Alaska Medical Assistance DUR Committee Meeting Minutes

Friday, November 16, 2018

Frontier Building, 3601 C Street; Room 896

1:00pm

Drug Utilization Review Committee

Members Present	Non Members Present
Dr. Erin Narus, PharmD (DHSS)	Dr. Umang Patel, PharmD (Magellan)
Dr. Charles Semling, PharmD(DHSS)	Elaine Edwards, RPh (Magellan)
Dr. Robert Carlson, MD	
Dr. Barb Piromalli, DO	
Dr. Ryan Ruggles, PharmD	
Keri McCutcheon, RPh	

Review of minutes from September 2018

A motion was made to approve the minutes by Dr. Piromalli and the motion seconded by Dr. Ruggles.

Review of Agenda

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 from 2017 to 2018. 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. The new PDL will address and override some of these new medications. The Suspend List process for new drugs to market was discussed by the committee which will decide if one or two trials are recommended for each product. Medications reviewed this meeting included Nuzyra, Seysara, Xyosted, Libtayo, Emgality, Vizimpro, Copiktra, Ajovy, Lumoxiti, Cassipa, Takhzyro, Diacomit, Galafold, Onpattro, Poteligeo, Panzyga, Epidiolex which became available since the September meeting. Discussion centered on committee decision to require status and placement on the 6 month trial period Interim PA List or to have criteria created for prior authorization. Keri McCutcheon suggested leaving tetracycline on the 6 month Interim PA list and oral oncology agents to require prior authorization on a case by case basis. A decision was made by the committee to remove medication from Suspend List and let the PDL handle it, monitor

utilization and report any irregularities to the attention of the committee which would call for review or create criteria for use. Once the Lt Governor signature is obtained for regulations to be official many drugs will be moved from the Suspended Interim PA List and placed on the PDL.
Motion to approve by Dr. Piromalli with second motion by Dr. Ruggles.

New Prior Authorizations, Quantity Limits, Edits

Dr. Semling reviewed new medications for prior authorization:

Orilissa™ -
Approval criteria must meet all of the following:
Diagnosis required for the management of severe pain associated with endometriosis, Age for 18-49 years, Patient is not pregnant, Patient has no known osteoporosis, Patient does not have severe hepatic impairment, Patient is not taking a strong organic anion transporting polypeptide 1B1 inhibitor i.e. cyclosporine, Patient has had an adequate trial of an oral combination contraceptive for at least 3 months, Patient has had a trial of either a long acting progestin-only contraceptive or GnRH agonist. Initial approval up to 6 months for both strengths Reauthorization approval up to 12 months for 150mg dose only. Denials will be given if information is opposite of any approval criteria. Quantity Limits are #30— 150mg tablets per month, #60 — 200mg tablets per month. With addition of diagnosis in criteria the above was motioned by Dr. Piromalli to be approved with second motion made by Dr. Ruggles and approved unanimously by the committee.

CGRP antagonist (Calcitonin Gene-related peptide receptor antagonists)
Approval criteria must meet all of the following:
Diagnosis required for the preventive treatment of migraine in adults, Patient is within the age range recommended by the FDA label, Prescribed in consultation with or is a headache specialist, pain specialist, or neurologist, Patient has the diagnosis of episodic or chronic migraine, Patient is experiencing 4 or more documented migraine days per month, medication is being used for prophylaxis, 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. Initial authorization will be for 3 months with reauthorization to be 6 months with documentation of reduction in the number of headaches per month. Denials will be given if information is opposite of any approval criteria.
Discussion centered on cost versus benefit. Medication will mostly reduce headaches to 2 to 4 headaches per month. Some patients may see improvement and see results that are worthwhile. Dr. Piromalli stated in some patients this can be helpful. Dr. Semling noted this is a preventative class and is similar with Botox. A trial and failure of traditional medications would be required. The medication shows it is well tolerated and has expected injection site adverse reactions. The committee made a motion to add the criteria as written motioned by Keri McCutcheon to be approved with second motion made by Dr. Piromalli. Approved unanimously by the committee.

Epidiolex®
Approval criteria must meet all of the following:
Indicated for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome, patient is 2 years of age or older, prescribed by or in consultation of a neurologist, patients seizures have not been controlled by at least a trial of 2 antiepileptic drugs, patient will use as an adjunctive therapy with at least one other antiepileptic drug, and serum transaminases and bilirubin levels are obtained prior to starting treatment. Initial approval up to 4 months with reauthorization approval up to 12 months if the patient is responding positively and doses have not exceeded 20mgkg/day. Doses start 2.5 to 5mg and increase based on response. Quantity Limits will be set at 5 — 100ml bottles (100mg/ml) per fill.
Denials will be given if information is opposite of any approval criteria. Dr. Semling started discussion noting there are limitations on trials. Dr. Piromalli brought up that conditions for these patients are so severe and

deserve special consideration. Dr. Semling noted that by the time the condition is diagnosed it is usually used as an adjunct therapy and 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. The committee made a motion to add the criteria above motioned by Dr. Piromalli to be approved with second motion made by Keri McCutcheon. Approved unanimously by the committee.

Xyrem®

Approval criteria must meet all of the following:
Diagnosis for the treatment of excessive daytime sleepiness with narcolepsy and cataplexy with narcolepsy, patient is 16 years of age or older, patient has a documented diagnosis supported by a letter of medical necessity for excessive daytime sleepiness with narcolepsy or cataplexy with narcolepsy, patient and provider are both enrolled in Xyrem REMS Program, Xyrem is being prescribed by a sleep specialist or neurologist, patient is not taking or using concomitant CNS depressants like opioids, benzodiazepines, alcohol, sedative hypnotics, muscle relaxants and other CNS depressant drugs, patient has been evaluated for major depressive disorder and history of substance misuse, patient has tried for a period of at least 30 days and failed at least one CNS stimulant drug (i.e. methylphenidate) or has a contraindication to stimulant use, patient has tried for a period of at least 30 days and failed at least one CNS promoting wakefulness like modafinil or has a contraindication to stimulant use. Initial approval up to 3 months with reauthorization approval up to 6 months if the patient is responding positively and doses have not exceeded 9 mg per day. Denials will be given if information is opposite of any approval criteria and patients have heart failure, hypertension, impaired renal function, or respiratory problems. Quantity Limits are 3-180ml bottles per fill. Doses to not exceed 9mg per day. Dr. Semling noted it is contraindicated when combined with alcohol or sedative hypnotics. Dr. Piromalli, Ms. McCutcheon, Dr. Carlson and Dr. Ruggles agreed a 30 day previous trial is appropriate with symptoms in mind. Discussion over requiring documentation of a drug screen prior to initiation of therapy since this is a highly abused product. The committee made a motion to add the criteria above motioned by Dr. Ruggles to be approved with second motion made by Dr. Piromalli. Approved unanimously by the committee.

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

HP Acthar® -

Approval criteria must meet all of the following:
Diagnosis for infantile spasms and children under 2 years of age and for treatment of exacerbations of MS in adults. It is also indicated for diseases of rheumatic, collagen, dermatologic, allergic states, ophthalmic, respiratory, and edematous states. Addition to the criteria to include that the patient does not have any of the following contraindications to the use of HP Acthar: Scleroderma, osteoporosis, systemic fungal infections, ocular herpes simples, recent uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyper function, or sensitivity to proteins of porcine origin. Also adding criteria the patient meets all of the criteria listed and has a diagnosis listed in Table 1 (West Syndrome or infantile spasms, MS) and Table 2 (Ankylosing Spondylitis, Optic Neuritis, Systemic Dermatomyositis, Proteinuria in Nephrotic Syndrome, Psoriatic arthritis, rheumatoid arthritis, symptomatic sarcoidosis, systemic Lupus Erythematosus or SLE) listings will require a Letter of Medical Necessity. Initial approval up to 4 weeks except for MS will be 21 days. Reauthorization approval will be given if they meet initial criteria with documented evidence of positive response to therapy. Quantity Limits are six 5ml vials per 30 days. Dr.Ruggles made a motion to approve the criteria with second motion made by Dr. Piromalli and approved unanimously by the committee.

Lidoderm® -
Approval criteria must meet all of the following:
Diagnosis for relief of pain associated with post herpetic neuralgia, Carpal tunnel syndrome, cervical radiculopathy, Complex regional pain syndrome (CRPS), Diabetic peripheral neuropathy (DPN), Idiopathic sensory polyneuropathy, Myofascial pain syndrome, neuropathic cancer pain for palliative care, trigeminal neuralgia, cervical neck pain or Low back pain. Quantity Limits are 2 patches per day. Criteria for Reauthorization approval of 1 year can be given if patient meets all of the criteria for the initial authorization and there is documented evidence of a positive clinical response to lidocaine patch therapy. Dr. Piromalli suggested adding cervical neck pain to the diagnosis criteria. Dr. Ruggles made a motion to approve the criteria with second motion made by Dr. Piromalli and approved unanimously by the committee.

Opioids – Initiatives, Monitoring, and Updates

Dental analgesia protocol update

A policy was shared by Dr. Semling from the Center for Evidence-based Policy regarding managing dental pain with alternatives to opioids. This policy showed how dentists preoperatively prescribe the lowest effective dose of opioids and the lowest quantity necessary while avoiding opioids in combination with benzodiazepines, sedative-hypnotics, or anxiolytics. Intraoperatively the policy highlighted how dentists are using preemptive analgesia with long-acting anesthetic injections and corticosteroid bursts to reduce edema and pain after oral surgery. Postoperatively dentists prescribe the lowest effective dose of opioids and the lowest quantity necessary. Dental prescribers are writing opioids in combination with first-line therapy avoiding multiple acetaminophen-containing preparations. The policy is to prescribe a 3 day limit and not exceed 12 tablets for people less than 25 years of age, avoiding codeine or tramadol to anyone under 18 years of age. Coordination of care is undertaken by checking the state prescription drug monitoring database and conferring with the patient's primary care provider. Recommendations also include pain management strategies using ice to the affected areas. Dr. Ruggles mentioned how a prescriber's location and training may prove to be a barrier for the information to be disseminated. Going forward Dr. Semling will be reaching out to the dental community to encourage open communication working toward managing opioid therapies and encourage good policies in dental practices.

Standards of Care-

Multiple Rx written same day for same medication circumventing quantity limits.

Policy guidance was reviewed by Dr. Semling with committee members for opioid prescriptions for members with Alaska Medicaid. Despite significant efforts by the State professional boards, legislature, and agencies to promote and demonstrate evidence-based practice guidance for opioid prescribing, the Alaska Medicaid Pharmacy program continues to receive reports of prescribers writing two separate prescriptions for the same opioid dosage unit. In an effort to ensure that all Alaska Medicaid enrolled prescribers and pharmacists are aware of the program's interpretation of acute and chronic opioid therapy prescribing, this policy guidance is being sent to all Medicaid enrolled prescribers and pharmacies in addition to reaching out to outlying prescribers individually. The letter will be sent once it has been approved by the Medicaid Drug Utilization Review Board. Pharmacies and prescribers will have time to review their practices to evaluate compliance with this clinical practice interpretation. After careful discussion with committee members a few changes will be

made. A revised form of the letter with dosage units defined, and treatment plan guidance rules will be added. Dr. Semling will provide a final version of the letter draft and it will be made available for the committee to review.

Intervention Informational Updates

Gabapentin/Lyrica® letter to be sent to providers

A letter was presented to committee members drafted by Dr. Semling to be sent to providers in awareness of gabapentin abuse potential. The letter will be bolded in areas of emphasis on the letter and sent off via fax to providers.

FDA/DEA Updates

Drug Safety Communications: The FDA warns about rare occurrences of a serious infection of the genital area with SGLT2 inhibitors for diabetes. Cases were reported to the FDA Adverse Event Reporting System (FAERS). A safety announcement has been posted by the FDA to notify healthcare professionals of potential for infections that can cause serious infections and even gangrene with products such as Invokana, Invokamet, Invokamet XR, Farxiga, Xigduo XR, Qtern, Jardiance, Glyxambi, Synjardy, Synjardy XR, Steglatro, Segluromet, and Steglujan. In addition during committee discussion and review of the FAERS report it was pointed out that Insulin Pen products have a warning that wrong dose errors have occurred and safety concerns increase when pharmacies are opening cartons to dispense a single insulin pen. The FDA is evaluating the need for regulatory action due to this practice.

Trend Reports

Total Opioid utilization was reviewed from last year's previous quarters compared to this year's quarters. Total MME has significantly dropped this year compared to last year. Dr. Semling and Keri McCutcheon mentioned how cash customers could not be tracked and this report will only show Magellan paid claims data. We are heading in the right direction.

Hepatitis C Cost avoidance report was reviewed as a quarter by quarter comparison. The report highlighted and showcased the hard work the DUR committee has done for the direct acting antivirals for hepatitis treatment. Not only were cost savings incurred by the program but the program doubled the number of patients treated and also realized a cost avoidance based on therapy regimens. There was an 8 to 10 Million dollar cost avoidance, coupled with 150 more people treated and a savings of $400,000 which helped get patients treatment.

New product review – HCPCS- Skin substitutes (tabled for future meeting)

Adjournment 4:01 p.m.

Motion for meeting to be adjourned made by Dr. Piromalli and seconded by Dr. Ruggles.

Next meeting January 18, 2019.