- Is being prescribed by or in consultation with a neurologist or a provider that specializes in DMD AND;
- 4. The patient has had an adequate trial and failure, for at least 6 months, of oral prednisone, or has a contraindication to prednisone, or has experienced significant adverse effects from prednisone use.

DENIAL CRITERIA 1,2,3

- Patient is less than 2 years of age <u>OR</u>;
- Patient does not have a diagnosis of Duchenne muscular dystrophy (DMD) documented by the mutation or absence of the dystrophin gene OR;
- Is not being prescribed by or in consultation with a neurologist or a physician that specializes in DMD <u>OR</u>;
- 4. The patient has not had an adequate trial and failure, for at least 6 months, of oral prednisone, or has no contraindications to, or has not experienced significant adverse effects from prednisone use.
- Being given concurrently with live vaccinations.

CAUTIONS1

- Monitor for changes in endocrine, cardiovascular, and renal function.
- Increased risk of infection due to immunosuppression and may mask the signs and symptoms of an infection.
- May cause behavioral and mood disturbances.
- Decreases in bone mineral density can occur with chronic use.

DURATION OF APPROVAL

- Initial Approval: up to 30 days
- Reauthorization Approval: up to 12 months

QUANTITY LIMIT

Up to 0.9mg/kg/day rounded to the nearest tablet dosage strength (6mg, 18mg, 30mg, 36mg, and 22.75mg/ml suspension)

Motion: Committee to review history of claims for prednisone or another corticosteroid. 1st: Dr. Barb Piromalli, DO, 2nd: Keri McCutcheon, RPh.

Review of existing Prior Authorizations, Quantity Limits, Edits

HMG-CoA Reductase Inhibitors ("statins")

Advicor®, Altoprev®, Crestor®, Lescol®, Lescol® XL, Lovastatin, Lipitor®, Livalo®, Mevacor®, Pravachol®, Pravastatin®, Simcor®, Simvastatin, Vytorin®, Zocor®

CRITERIA FOR APPROVAL:

- Coverage will be given for Atorvastatin, Lovastatin, Pravastatin, Rosuvastatin, or Simvastatin.
- Coverage will be given for any other statin if the patient has been compliantly taking Atorvastatin, Lovastatin, Pravastatin, Rosuvastatin, or Simvastatin for 75 of the last 90 days without an acceptable reduction in LDL or experienced an adverse drug reaction with Atorvastatin, Lovastatin, Pravastatin,
- Rosuvastatin, or Simvastatin.

DISPENSING LIMIT:

- 1. The dispensing limit is a thirty (30) days' supply.
- 2. The quantity limit for all products is one (1) tablet per day with the exception of two (2) tablets or capsules per day for Lescol®, Mevacor® and Lovastatin.

Motion: Retire criteria and add new generics to 90-day list: Dr. Ryan Ruggles, PharmD 2nd: Keri McCutcheon, RPh

Sympazan™, Onfi® (Clobazam)

Schedule IV Controlled Substance

FDA Indication and Usage:

Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age or older

Dosage Form/Strength:

Tablet: 10mg, 20mg

Oral suspension: 2.5 mg/mL in 120mL bottles

Films: 5mg, 10mg, 20 mg

Criteria for Approval:

1. Diagnosis of Lennox-Gastaut Syndrome; AND

- Current therapy with at least one other antiepileptic medication including documentation of current and prior therapies; AND
- 3. Recipient is 2 years of age or older; AND
- 4. Patient has tried and failed generic clobazam.

Length of Authorization:

Coverage may be approved for up to 6 months.

Quantity Limit:

Maximum 2 doses per day (not to exceed 40mg per day).

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

RELISTOR® (methylnaltrexone bromide)

Available 8mg/0.4ml syringe, 12mg/0.6ml kit, 12mg/0.6ml syringe, 12mg/0.6ml vial, 150mg tablet

FDA INDICATIONS AND USAGE¹

RELISTOR is an opioid antagonist that comes as a tablet and an injection. The tablet is indicated for the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain while the injection is indicated for the treatment of OIC in adults with chronic non-cancer pain and OIC in adults with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient.

APPROVAL CRITERIA^{1,2}

- Patient is 18 year of age or older; AND
- Diagnosis of Opioid-induced constipation (OIC) in adults with chronic non-cancer pain OR OIC in adults with advanced illness who are receiving palliative care; AND
- 3. Recipient has been taking opioids for a period longer than 4 weeks; AND
- 4. Recipient does not have or suspected mechanical gastrointestinal obstruction; AND
- 5. Submit dates of trial or inadequate response from at least 2 laxative therapies.

DENIAL CRITERIA^{1,2}

- Patient is less than 18 years of age; OR
- Recipient does not have a diagnosis of Opioid-induced constipation (OIC) in adults with chronic non-cancer pain OR OIC in adults with advanced illness who are receiving palliative care; AND
- 3. Recipient has not taken opioids for a period longer than 4 weeks; AND
- Recipient is at risk or has a suspected mechanical gastrointestinal obstruction; AND
- Dates of trial or inadequate response from at least 2 laxative therapies has not been submitted.

CAUTIONS1

- There is a potential for gastrointestinal perforation.
- May cause severe or persistent diarrhea.
- · Patients should be monitored for symptoms of opioid withdrawal.

DURATION OF APPROVAL

Approval: up to a maximum of 4 months

OUANTITY LIMITS

30 day supply at FDA approved dosage.

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

End of Public Meeting

Ad	journment 3:50	p.m.
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Next meeting date November 15th, 2019.