Alaska Medical Assistance DUR Committee Meeting Minutes

Friday, September 18, 2020

Meeting was held Telephonically due to COVID-19. 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)
Jenna Hiestand, MD	
Ryan Ruggles, PharmD	
Robert Carlson, MD	
Barb Piromalli, DO	

Review of minutes from May 2020

- Minutes approved. A motion was made to approve the minutes by Jenna Hiestand, Second by Barb Piromalli.
- 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

Charles Semling reviewed Prescription and Cost Trends. Total Amt Paid increased by about 1 million claims. PMPM increased 5% since last year at this time. However, claims went down in July 2020, compared to July 2019, which is probably due to COVID-19 edits in which the State increased the days' supply limits. See Table 1. Below

Table 1.

MRxExplore

Program Trend Snapshot

Data Source : ALASKA MEDICAID
Service Date : Aug - 2019 to Jul - 2020

Clinical Metrics - Annual Trend Report

	Latest Month (Jul - 2020)	SMLY (Jul - 2019)	%SMLY*	Last 12 Months Average	Fiscal YTD** (Jul - 2020 -> Jul - 2020)
Total Amt Paid	$14,786,778.71	$13,730,656.48	8%	$14,072,527.19	$14,786,778.71
Claims Count	118,794	119,380	0%	117,986	118,794
Paid/Claim	$124.47	$115.02	8%	$119.27	$124.47
Paid PMPM	$63.25	$60.51	5%	$60.90	$63.25
Paid PUPM	$400.12	$363.00	10%	$371.30	$400.12
Claims/User/Month	3.2	3.2	2%	3.1	3.2
Generic Utilization	86.53%	85.29%	1%	85.79%	86.53%
Generic Subsititution	93.57%	93.34%	0%	93.08%	93.57%
Co-Pay/Claim	$0.63	$0.61	4%	$0.60	$0.63
Member-Months	233,787	226,912	3%	231,060	233,787
User-Months	36,956	37,825	(2%)	37,901	36,956
% Users	15.81%	16.67%	(5%)	16.40%	15.81%
% Single-Source	7.53%	8.63%	(13%)	7.84%	7.53%

Key

* %SMLY = % Change between Latest Month and Same Month Last Year
** Fiscal YTD = Client Specific Fiscal Year

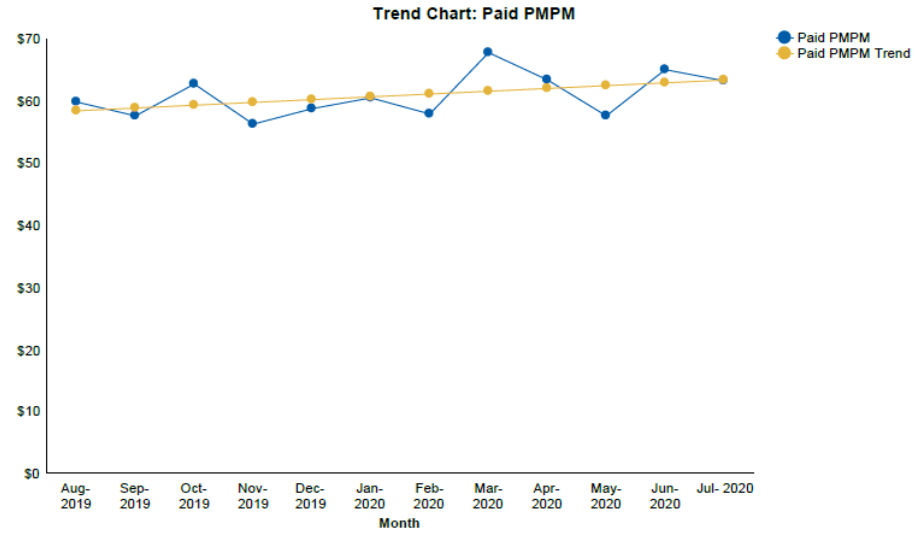
Dr. Semling commented that the PMPM/PUPM trend line is flat with it trending down in July. This was due to the increase in refill tolerance. The PUPM follows the same trend with spend increasing in March and April more than in July and this may be due to members stockpiling in April due to COVID-19. See Graphs 1 and Graph 2 below.

Graph 1.

MRxExplore

Annual Trend Chart - Paid PMPM

Data Source : ALASKA MEDICAID
Service Date : Aug - 2019 to Jul - 2020



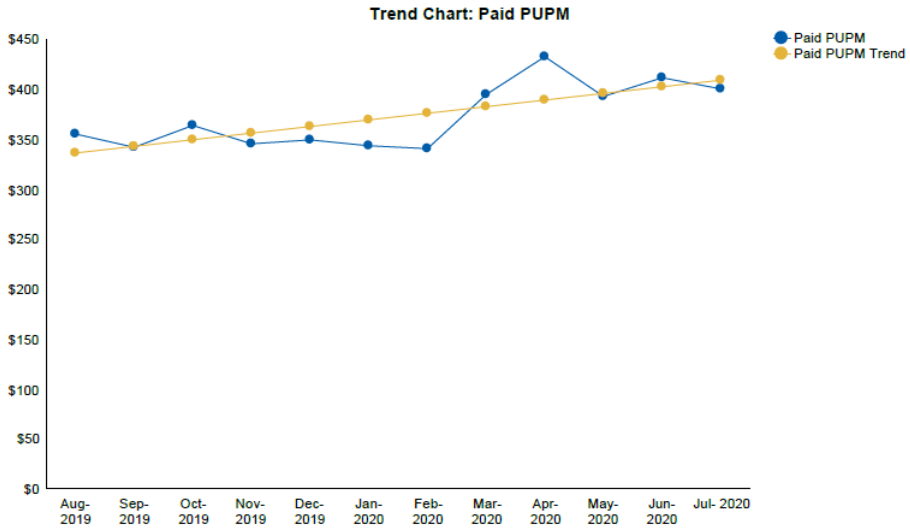
Month/Year	Paid PMPM
Aug- 2019	$59.84
Sep- 2019	$57.60
Oct- 2019	$62.73
Nov- 2019	$56.27
Dec- 2019	$58.76
Jan- 2020	$60.50
Feb- 2020	$57.90
Mar- 2020	$67.79
Apr- 2020	$63.40
May- 2020	$57.61
Jun- 2020	$65.04
Jul- 2020	$63.25

Graph 2.

MRxExplore

Annual Trend Chart - Paid PUPM

Data Source : ALASKA MEDICAID
Service Date : Aug - 2019 to Jul - 2020



Month/Year	Paid PUPM
Aug- 2019	$354.92
Sep- 2019	$341.62
Oct- 2019	$363.52
Nov- 2019	$345.12
Dec- 2019	$349.00
Jan- 2020	$343.16
Feb- 2020	$340.25
Mar- 2020	$394.51
Apr- 2020	$432.38
May- 2020	$392.58
Jun- 2020	$411.33
Jul- 2020	$400.12

Dr. Semling went over the top 10 therapeutic classes by volume and cost.
Opioids went down in trend. Bronchodialators decreased, which is expected since no fires were at the time. Antivirals which is category for Hepatitis C, continue to decrease in trend as we treat and cure members.

The committee commented that the drug class of "miscellaneous" is not a good representation of the top drugs by total paid amount and total claim count. Magellan will take this back to have the reports redone that will break down the "miscellaneous" drug class into a more descriptive drug class for the committee to see.

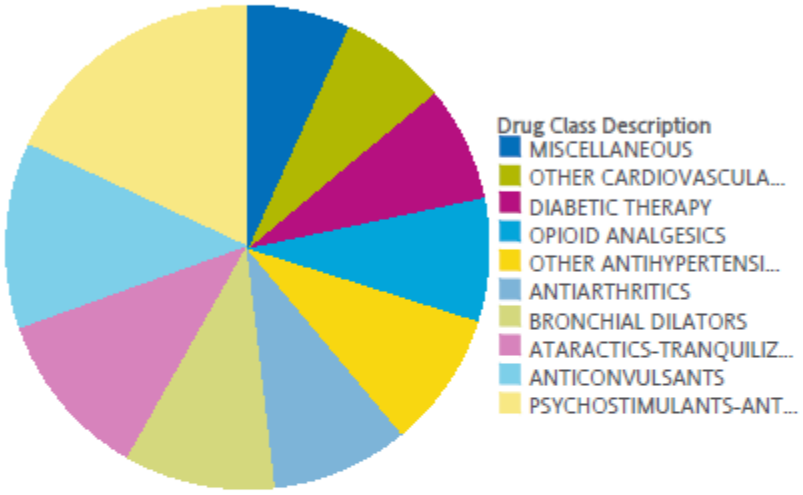
See Graph 3 and Graph 4.

Graph 3.

MagellanRx MANAGEMENT

Top 10 Therapeutic Class

Client : ALASKA MEDICAID
Service Date : Jul 1, 2020 to Jul 31, 2020



Claim Count

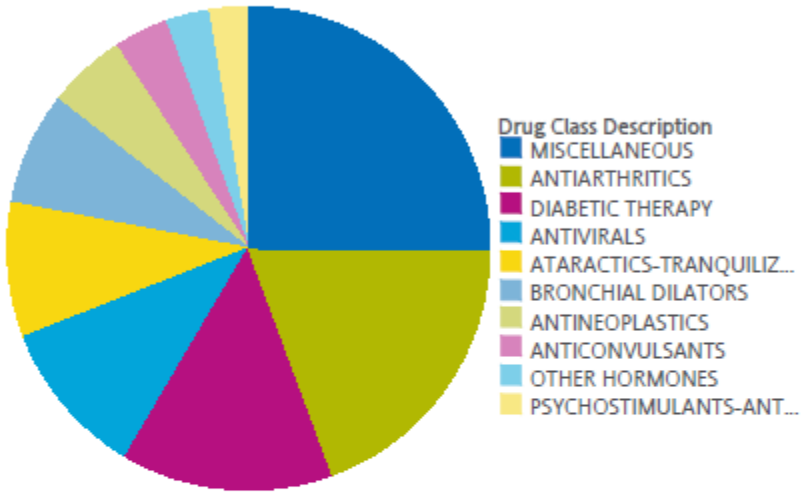
Therapeutic Class Code	Drug Class Description	Claim Count
11	PSYCHOSTIMULANTS-ANTIDEPRESSANTS	11,768
48	ANTICONVULSANTS	8,104
07	ATARACTICS-TRANQUILIZERS	7,339
15	BRONCHIAL DILATORS	6,572
42	ANTIARTHRITICS	5,976
71	OTHER ANTIHYPERTENSIVES	5,910
40	OPIOID ANALGESICS	5,355
58	DIABETIC THERAPY	5,001
76	OTHER CARDIOVASCULAR PREPS	4,679
99	MISCELLANEOUS	4,419
Overall - Summary		65,123

Graph 4.

MagellanRx MANAGEMENT

Top 10 Therapeutic Class

Client : ALASKA MEDICAID
Service Date : Jul 1, 2020 to Jul 31, 2020



Total Paid Amount

Therapeutic Class Code	Drug Class Description	Total Paid Amount
99	MISCELLANEOUS	$2,674,865.28
42	ANTIARTHRITICS	$2,054,116.51
58	DIABETIC THERAPY	$1,510,780.29
33	ANTIVIRALS	$1,123,839.92
07	ATARACTICS-TRANQUILIZERS	$960,141.23
15	BRONCHIAL DILATORS	$800,352.22
30	ANTINEOPLASTICS	$558,203.79
48	ANTICONVULSANTS	$385,823.92
64	OTHER HORMONES	$310,494.68
11	PSYCHOSTIMULANTS-ANTIDEPRESSANTS	$289,308.10
Overall - Summary		**$10,667,925.94**

Dr. Semling went over the top 25 drugs with Humira being at the top drug by total amount paid (Table 2.)

Table 2.

MagellanRx MANAGEMENT

Top 25 Drug Classes/Drugs Dispensed by Total Amount Paid

Client : ALASKA MEDICAID
Service Date : Jul 1, 2020 to Jul 31, 2020

Rank	Drug Name	Total Paid Amount	% of Total Paid Amt
1	HUMIRA(CF) PEN 40 MG/0.4 ML	$862,459.99	18.56%
2	MAVYRET 100-40 MG TABLET	$482,361.66	10.38%
3	BIKTARVY 50-200-25 MG TABLET	$283,050.46	6.09%
4	BUPRENORP-NALOX 8-2 MG SL FILM	$224,915.57	4.84%
5	LANTUS SOLOSTAR 100 UNIT/ML	$216,776.59	4.67%
6	STELARA 90 MG/ML SYRINGE	$209,901.76	4.52%
7	VIVITROL 380 MG VIAL + DILUENT	$209,493.88	4.51%
8	HUMIRA PEN 40 MG/0.8 ML	$196,701.22	4.23%
9	HUMIRA(CF) 40 MG/0.4 ML SYRING	$195,716.13	4.21%
10	ENBREL 50 MG/ML SYRINGE	$163,202.39	3.51%
11	RIXUBIS 3,000 UNIT NOMINAL	$146,610.78	3.16%
12	ELIQUIS 5 MG TABLET	$144,889.95	3.12%
13	VICTOZA 3-PAK 18 MG/3 ML PEN	$139,871.83	3.01%
14	DUPIXENT 300 MG/2 ML SYRINGE	$137,056.64	2.95%
15	TRIKAFTA 100/50/75 MG-150 MG	$120,841.95	2.60%
16	RAVICTI 1.1 GRAM/ML LIQUID	$106,704.01	2.30%
17	ENBREL 50 MG/ML SURECLICK	$106,314.15	2.29%

It was commented that Humira is about 6% of the State's total drug spend.

Table 3.

MagellanRx MANAGEMENT

Top 25 Drug Classes/Drugs Dispensed by Total Amount Paid

Client : ALASKA MEDICAID
Service Date : Jul 1, 2020 to Jul 31, 2020

Rank	Therapeutic Class Code	Therapeutic Class	Total Paid Amount	% of Total Amt Paid
1	99	MISCELLANEOUS	$2,674,865.28	19.81%
2	42	ANTIARTHRITICS	$2,054,116.51	15.22%
3	58	DIABETIC THERAPY	$1,510,780.29	11.19%
4	33	ANTIVIRALS	$1,123,839.92	8.33%
5	07	ATARACTICS-TRANQUILIZERS	$960,141.23	7.11%
6	15	BRONCHIAL DILATORS	$800,352.22	5.93%
7	30	ANTINEOPLASTICS	$558,203.79	4.13%
8	48	ANTICONVULSANTS	$385,823.92	2.86%
9	64	OTHER HORMONES	$310,494.68	2.30%
10	11	PSYCHOSTIMULANTS-ANTIDEPRESSANTS	$289,308.10	2.14%
11	77	ANTICOAGULANTS	$281,674.27	2.09%
12	95	ALL OTHER DERMATOLOGICALS	$264,199.83	1.96%
13	87	ELECTROLYTES & MISCELLANEOUS NUTRIENTS	$240,970.57	1.79%
14	90	BIOLOGICALS	$226,412.21	1.68%
15	51	GLUCOCORTICOIDS	$209,599.88	1.55%
16	12	AMPHETAMINE PREPARATIONS	$195,343.52	1.45%
17	40	OPIOID ANALGESICS	$194,718.09	1.44%

Prospective Drug Utilization Review/Clinical Topic Areas

New Prescription Medications (Interim 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 are specific criteria the DUR committee determines necessary to be set and recommended.

There were no objections from the committee.

New Prior Authorizations, Quantity Limits, Edits

Dr. Semling reviewed new medication criteria for prior authorizations:

Strensiq™

(asfotase alfa)

FDA INDICATIONS AND USAGE[1]

Strensiq™ is a tissue nonspecific alkaline phosphatase indicated for the treatment of patients with perinatal/infantile- and juvenile- onset hypophosphatasia (HPP).

APPROVAL CRITERIA[1,2,3]

1. Medication is being prescribed by or in consultation with an endocrinologist or a specialist experienced in treating metabolic disorders **OR;**
2. Patient has a documented diagnosis of perinatal/infantile- and juvenile- onset hypophosphatasia confirmed by elevated urine concentration of phosphoethanolamine (PEA), elevated serum concentration of pyridoxal 5'-phosphate (PLP) in the absence of vitamin supplements within one week prior, or elevated urinary inorganic pyrophosphate (PPi) **AND;**
3. The patient was less than 18 years of age at onset **AND;**
4. The patient has clinical manifestations of hypophosphatasia (I.E. skeletal abnormalities, respiratory problems, failure to thrive, rickets, etc.) **AND;**
5. The patient has had a low baseline ALP activity adjusted for age **AND;**
6. Patient has at least one variant in the ALPL gene.

DENIAL CRITERIA[1,2]

1. Failure to meet approval criteria **OR;**
2. The provider has failed to provide the patients weight for dosing.

CAUTIONS[1]

- Hypersensitivity reactions have occurred including anaphylaxis.
- Lipodystrophy has been observed and is recommended to rotate injection sites.
- Monitor for Ectopic Calcifications in the eye and kidney using ophthalmologic examinations and renal ultrasounds at baseline and periodically during treatment.

DURATION OF APPROVAL

- Approval: Up to 3 months
- Reauthorization: Up to 12 months

REFERENCES / FOOTNOTES:

1.Strensiq™[Package Insert]. Boston, MA. Alexion Pharmaceutical, INC; June 2020. Available at: https://alexion.com/documents/strensiq_uspiAccessed:July 15, 2020.
2.Hypophosphatasia. U.S.National Library of Medicine. September 2017. Published January 2018. Accessed: July 15, 2020.
3.Whyte MP, Mahuren JD, Vrabel LA, Coburn SP. Markedly increased circulating pyridoxal-5'-phosphate levels in hypophosphatasia. J Clin Invest. 1985;76(2):752-756.

QUANTITY LIMITS

- Up to a maximum of 9mg/kg per week

Motion to approve with changes (1 BULLET OR instead of AND): 1st: Jenna Heistand, 2nd Barb Piromalli

Nexletol™, Nexlizet™

(bempedoic acid, bempedoic acid/ezetimibe)

FDA INDICATIONS AND USAGE[1,2]

Nexletol™ is an adenosine triphosphate-citrate lyase (ACL) inhibitor indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C. Nexlizet™ contains the active ingredient bempedoic acid, in combination with ezetimibe, a cholesterol absorption inhibitor.

APPROVAL CRITERIA[1,2,3]

1. Patient is 18 years of age or older **AND**;
2. Patient has a documented and confirmed diagnosis Heterozygous Familial Hypercholesterolemia (HeFH) **OR**;
3. Patient has a history of clinical atherosclerotic cardiovascular disease (ASCVD) including one or more of the following:
    a. Angina (stable or unstable)
    b. Acute coronary syndrome or prior myocardial infarction
    c. Coronary artery disease
    d. History of stroke or transient ischemic attack
    e. Stroke
    f. Peripheral artery disease
    g. Coronary or other arterial revascularization
4. Is being prescribed by or in consultation with a cardiologist, endocrinologist, or a physician that specializes in the treatment of cardiovascular disease and/or lipid disorders **AND**;
5. The patient is on concomitant statin therapy at maximally tolerated dose or has a contraindication or intolerance to at least two different statin medications **AND**;
6. The patient has a documented reduction of LDL-C less than 50% from the baseline or patient has

ASVCD and LDL-C is greater than 70mg/dL or no history of ASCVD and a LDL-C is greater than 100mg/dL.

DENIAL CRITERIA[1,2]

1. Failure to meet approval criteria **OR;**
2. Patient will be taking more than 20mg of simvastatin or 40 mg of pravastatin daily **OR;**
3. Patient is currently using a Pcsk9 inhibitor.

CAUTIONS[1,2]

- Hyperuricemia has occurred with use. Monitor serum uric acid levels as clinically indicated.
- Tendon rupture has occurred, discontinue at first sign of tendon rupture and avoid use in patients with previous tendon rupture,

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Re-authorization: up to 12 months

QUANTITY LIMIT

- 30 tablets

REFERENCES / FOOTNOTES:

1. Nexletol [prescribing information]. Ann Arbor, MI: Esperion Therapeutics, Inc.; February 2020.
2. Nexlizet [prescribing information]. Ann Arbor, MI: Esperion Therapeutics, Inc.; February 2020.
3. Ray KK, Bays HE, Catapano AL, Lalwani ND, Bloedon LT, Sterling LR, et al. Safety and efficacy of bempedoic acid to reduce LDL cholesterol. N Engl J Med. 2019;380(11):1022–32.

Motion to approve: 1st: Jenna Heistand, 2nd Robert Carlson

Oxervate™

(cenegermin-bkbj)

FDA INDICATIONS AND USAGE[1,3]

Oxervate™ (cenegermin-bkbj) is a recombinant human nerve growth factor indicated for the treatment of neurotrophic keratitis (NK). NK is a degenerative disease that decreases corneal sensitivity and healing, leaving the cornea to be more susceptible to injury and decreased reflex tearing.

APPROVAL CRITERIA[1,2,3]

1. Patient is 2 years of age or older **AND**;
2. Patient has a documented diagnosis of stage 2 (persistent epithelial defect) or stage 3 (corneal

ulcer) neurotrophic keratitis in one or both eyes **AND**;
3. Is being prescribed by or in consultation with an ophthalmologist or optometrist **AND**;
4. The patient has evidence of decreased corneal sensitivity in at least one eye **AND**;
5. The patient has a documented treatment with one or more conventional non-surgical treatments for neurotrophic keratitis.

DENIAL CRITERIA

4. Failure to meet approval criteria.

CAUTIONS[1]

- The most common adverse reactions are eye pain, ocular hyperemia, eye inflammation and increased lacrimation.
- Patients should remove contact lenses before applying OXERVATE and wait 15 minutes after instillation of the dose before reinsertion.
- Patients should follow proper administration and storage procedures outlined in the package insert.

DURATION OF APPROVAL

- Initial Approval: up to 8 weeks (treatment duration not to exceed 8 weeks)
- Retreatment, lost or stolen, or spilled medication should not be authorized.

QUANTITY LIMIT

- Up to maximum of 8 kits per affected eye (1 kit contains 7 multiple-dose vials)

REFERENCES / FOOTNOTES:

1.Oxervate™[prescribing information]. Boston, MA: Dompe U.S. Inc.; October2019.
2.Sacchetti, M., Lambiase, A. Diagnosis and management of neurotrophic keratitis. Clinical Ophthalmology 2014;8: 571-9.3.Evaluation of Safety and Efficacy of rhNGF in Patients With Stage 2 and 3 Neurotrophic Keratitis. -Full Text View -ClinicalTrials.gov. (2019). Retrieved from https://clinicaltrials.gov/ct2/show/NCT01756456

Motion to Approve: 1st Barb Piromalli, 2nd Robert Carlson

Calcitonin gene-related peptide receptor antagonists oral and injectable (i.e. fremaexumab, ubrogepant, etc.)

FDA INDICATIONS AND USAGE[1,2,4]

Injectable calcitonin gene-related peptide (CGRP) receptor antagonists are indicated for the preventive treatment of migraine in adults. Oral CGRP antagonists are indicated for the acute treatment of migraine with or without aura in adults.

APPROVAL CRITERIA[1,2,3,4,5,6]

Injectable CGRP indicated for preventative treatment

1. Patient is within the age range recommended by the FDA label **AND;**
2. Prescribed in consultation with or is a headache specialist, pain specialist, or neurologist **AND;**
3. Patient has the diagnosis of episodic or chronic migraine **AND;**
4. Patient is experiencing 4 or more migraine days per month **AND;**
5. Medication is being used for prophylaxis **AND;**
6. Patient has trialed at least 2 prophylactic medications from different therapeutic classes (i.e. beta blocker, antiepileptic, antidepressant, etc) for at least 2 months each.

Oral CGRP indicated for treatment of acute migraine

1. Patient is 18 years of age or older **AND;**
2. Patient has the diagnosis of migraine with or without aura **AND;**
3. Prescribed in consultation with or is a headache specialist, pain specialist, or neurologist **AND;**
4. The provider has ruled out medication overuse as a cause of migraines **AND;**
5. Patient has trialed at least 1 prophylactic medication (i.e. beta blocker, antiepileptic, antidepressant, etc.) for at least 2 months **AND;**
6. Patient has trialed 2 different triptans or has a contraindication (i.e. cardiovascular) to their use **AND;**
7. Patient is not taking any strong CYP3A4 inhibitor concomitantly.

DENIAL CRITERIA[1,2,3]

1. Failure to meet approval criteria.

CAUTIONS[1]

- Most common adverse reaction were injection site reactions for the injectables.
- Concomitant use of strong CYP3A4 inhibitors is contraindicated with oral CGRP inhibitors.

DURATION OF APPROVAL

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

QUANTITY LIMITS

- 34 days

REFERENCES / FOOTNOTES:

1. Aimovig™ [Package Insert]. Thousand Oaks, CA: Amgen Inc. May 2018. Available at: https://pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/aimovig/aimovig_pi_hcp_english.ashx. Accessed October 15, 2018.
2. Ajovy™[Package Insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc. Available at: https://www.ajovy.com/globalassets/ajovy/ajovy-pi.pdf. Accessed October 15, 2018.
3. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Neurology. 2012 April 24 ;(17):1337-45.
4. ICER Calcitonin Gene-Related Peptide (CGRP) Inhibitors as Preventive Treatments for Patients with Episodic or Chronic Migraine: Effectiveness and Value (July 3, 2018)5.Ubrelvy™ [Package Insert]. Madison, NJ: Allergan USA, Inc. December 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/211765s000lbl.pdf6.Nurtec™ODT[Package Insert]. New Haven, CT: Biohaven Pharmaceuticals, Inc. February 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212728s000lbl.pdf

Motion to Approve: 1st: Jenna Heistand, 2nd: Barb Piromalli

Orilissa™ (elagolix), Oraihnn™ (elagolix, estradiol, norethindrone acetate)

FDA INDICATIONS AND USAGE[1,3]

Orilissa™ is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of severe pain associated with endometriosis. Oriahnn™ is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.

APPROVAL CRITERIA[1,2]

Orilissa™

1. Patient is 18-49 years of age **AND**;
2. Patient has a diagnosis of endometriosis **AND;**
3. Patient is not taking a strong organic anion transporting polypeptide 1B1 inhibitor (i.e. cyclosporine) **AND;**
4. Patient has had an adequate trial of an oral combination contraceptive for at least 3 months **AND;**
5. Patient has had a trial of NSAID product for at least 1 month.

Oriahnn™

1. Patient is 18 years of age or older **AND;**
2. Patient has been diagnosed with uterine leiomyomas (fibroids) **AND;**
3. Medication is being used for heavy menstrual bleeding **AND;**
4. Patient does not have a history of thrombotic or thromboembolic disorders **AND;**
5. Patient is not taking a strong organic anion transporting polypeptide 1B1 inhibitor (i.e. cyclosporine) **AND;**
6. Patient has had an adequate trial of an oral contraceptive or oral progesterone for at least 3 months **AND;**
7. Patient has had a trial of NSAID product for at least 1 month.

DENIAL CRITERIA[1,2,3]

1. Failure to meet approval criteria **OR;**
2. Patient is pregnant **OR;**
3. Patient has known osteoporosis **OR;**
4. Patient has known hepatic impairment or liver disease.

CAUTIONS[1]

- Elagolix may be associated with potentially irreversible bone loss.
- May reduce the ability to recognize pregnancy.
- May increase suicidal ideation and mood disorders.
- May increase liver transaminases and should be monitored.
- Has the potential to decrease efficacy of estrogen containing contraceptives.

DURATION OF APPROVAL[1]

- Initial Approval: up to 6 months
- Reauthorization Approval for Orilissa™: up to 12 months for 150mg dose only
- Reauthorization Approval for Oriahnn™: up to 12 months (not to exceed 24 months total duration of treatment)

QUANTITY LIMITS

- 30 – 150mg tablets per month (Orilissa™)
- 60 – 200mg tablets per month (Orilissa™)
- 56 capsules contained in 4 blister packs (Oriahnn™)

REFERENCES / FOOTNOTES:

1. Orilissa™ (elagolix) [prescribing information]. North Chicago, IL: AbbVie Inc.; July2018. Available at: https://www.rxabbvie.com/pdf/orilissa_pi.pdf. Accessed September2018.
2. Schrager S, Falleroni J, Edgoose J. Evaluation and Treatment of Endometriosis. American Family Physician. 2013 Jan 15;87(2):107-113.
3. Oriahnn™ [package insert]. North Chicago, IL: AbbVie Inc.; Revised 05/2020.

Motion to Approve: 1st: Charles Ryan, 2nd: Ryan Ruggles

Epidiolex® (Cannabidiol)

FDA INDICATIONS AND USAGE[1]

Epidiolex is indicated, in patients 2 years of age and older, for the treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, and Tuberous Sclerosis Complex.

APPROVAL CRITERIA[1,2]

1. Patient is 1 years of age or older **AND**;
2. Patient has the diagnosis of Lennox-Gastaut, Dravet syndrome, or Tuberous Sclerosis Complex **AND;**
3. Prescribed by or in consultation of a neurologist **AND;**
4. Patients seizures have not been controlled by at least a trial of 2 antiepileptic drugs **AND;**
5. Patient will use as an adjunctive therapy with at least one other antiepileptic drug **AND;**
6. Serum transaminases and bilirubin levels are obtained prior to starting treatment.

DENIAL CRITERIA[1,2]

1. Patient is less than 1 years of age **OR**;
2. Patient does not the diagnosis of Lennox-Gastaut, Dravet syndrome, or Tuberous Sclerosis Complex **OR;**
3. Not being prescribed by or in consultation of a neurologist **OR;**
4. Patients seizures have been controlled by other antiepileptic drugs **OR;**
5. Patient is not using as an adjunctive therapy with at least one other antiepileptic drug **OR;**
6. Serum transaminases and bilirubin levels have not been obtained prior to starting treatment.

CAUTIONS[1]

- Can cause elevated transaminase levels especially when used with valproate. Monitoring should occur prior to start, 1 month, 3 months, 6 months and as clinically indicated.
- Caution should be used when driving or operating machinery due to somnolence and sedative effects.
- Patients should be monitored for suicidal thoughts or behaviors.

DURATION OF APPROVAL

- Initial Approval: up to 4 months
- Reauthorization Approval: up to 12 months if the patient is responding positively and doses have not exceeded 20mg/kg/day

QUANTITY LIMITS

- 5 – 100ml bottles (100mg/ml)
- Doses do not exceed 20mg/kg/day

REFERENCES / FOOTNOTES:

1.EpidiolexPrescribing Information. Carlsbad, CA: Greenwich Biosciences, Inc.; July 2020. Available at: https://www.epidiolex.com/sites/default/files/pdfs/VV-MED-03633_EPIDIOLEX_(Cannabidiol)_USPI.pdf.Accessed August 3, 2020.

2.American Academy ofNeurology and the American Epilepsy Society. Treatments for Refractory Epilepsy; Guideline Summary for Clinicians. Available at: http://tools.aan.com/professionals/practice/pdfs/clinician_ep_treatment_e.pdf.AccessedOctober 10, 2018.

Motion to Approve: 1st: Ryan Ruggles, 2nd: Barb Piromalli

Opioid Report

Dr. Semling reviewed the quarterly opioid trend report. Overall, the opioid trend continues to decrease. At the beginning of the next year in 2021, the MME edit will be decreased by 50 MME for the Max daily amount of 200 MME.

From April 2020 to September 2020, members filling opioids went from 11,002 members to 9390 members. Dr. Semling then reviewed the breakdown of claims and members by Long-Acting and Short-Acting opioids. The committee discussed the breakdown of only short-acting opioid users and discussed the top prescribers dispensing opioids. Dr. Heistand commented that she would like to know what the antipsychotic drugs are that are being dispensed with opioids. Magellan to bring that information for next report.

RetroDUR Letter

The DUR board then reviewed a prescriber letter. The letter is an educational letter to medical providers to raise awareness about the growing concern regarding the potential for abuse and side effects with the concomitant use of benzodiazepines and sedative Z-drugs.

The committee discussed how the letter should be more directed to each medical provider to let them know how many claims or patients that the State identified. The State will work with Magellan to provide this information to the medical providers in the letter.

Safety Reports

Dr. Semling discussed some drug safety communications made by the Food and Drug Administration (FDA) for caution against the use of hydroxychloroquine or chloroquine for COVID-19 and a recommendation to health care professionals to discuss naloxone with all patients when prescribing an opioid pain reliever or medicines to treat opioid use disorder.

FEARS Reports

Dr. Semling reviewed the FEARS Report with the committee, which is a report from the FDA adverse Event Reporting System.

End of Public Meeting

Adjournment 3:18 p.m.

Next meeting date November 20th, 2020.