

# Alaska Medical Assistance DUR Committee Meeting Minutes

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Friday, September 21, 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. Jenna Hiestand, MD	
Dr. Heath McAnally, MD	
Dr. Barb Piromalli, DO	
Dr. Ryan Ruggles, PharmD	
Keri McCutcheon, RPh	

### Introduction of members

Dr. Erin Narus introduced and welcomed Dr. Charles Semling as Alaska Medicaid’s new DUR Coordinator who has served on the Alaska Medicaid DUR and P & T Committees. He has also served Alaskans as a community retail pharmacist for greater than 13 years. Kerri McCutcheon RPh was also introduced as a new member to the committee. In addition, the committee made general introductions.

### Review of minutes from April 2018

Minutes were approved with motion by Dr. Ryan Ruggles and Dr. Jenna Hiestand.

### Review of Agenda

### New Product Reviews

Dr. Erin Narus commented a new skin substitute product will be tabled to gain more information and clarity on the product until the next DUR Committee November review.

## Prospective Drug Utilization/Clinical Topic Areas:

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

The DUR Committee members will review new medications to market from 2017 to 2018. Newer drugs to market will be reviewed after 6 months new to the market and later 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. Dr. Erin Narus also reminded the committee that for any new and existing products there is a pharmacy edit in place requiring PA for cost exceeding the limit of \$7500 for all drugs. Dr. Charles Semling referred the committee to future discussions of new and existing products such as Yescarta (treatment for small lymphomas with cost greater than \$400,000) will be reviewed balancing cost versus benefit to patients. Once the drugs are on the list they will be reviewed by the committee and efficacy will be discussed.

### New and Existing Prior Authorizations, Quantity Limits, Edits

Dr. Charles Semling reviewed the following medications with committee members:

**Eucria** is a newer agent for atopic dermatitis. The committee is tasked with building inclusion criteria for approval with basic recommendations from the package insert. Dr. Semling stated the product has a fair amount of utilization and is FDA approved for individuals 2 years of age and older. The approved diagnosis is Mild to Moderate Dermatitis. Tacrolimus is usually trialed for at least four weeks prior to use of medication. The committee as a whole discussed it was necessary to require at least 1 medium and 1 high potency steroid trial. If contraindications exist for treatment with tacrolimus or pimecrolimus prior authorizations would be readily available for use. Dr. Piromalli and Keri McCutcheon stated there are multiple steroids available and use on the face would be a concern in high potency steroid use. Dr. Ruggles stated there could be concomitant infection which poses a contraindication. Dr. Narus explained we should provide clarity around the specific contraindications and ensure there is a true contraindication. Approval for use would need to be well defined to the label and not to include any listed contraindications. Overall there was agreement the contraindication should be scrutinized. Committee discussion and agreement to include age, diagnosis, trials of at least one medium to high potency corticosteroid for at least 2 weeks or a contraindication to corticosteroid use would be accepted along with at least one trial of tacrolimus or pimecrolimus for at least a month unless contraindicated. Quantity limits will be based on the location or part of the body being treated starting with application of a thin film allowing one 60 gram tube per month. Comments from committee included Dr. Carlson's comment that it is used for mild to moderate cases so it would not be the medication as the last resort or used in complicated cases. Dr. Carlson and Dr. Ruggles suggested if there is no worsening of the condition and the patient is stable on the medication it should be allowed for renewal. The committee approved Dr. Semling's suggestion to start with a 3 month approval for initial authorization. Renewal would be based on documentation presented for approval up to 12 months if patient condition improved.

**Cambia** - Diclofenac oral powder for diagnosis of acute migraines available in a box of 9 packets, 1 each Diclofenac Potassium 50mg, Powder for oral solution and cost is estimated at \$225. Cost of therapy versus other therapy is clinical reason enough for prior authorization. Caution is given for review of profiles for patients prescribed Cambia that have no trials of other NSAIDs or other diclofenac dosage forms. The FDA supports a one-time dose for the diagnosis of Migraines with or without aura for patients greater than or equal to 18 years. It is recommended to trial and fail 2 other NSAIDs which would include oral diclofenac along with 1 liquid NSAID, 2 triptans, and not to be used for daily use. The committee reviewed criteria written to include age, diagnosis, and trials of at least two other NSAIDS, including diclofenac potassium tablets, for difficulty swallowing then at least one liquid NSAID must have been trialed, and a trial of at least two triptans unless contraindications exists. Medication should not be used daily. Initial approval will be for 6 months with a renewal authorization extended for 12 months. Dr. Ruggles moved to approve the criteria and it was seconded by Dr. Carlson. The Committee unanimously approved criteria as stated.

**Viberzi**- Viberzi is increasing in utilization with AK Medicaid patients. It binds to various opioid receptors and is used in the treatment of IBS with diarrhea for patients greater than or equal to 18 years. Dr. Hiestand brought up necessary concerns to restrict for use due to the abuse potential the drug poses. Dr. Semling and Dr. Narus agreed it is important to consider appropriate treatment practices with opioid receptor agonists. For approval on prior authorization clinically it is common to require trials of one anti-spasmodic (hyoscyamine) and one anti-diarrheal (loperamide) or a tricyclic antidepressant (TCA). In addition, Dr. Semling stated 1 TCA or 1 serotonin reuptake inhibitor (SSRI) trial for a period of at least 8 weeks is encouraged. These are the common clinical standards to be required prior to use of Viberzi. Committee discussion included comments regarding benzodiazepine use and trials of medications were important to rule out overuse and treatment with benzodiazepines was a strong concern. It is important to note First Data Bank places Pro-DUR edits with benzodiazepine use and the manufacturer publishes warnings associated with abuse potential supporting concern is high. All committee agreed to include diagnosis, age and restriction of concomitant opioids or benzodiazepines along with trials required of at least one TCA or SSRI for a period of 8 weeks, a trial of at least one antispasmodic agent (i.e. hyoscyamine) and lastly a trial of at least one antidiarrheal agent (i.e. loperamide). Initial approval will be for 3 months with 12 month renewal with improvement in quality of life and decreased stool frequency. Viberzi will have a restricted quantity limit of 60 tablets per month for each strength. Denial criteria was accepted by the committee and included diseases concerning gut absorption to be contraindicated. Dr. Piromalli moved to approve criteria as above and seconded by Dr. Hiestand.

**Gralise/Horizant**- (Gabapentin ER) – Gabapentin use has greatly increased and the medication is being used for many other diagnoses. Dr. Semling stated a review is underway looking at utilization of Lyrica and gabapentin where 2100 providers had prescribed at least one of these products over the last year. The medication can be costly and does not take much of a dose increase to achieve potentiation. Dr. Narus stated Lyrica usage is hard to manage due to increased use affects so many members. Challenges exist with use for high need with neuropathic pain and appropriate usage must be balanced. Placing an edit in the pharmacy system poses challenges. Dr. Semling verified there are 17,000 claims with Lyrica alone and it is hard to go back and require

prior authorization once members are established on the medication. Dr. Hiestand stated Alaska has high use of gabapentin with increased use coming from substance abuse facilities. Keri McCutcheon mentioned that gabapentin used alone in high doses should benefit patients and would commonly decrease the need for any other medications. Dr. Narus and Dr. Ruggles proposed sending out education to providers in form of letters annually or bi-annually. Dr. Semling will draft a letter and gather data to support the message. The letter will be presented at next meeting. Keri McCutcheon, Dr. Ruggles, and Dr. Hiestand challenged if there were other media resources to reach providers and get the word out. Provider outreach is a challenge. Thirty day notices and remittance advices can cause alert fatigue. Fax information was discussed to be a reliable and consistently read message. Emails pose a challenge however they could be effective if brief and short enough to easily read. Dr. Narus mentioned many state license boards, federal departments, and the PDMP require email addresses to inform members of important notices. Possible collaboration with these entities may be helpful. Dr. Carlson suggested using a model that already works to disseminate the information which can provide the committee better feedback. Dr. Semling will follow up with options to disseminate the information.

Use of Gralise or Horizant increases cost especially with more utilization when gabapentin immediate release is not properly trialed. Currently there are 40 people on this medication and discussion with the committee around an adequate trial is needed. Cost of product could be \$300-\$600 per month. How many weeks to trial is adequate? 4, 8 or 12 weeks appears needed since it takes time to titrate up to proper dosing. The half-life for Horizant is 6 hours and the half-life for Gralise is 5 to 7 hours. Dr. Hiestand questioned reasons why this was covered at all and Dr. Semling stated it was utilized and filled since it was removed from the suspend list without specific guidelines. Dr. Semling stated an adequate trial of 1800mg for 12 weeks should be an adequate trial. Dr. Carlson also explained it works well but takes a long time for patient adjustment at maximum doses. Dr. Hiestand and Dr. Carlson agreed PHN would be an acceptable diagnosis to spend the extra cost on the extended release formulation. A length of a proper trial is tricky with this medication as use of high doses are often needed. Gralise and Horizant are not interchangeable with other products based on pharmacokinetics. Initial approval was accepted to be for 6 months with reauthorization and renewal for 12 months. Criteria was reviewed for diagnosis of Post-herpetic Neuralgia and Restless Leg Syndrome (RLS) for Horizant with adequate trials of generic gabapentin of 1800mg with adequate response for 8 weeks and 4 weeks of pramipexole and ropinerole (RLS) with no contraindications or adverse events. Quantity limits were set at thirty units for 300mg and ninety units for the 600mg.

## Standards of Care – MAT Providers Standards of Care Attestation

The MAT Provider Attestation will compile information from the provider which will help certification of providers to waive status to require prior authorization for buprenorphine products to provide medication administered therapy. Dr. Semling reviewed with the committee the checklist for a drafted attestation form developed to assist in credentialing prescribers. If prescribers comply with the application checklist to verify standards of care will be met, they could be approved and give a one year prior authorization for oral buprenorphine products. Once approved this credentialing will minimize the administrative burden when needing prior authorization for patients on oral buprenorphine therapy. This application will be sent to the call center and reviewed by the state who will validate prescribers for proper attestation.

The committee reviewed the attestation line by line. Discussion regarding necessity to provide training certificates when submitting the form was questioned by Dr. Hiestand as training certificates are burdensome and the waiver is already required for practice standards. To manage the process it was suggested to require only last digits of the DATA 2000 waiver and approximate number of years practicing in the field so the state can perform the audit. Dr. Hiestand asked if one form can be filled out for the entire practice. Dr. Narus and Dr. Semling assured the committee it would be acceptable to send in the front sheet for each individual provider along with back sheets not duplicated. This credentialing will save time, increase compliance, improve therapy and provide continuity of care for patients.

Dr. McAnally joined the call and added value to the discussion, as Dr. Semling was reviewing the form. The committee was posed a question if the PA attestation should allow treatment of all dual and single agent products or limit the waiver to dual agents only and restrict single agent oral buprenorphine to pregnant females. Dr. Narus noted there are challenges that exist on these products and members deserve a high quality of care. This is important to the state to take careful consideration with this population. After careful dialogue the committee approved the attestation for prior authorization for dual agents and to reserve single oral agents for pregnant women. This decision will alleviate paperwork and improve access to important medication for a majority of members. Dr. Carlson agreed keeping edits simpler is a positive step. The full committee was in favor of the attestation form. Providers will be notified if approved or denied with an annual approval given. Prior to denial the state will reach out to the provider to work with them on how best to comply with the checklist to decrease the administrative burden for these patients.

### Adjournment 4:02 p.m.

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

Next meeting set for November 16, 2018.