

Alaska Medical Assistance DUR Committee Meeting Minutes

Friday, April 17, 2020

This was a telephonic meeting only due to COVID-19

Frontier Building, 3601 C Street; Room 896

1:00pm

Drug Utilization Review Committee

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	
Keri McCutcheon, RPh	

Review of minutes from January 2020

- Minutes approved. A motion was made to approve the minutes by Jenna Hiestand Second by Keri McCutcheon.
- 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. PMPM increased 8%. Increase costs due to the expanded early refill edits that had been placed earlier in the year. Table 1. Below

Table 1.

Data Source : ALASKA MEDICAID
 Service Date : Apr - 2019 to Mar - 2020

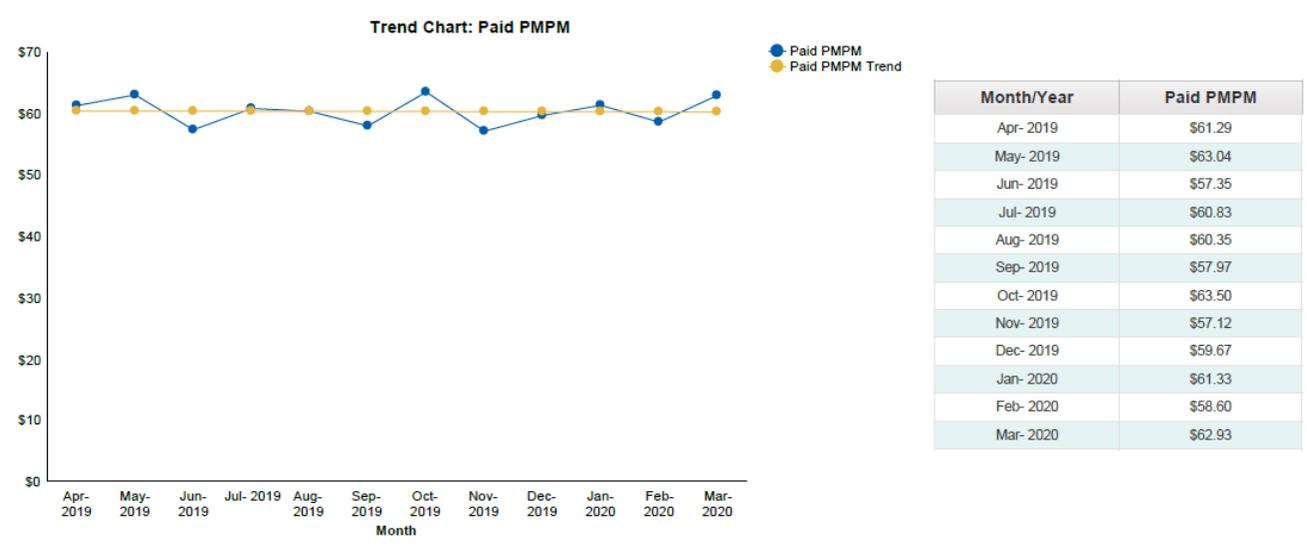
	Latest Month (Mar - 2020)	SMLY (Mar - 2019)	%SMLY*	Last 12 Months Average	Fiscal YTD** (Jul - 2019 -> Mar - 2020)
Total Amt Paid	\$14,096,053.03	\$13,102,210.59	8%	\$13,590,446.94	\$122,201,131.21
Claims Count	118,692	119,350	(1%)	118,548	1,064,544
Paid/Claim	\$118.76	\$109.78	8%	\$114.64	\$114.79
Paid PMPM	\$62.93	\$58.44	8%	\$60.33	\$60.25
Paid PUPM	\$369.96	\$332.75	11%	\$351.82	\$352.32
Claims/User/Month	3.1	3.0	3%	3.1	3.1
Generic Utilization	85.78%	84.67%	1%	85.53%	85.58%
Generic Substitution	92.83%	92.21%	1%	93.06%	93.01%
Co-Pay/Claim	\$0.60	\$0.60	2%	\$0.59	\$0.59
Member-Months	224,011	224,198	0%	225,273	2,028,147
User-Months	38,102	39,376	(3%)	38,629	346,846
% Users	17.01%	17.56%	(3%)	17.15%	17.10%
% Single-Source	7.60%	8.18%	(7%)	8.09%	7.99%

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 increased due to the expanded early refill edits placed earlier in the year. See Graphs 1 and Graph 2 below.

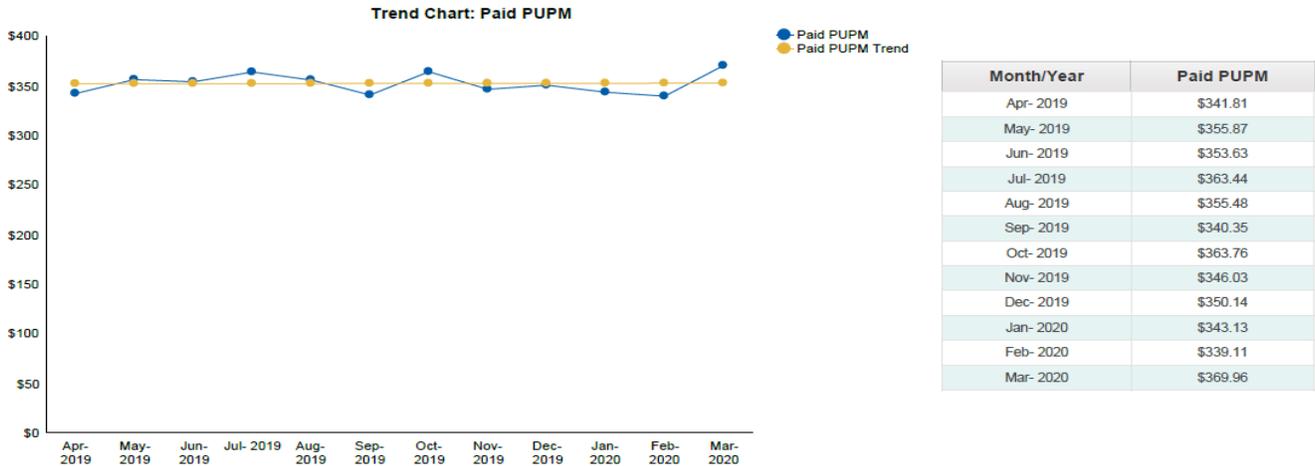
Graph 1.

Data Source : ALASKA MEDICAID
 Service Date : Apr - 2019 to Mar - 2020



Graph 2.

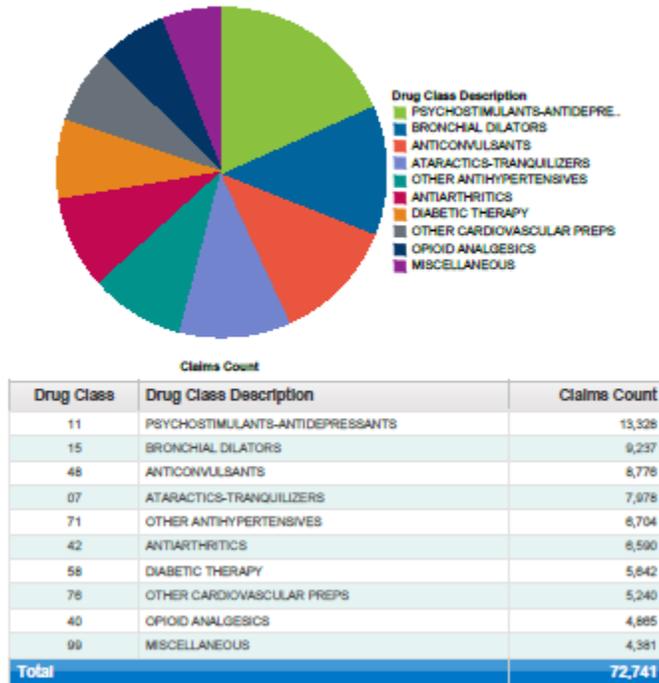
Data Source : ALASKA MEDICAID
 Service Date : Apr - 2019 to Mar - 2020



Dr. Semling went over the top 10 therapeutic classes by volume and cost. Stimulants are number 1 in volume. Increase in bronchial dilators are as expected due to COVID-19. See Graph 3 and Graph 4.

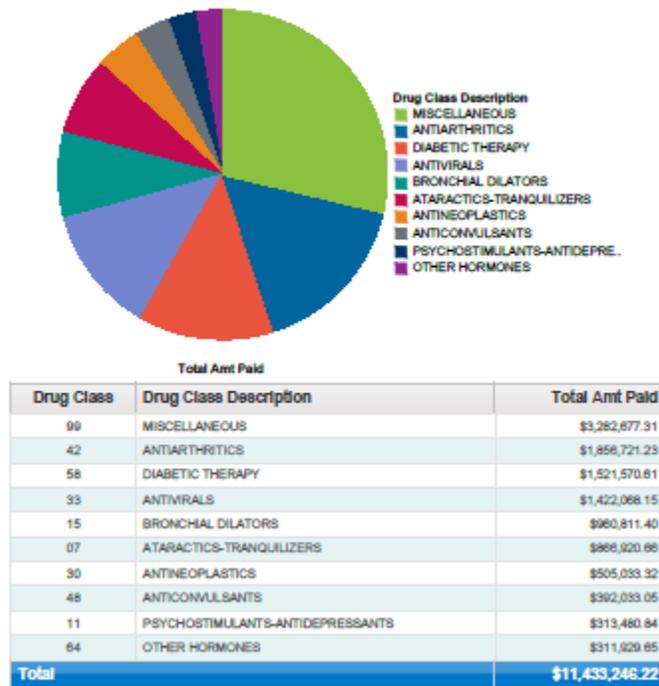
Graph 3.

Data Source : ALASKA MEDICAID
 Service Date : Mar-2020



Graph 4.

Data Source : ALASKA MEDICAID
 Service Date : Mar-2020



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

Table 2.

Data Source : ALASKA MEDICAID
 Service Date : 1 Month (Mar-2020)

Rank	Drug Name	Total Amt Paid	% of Total Amt Paid
1	HUMIRA(CF) PEN 40 MG/0.4 ML	\$662,602.02	13.31%
2	MAVYRET 100-40 MG TABLET	\$493,719.03	9.92%
3	BIKTARVY 50-200-25 MG TABLET	\$286,900.85	5.76%
4	HUMIRA PEN 40 MG/0.8 ML	\$262,514.83	5.27%
5	ADVATE 2,401-3,600 UNIT VIAL	\$237,622.03	4.77%
6	LANTUS SOLOSTAR 100 UNIT/ML	\$233,834.23	4.70%
7	VIVITROL 380 MG VIAL + DILUENT	\$216,097.31	4.34%
8	ENBREL 50 MG/ML SYRINGE	\$200,493.15	4.03%
9	BUPRENORP-NALOX 8-2 MG SL FILM	\$186,305.53	3.74%
10	SYNAGIS 100 MG/1 ML VIAL	\$182,071.26	3.66%
11	XYNTHA SOLOFUSE 3,000 UNIT KIT	\$160,393.82	3.22%
12	DUPIXENT 300 MG/2 ML SYRINGE	\$159,021.59	3.19%
13	IDELVION 2,000 UNIT RANGE VIAL	\$158,384.66	3.18%
14	TRIKAFTA 100/50/75 MG-150 MG	\$151,670.31	3.05%
15	HUMIRA(CF) 40 MG/0.4 ML SYRING	\$150,340.88	3.02%
16	VICTOZA 3-PAK 18 MG/3 ML PEN	\$146,528.28	2.94%
17	RIXUBIS 3,000 UNIT NOMINAL	\$144,134.80	2.90%
18	STELARA 90 MG/ML SYRINGE	\$131,849.44	2.65%
19	SUBOXONE 8 MG-2 MG SL FILM	\$126,674.86	2.54%
20	TECFIDERA DR 240 MG CAPSULE	\$125,903.62	2.53%
21	ELIQUIS 5 MG TABLET	\$119,159.44	2.39%
22	SUBLOCADE 300 MG/1.5 ML SYRING	\$117,193.08	2.35%
23	ALBUTEROL HFA 90 MCG INHALER	\$116,097.20	2.33%
24	RAVICTI 1.1 GRAM/ML LIQUID	\$106,704.01	2.14%
25	SPIRIVA 18 MCG CP-HANDIHALER	\$101,978.90	2.05%
Total		\$4,978,195.13	100.00%

Dupixent made the top 25 drugs by total amount paid, which we will be talking about later (Table 3.).

Table 3.

Data Source : ALASKA MEDICAID
 Service Date : 1 Month (Mar-2020)

Rank	Drug Class	Drug Class Desc	Total Amt Paid	% of Total Amt Paid
1	99	MISCELLANEOUS	\$3,282,677.31	22.90%
2	42	ANTIARTHRITICS	\$1,856,721.23	12.95%
3	58	DIABETIC THERAPY	\$1,521,570.61	10.61%
4	33	ANTIVIRALS	\$1,422,068.15	9.92%
5	15	BRONCHIAL DILATORS	\$960,811.40	6.70%
6	07	ATARACTICS-TRANQUILIZERS	\$866,920.66	6.05%
7	30	ANTINEOPLASTICS	\$505,033.32	3.52%
8	48	ANTICONVULSANTS	\$392,033.05	2.73%
9	11	PSYCHOSTIMULANTS-ANTIDEPRESSANTS	\$313,480.84	2.19%
10	64	OTHER HORMONES	\$311,929.65	2.18%
11	51	GLUCOCORTICIDS	\$286,191.82	2.00%
12	77	ANTICOAGULANTS	\$268,340.49	1.87%
13	90	BIOLOGICALS	\$265,028.05	1.85%
14	87	ELECTROLYTES & MISCELLANEOUS NUTRIENTS	\$248,409.71	1.73%
15	95	ALL OTHER DERMATOLOGICALS	\$238,794.19	1.67%
16	71	OTHER ANTIHYPERTENSIVES	\$220,824.37	1.54%
17	10	CNS STIMULANTS	\$220,561.94	1.54%
18	12	AMPHETAMINE PREPARATIONS	\$199,789.40	1.39%
19	76	OTHER CARDIOVASCULAR PREPS	\$188,077.43	1.31%
20	40	OPIOID ANALGESICS	\$188,052.53	1.31%
21	41	NON-OPIOID ANALGESICS	\$143,458.69	1.00%
22	69	ENZYMES	\$123,756.92	0.86%
23	20	OPHTHALMIC PREPARATIONS	\$116,028.49	0.81%
24	01	ANTI-ULCER PREPS/GASTROINTESTINAL PREPS	\$99,120.78	0.69%
25	27	OTHER ANTIBIOTICS	\$98,215.05	0.69%
Total			\$14,337,896.08	100.00%

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.

ICER Asthma Biologic Report

Dr. Semling went over the ICER Asthma Biologic Report as evidence to add clinical criteria to the biologic drugs for Asthma.

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.

Dupixent® (dupilumab)

FDA INDICATIONS AND USAGE¹

Dupixent® is an interleukin-4 receptor antagonist indicated for the treatment of moderate to severe atopic dermatitis, as an add-on maintenance treatment for moderate to severe asthma, and for the maintenance treatment of rhinosinusitis with nasal polyposis. Inhibition of the receptor interleukin-4 receptor alpha limits cytokine-induced responses, including the release of proinflammatory cytokines, chemokines, and IgE.

APPROVAL CRITERIA

Atopic Dermatitis^{1,2,3}

1. Patient is 12 years of age or older **AND;**
2. Prescribed by or in consultation with an allergist, immunologist, or dermatologist **AND;**
3. Documentation of the affected baseline body surface area affected and severity of symptoms **AND;**
4. Must have tried and failed or has a contraindication to at least two of the following for a period of 30 days:
 - a. > 18 years of age a medium to high potency topical corticosteroid or <18 years of age a low potency topical corticosteroid
 - b. Topical calcineurin inhibitor
 - c. Phosphodiesterase 4 inhibitor

Moderate to Severe Asthma^{1,4,5}

1. Patient is 12 years of age or older **AND;**
2. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist **AND;**
3. Patients has eosinophilic phenotype with an eosinophil count ≥ 300 cells/mcL **OR;**
4. Patient has ongoing symptoms of asthma with a minimum with a minimum 3-month trial of a combination inhaled corticosteroid plus a long acting beta agonist **AND;**
5. Not being used for relief of acute bronchospasms or status asthmaticus.

Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP) ^{1,6}

1. Patient is 18 years of age or older **AND;**
2. Prescribed by or in consultation with an allergist, immunologist, or ENT specialist **AND;**
3. Patient has been diagnosed with CRSwNP that has been inadequately controlled by a first line therapy **AND;**
4. Dupixent® is an add on therapy to and intranasal or oral corticosteroid and 3-4-week courses of antibiotics.

DENIAL CRITERIA^{1,2,3,4,5,6}

1. Failure to meet approval criteria **OR;**
2. Being used in conjunction with another biologic medication (I.E. Enbrel, Xolair, Remicaide, etc.)

CAUTIONS¹

- Monitor for hypersensitivity reactions after administration.
- Patient should be monitored for new or worsening eye symptoms.
- Corticosteroids should not be discontinued abruptly upon initiation of therapy.
- Monitor patients for vasculitic rash, worsening pulmonary symptoms, or neuropathies.

DURATION OF APPROVAL

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

QUANTITY LIMITS

- Initial Dose up to 600mg
- Subsequent doses up to 300mg no sooner than every other week

Motion to approve with Changes: Jenna Heistand, Keri McCutcheon

Oxbryta™ (voxelotor)

FDA INDICATIONS AND USAGE¹

Oxbryta™ is indicated to treat sickle cell disease in patients 12 years of age and older. It is a hemoglobin S polymerization inhibitor that was approved under the accelerated pathway. The drug is thought to inhibit red blood cell sickling, improve red blood cell deformity, and reduce whole blood viscosity.

APPROVAL CRITERIA^{1,2}

1. Patient is 12 years of age or older AND;
2. Patient has the diagnosis of sickle cell disease AND;
3. Prescribed by or consultation with a hematologist or a provider that specializes in sickle cell disease AND;
4. Documentation that the patient has had at least one vaso-occlusive crisis within the past 6 months AND;
5. Has a documented baseline hemoglobin AND;
6. Patient has tried and failed or has a contraindication to hydroxyurea for at least 3 months.

DENIAL CRITERIA^{1,2}

1. Failure to meet approval criteria OR;
2. Patient is receiving concomitant, prophylactic blood transfusions OR;
3. Concomitantly being prescribed with Adakveo.

CAUTIONS¹

- Concomitant use of moderate to strong CYP3A4 inhibitors should be avoided.
- Monitor for hypersensitivity reactions and manage promptly.

DURATION OF APPROVAL

- Approval: Up to 3 months
- Reauthorization: Up to 12 months with documentation showing an increase in hemoglobin and/or decrease in vaso-occlusive crisis related emergencies.

QUANTITY LIMITS

- 90 – 500mg tablets per 30 days

Motion to approve: Dr. Jenna Heistand. 2nd: Dr. Ryan Ruggles

Xolair® (omalizumab)

FDA INDICATIONS AND USAGE¹

Xolair® is indicated to treat moderate to severe persistent asthma, age 6 years and older, who have had a positive skin test or in vitro reactivity to perennial aeroallergen and those symptoms are inadequately controlled with inhaled corticosteroids. It is also indicated for the treatment of chronic idiopathic urticaria, age 12 years and older, who remain symptomatic despite H1 antihistamine treatment.

APPROVAL CRITERIA^{1,2,4}

Moderate to Severe Asthma

1. Patient is 6 years of age or older **AND;**
2. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist **AND;**
3. Patient is not being treated for acute bronchospasm or status asthmaticus **AND;**
4. Patient has a positive skin test or in vitro testing (I.E. for allergen specific IgE antibodies) and/or one or more seasonal aeroallergens **AND;**
5. Baseline IgE level is ≥ 30 IU/mL **AND;**
6. Patient's asthma symptoms have not been adequately controlled for at least three months while being treated with a corticosteroid combination with a long acting beta agonist, leukotriene modifier, theophylline, or an oral corticosteroid.

Chronic Idiopathic Urticaria^{1,3}

1. Patient is 12 years of age or older **AND;**
2. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist **AND;**
3. Patient has had urticaria for at least 6 weeks with symptoms present on 3 or more days a week while taking a non-sedating antihistamine titrated to a maximum dose **AND;**
4. Patient has tried and fail or has an intolerance to a combination of leukotriene modifier, plus a non-sedating antihistamine for at least 2 months.

DENIAL CRITERIA^{1,2,3,4}

1. Patient has failed to meet approval criteria **OR;**
2. Patient is currently using an anti-interleukin 4 or 5 inhibitor.

CAUTIONS¹

- Xolair should be administered in a healthcare setting that is prepared for anaphylaxis.
- Malignancies have been observed with use.
- Xolair should be stopped if patient develops symptoms similar to serum sickness.
- Patients should be monitored for eosinophilic conditions especially upon reduction of oral steroids.

DURATION OF APPROVAL

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

QUANTITY LIMITS

- For Asthma = 3-150 mg vials, Max dose 375 mg
- For Urticaria = 2 -150mg vials, Max dose 300mg

Motion to approve Keri McCutcheon, RPh. 2nd: Dr. Ryan Ruggles

Interleukin-5 Inhibitors Nucala[®], Cinqair[®], Fasentra[®]

FDA INDICATIONS AND USAGE¹

Interleukin-5 (IL-5) inhibitors are indicated as an add-on maintenance treatment for patients with severe asthma, the eosinophilic phenotype. Nucala[®] is also indicated for the treatment of eosinophilic granulomatosis with polyangiitis. Interleukin -5 is the major cytokine responsible for the growth and differentiation, recruitment, activation, and survival of eosinophils. Inhibition of IL-5 reduces the production and survival of eosinophils and inflammation.

APPROVAL CRITERIA

Maintenance Treatment of Severe Asthma^{1,2,3,4,5,6,7}

1. Patient is 6 years of age or older for Nucala[®], 12 years of age or older for Fasentra[®] or 18 years of age or older for Cinqair[®] **AND;**
2. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist **AND;**
3. Patient has the diagnosis of severe asthma **AND;**
4. The member has one of the following blood eosinophil counts:
 - A) For Nucala[®]:
 - a) Blood eosinophil count > 150 cells/mcL with 6 weeks of treatment initiation **OR;**
 - b) Blood eosinophil count > 300 cells/mcL in the past 12 months **OR;**
 - B) For Fasentra[®]:
 - a) Blood eosinophil count ≥ 150 cells/mcL within 4 weeks of treatment initiation **OR;**
 - C) For Cinqair[®]:
 - a) Blood eosinophil count > 400 cells/mcL within 4 weeks of treatment initiation **AND;**
5. Patient has ongoing symptoms of asthma with a minimum 3-month trial of a combination inhaled corticosteroid plus a long acting beta agonist, leukotriene modifier or theophylline, or is intolerant to all of these medications **AND;**
6. Requested medication will be used concurrently with other asthma controller medications.

Eosinophilic Granulomatosis with Polyangiitis^{1,8}

1. Request is for Nucala[®] **AND;**
2. Patient is 18 years of age or older **AND;**

3. Prescribed by or in consultation with an allergist, immunologist, rheumatologist, or pulmonologist **AND;**
4. Patient diagnosis of eosinophilic granulomatosis with polyangiitis based on the presence of at least four of the following diagnostic criteria:
 - a) Asthma
 - b) Eosinophilia (>10% eosinophils on the differential leukocyte count)
 - c) Mononeuropathy or polyneuropathy
 - d) Migratory or transient pulmonary infiltrates on chest x-rays
 - e) Paranasal sinus abnormalities
 - f) Biopsy containing a blood vessel with extravascular eosinophils
5. Patient has been stable on corticosteroids for at least 4 weeks or the prescriber has indicated clinical inappropriateness of corticosteroid therapy.

DENIAL CRITERIA^{1,2,3}

1. Failure to meet approval criteria **OR;**
2. Being used in conjunction with another biologic medication (I.E. Enbrel, Xolair, Remicaide, etc.) **OR;**
3. Being used for relief of acute bronchospasms or status asthmaticus.

CAUTIONS^{1,2,3}

- Monitor for hypersensitivity reactions after administration.
- Patient should be monitored for new or worsening eye symptoms.
- Corticosteroids should not be discontinued abruptly upon initiation of therapy.
- Monitor patients for vasculitic rash, worsening pulmonary symptoms, or neuropathies.

DURATION OF APPROVAL

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

QUANTITY LIMITS

- Fasenra® - 30 mg subcutaneously every 28 days for the first 3 doses, and then once every 8 weeks
- Nucala® -100 mg subcutaneously once every 28 days for severe asthma
-300mg every 28 days for Eosinophilic Granulomatosis with Polyangiitis
- Cinqair®: 3 mg/kg IV once every 28 days

Motion to approve Keri McCutcheon, RPh. 2nd: Dr. Jenna Heistand

Review of **existing** Prior Authorizations, Quantity Limits, Edits

The below existing Prior authorizations were updated.

Orexin Receptor Antagonists

Belsomera[®], Dayvigo[™]

EDA INDICATIONS AND USAGE^{1,2}

Orexin receptor antagonists are indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

APPROVAL CRITERIA^{1,2,3,4}

1. Patient has a diagnosis of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance **AND;**
2. Patient is 18 years of age or older **AND;**
3. Other causes of sleep disturbance, such as a physical or psychiatric disorder, have been ruled out **AND;**
4. A diagnosis of sleep disturbance caused by a medication has been considered and addressed as clinically appropriate by one of the following:
 - a. Medication-induced sleep disturbance has been ruled out, **OR**
 - b. Medications which are causing sleep disturbance have been discontinued as clinically appropriate, **OR**
 - c. Medications which are causing sleep disturbance have been adjusted to minimize the effects on sleep (for example, dosing the medication earlier in the day, or decreasing the medication dosage) as clinically appropriate **AND;**
5. There is documentation that the patient has tried and failed two prescription sleep aids **AND;**
6. The patient has had a documented trial of cognitive behavior therapy (CBT) which must include education on sleep hygiene improvements and common misconceptions about sleep/insomnia.

DENIAL CRITERIA^{1,2,3}

1. Failure to meet approval criteria **OR;**
2. Patient has a narcolepsy diagnosis **OR;**
3. Patient is taking another sedative hypnotic agent concurrently

CAUTIONS^{1,2}

- May impair alertness and motor coordination including morning impairment.
- May worsen depression or suicidal ideation.
- Sleep-walking, sleep-driving, and engaging in other activities while not fully awake has been observed.
- Sleep Paralysis, Hypnagogic/Hypnopompic Hallucinations, and Cataplexy-like Symptoms may occur.

DURATION OF APPROVAL

- Approval: Up to 3 months
- Reauthorization: Up to 6 months

Motion to approve with changes for duration of approval of up to 6 months since it is a controlled substance:
Keri McCutcheon, 2nd Dr. Jenna Heistand

Opioid Report

The opioid report was reviewed for trends. Overall, the trend is declining. Upon review, the committee wanted to know which antipsychotic are most commonly prescribed with opioids. Dr. Semling will take that back as a follow-up and Magellan to add that information to the next report. The committee would also like to see which patients are tapering. Magellan to go back and look at the individual prior authorizations. Dr. Semling announced that under contract with the University of Washington, practitioners will be able to call and ask for assistance for opioid treatment plans.

Safety Reports

Dr. Semling reviewed safety reports for the following drugs:

Safety clinical trial shows possible increased risk of cancer with weight-loss medicine Belviq, Belviq XR (lorcaserin)

FDA strengthens warning that untreated constipation caused by Schizophrenia medicine clozapine (Clozaril) which can lead to serious bowel problems.

FDA requires Boxed Warning about serious mental health side effects for asthma and allergy drug montelukast (Singulair); advises restricting use for allergic rhinitis.

FEARS Reports

Dr. Semling reviewed the FEARS Reports for December 2019/ Potential Signals of Serious Risks/New Safety information Identified by the FDA Adverse Event Reporting System (FAERS).

There were no comments from the committee.

End of Public Meeting

Adjournment 2:37 p.m.

Next meeting date September 18th, 2020.