Alaska Medical Assistance DUR Committee Meeting Minutes

Friday, January 18, 2019
Frontier Building, 3601 C Street; Room 896
1:00pm

Drug Utilization Review Committee

<table>
<thead>
<tr>
<th>Members Present</th>
<th>Non Members Present</th>
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<tbody>
<tr>
<td>Dr. Erin Narus, PharmD (DHSS)</td>
<td>Dr. Umang Patel, PharmD (Magellan)</td>
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<td>Dr. Charles Semling, PharmD (DHSS)</td>
<td>Dr. Marti Padilla, PharmD, (Magellan)</td>
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<td>Dr. Jenna Hiestand, MD</td>
<td>Vicki Bohanon (Magellan)- Telephone</td>
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<td>Dr. Ryan Ruggles, PharmD</td>
<td>Dr. Julius Goslin (Medical Director)</td>
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<td>Dr. Barb Piromalli, DO</td>
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<td>Keri McCutcheon, RPh</td>
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Review of minutes from November 2018

- Minutes approved. A motion was made to approve the minutes by Dr. Hiestand, MD) Seconded by Dr. Ruggles
- No changes or issues with previous minutes. Will be posted online for public viewing.

Review of Agenda

Dr. Semling went over the Agenda to the committee members.

Comments/Suggestions from Committee members

Keri McCutcheon stated that there are issues with PA for Discharges. PA for discharges should be prioritized. Low Dose Seroquel QL is the one experienced most often. Magellan should be prioritizing to override.

Dr. Ruggles, recommended to call providers to communicate. Dr. Semling stated they are working with MagellanRx to fax blast pharmacies.

Dr. Narus stated that they are trying to figure out cross agency communications, in terms of email lists. For the most common drug, Seroquel 30 day supply, there was inappropriate prescribing for sleepers just to give a little background on the edit. Dr. Narus stated that we can change to a 1/day quantity. The majority are of pediatric indications. Inappropriate prescribing is mostly with 25mg and 50mg for PRN dose for anxiety.
Overview of Medicaid Prescription and Cost Trends

Charles Semling reviewed Prescription and Cost Trends.

Claims/month: there is an overlap 200 individuals in first year just under 100 folks for HepC and treated twice as many after criteria changed and Mavyret became available. Cost savings were in 6 million dollar range. Cost avoidance was 8 million by going with new agent, which was significant. Dr. Hiestand asked if most people are finishing the 8 week course and have they been undetected after treatment? Dr. Semling stated that they had about 3 re-treatments, but overall good. 1 re-treatment was re-exposure.

PMPM: Spend $57 & $56 the prior year.
Claims/User/Month
Three claims is pretty standard over last year. Specialty medications are driving cost.

Generic Substitution:
Currently there is a 91% generic substitution rate. The 8% is probably due to Coumadin and Synthroid. Dr. Narus stated that under the 340B program there are manufacturers that will offer certain rates for certain facilities/population and get an upfront discount. Sometimes the generic is more expensive because of the rates the manufacturers give for rebates for brands depending on contract price. Often times it is better to lose 8% to branded drug than to force them to dispense generic.

Last 12 month average:
July-Nov pharmacy spend was 62 million for about 560,000 claims.
Actually very close from year over year. Prescription spend is doing really well management wise. Dr. Narus commented that states who participate with the manufacturers federal drug rebate program, the Net cost is actually less than shown above. The numbers continue to show downward trends or at least a flat line despite challenges, such as, increase costs of biologics, which is a good trend to have. The state does not specifically define "specialty", as they are looking/focusing on drug classes. Specialty is used in a generic term for “high cost” drugs. If there are certain trends that are noticed, then it will be brought to the committee for review.
PMPM annual trend chart.

Dec 2017 to Nov 2018, costs for each member: Trend is almost flat even though prices have increased for some drugs.

PUPM annual trend chart.

Increased trend due to increased costs but not as expected. Year over year increased a little bit. Nov 342 PUPM, 100/claim per member.
Top 10 Therapeutic Classes

This data is for the month of November only. The Psychostimulants-antidepressants are the top drug class. Dr. Ruggles commented that many diabetics will go hand in hand with the top drug class. Anticonvulsants have many uses, such as preventing migraines.

Top 10 Therapeutic Classes by Dollar Amount

Nov 2018
Miscellaneous category: Marti Padilla, from Magellan Rx, will come back with drug names that fall into the miscellaneous category. Diabetes is increasing becoming more expensive because of new drugs: For example, Byetta. Medicaid only allows 34 day supply.
Top 25 Drugs by Total Amt Paid was reviewed.

Marti Padilla stated that miscellaneous drugs include the drugs for opioid dependence treatment, such as Suboxone and Vivitrol. Dr. Semling discussed the top drugs. Costs are before rebates. There is about a 2-4 months lag in rebates from the manufacturers.

**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 is specific criteria the DUR committee determines necessary to be set and recommended.

**New Prior Authorizations, Quantity Limits, Edits**

Dr. Semling reviewed new medication criteria for prior authorization:

**Baxdela®**

**INDICATIONS AND USAGE**

Baxdela is a fluoroquinolone antibiotic used to treat susceptible gram-positive and gram-negative acute bacterial skin and skin structure infections (ABSSSI). This includes the Gram-positive organisms Staphylococcus aureus (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), Streptococcus pyogenes, and Enterococcus faecalis and the Gram-negative organisms Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae, and Pseudomonas aeruginosa.

**APPROVAL CRITERIA**

1. Patient is 18 years of age or older AND;
2. Patient has a confirmed diagnosis of acute bacterial skin and skin structure infection AND;
3. A culture and sensitivity report shows that the pathogen is either gram-positive or gram-negative and is susceptible to Baxdela or provides documentation that a culture and sensitivity report is not feasible AND;
4. Patient has tried and failed at least two other antibiotics, one of which must be a fluoroquinolone, indicated for the patient diagnosis OR;
5. Patient has a contraindication or intolerance to all other Alaska Medicaid covered antibiotics used to treat ABSSSI.

**DENIAL CRITERIA**

1. Patient is less than 18 years of age OR;
2. Patient does not have confirmed diagnosis of acute bacterial skin and skin structure infection OR;
3. A culture and sensitivity report shows that the pathogen is either gram-positive or gram-negative and is not susceptible to Baxdela or fails to provide documentation that a culture and sensitivity report is not feasible OR;
4. Patient has failed and failed at least two other antibiotics, one of which must be a fluoroquinolone, indicated for the patient diagnosis OR;
5. Patient does not have a contraindication or intolerance to all other Alaska Medicaid covered antibiotics used to treat ABSSSI.

The committee decided to Switch #3 above to the following:
A Culture report showing that the pathogen is one listed in the FDA indications above or provides documentation that a culture and sensitivity reports is not feasible AND;

Denial Criteria is to mirror the changes of the approval part above on #3.

Dr. Ruggles moved to approve with changes noted above.
Second by Dr. Piromalli.

Lucemyra™ -
Approval criteria must meet all of the following:

**FDA INDICATIONS AND USAGE**

Lucemyra™ is a central alpha-2 receptor adrenergic agonist indicated for the mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.

**APPROVAL CRITERIA**:1,2,3

1. Patient is 18 years of age or older AND;
2. Patient has a confirmed diagnosis of opioid dependence or opioid use disorder AND;
3. Prescribe by or in consultation with a pain management or addiction specialist AND;
4. Patient is undergoing or is scheduled to undergo abrupt opioid discontinuation AND;
5. Patient has a normal QT interval AND;
6. Patient has one of the following:
   a. Tried and failed clonidine with in the last 6 months
   b. Has a contraindication to clonidine
   c. Has had a clinically significant adverse effect from clonidine use
   d. Lucemyra™ has been initiated in the emergency department

**DENIAL CRITERIA**:1,2,3

1. Patient is less than 18 years of age OR;
2. Patient does not have a confirmed diagnosis of opioid dependence or opioid use disorder OR;
3. Lucemyra™ is not being prescribed by or in consultation with a pain management or addiction specialist OR;
4. Patient is not undergoing or is not scheduled to undergo abrupt opioid discontinuation OR;
5. Patient has an abnormal QT interval OR;
6. Patient does not have one of the following:
   a. Tried and failed clonidine with in the last 6 months
   b. Has a contraindication to clonidine
   c. Has had a clinically significant adverse effect from clonidine use
   d. Lucemyra™ has been initiated in the emergency department

Dr. Semling had a question to the committee on the quantity limits that should be applied to Lucemyra. Dr. Ruggles, recommended 2 courses of therapy per year, then after that then need recovery plan going forward. The committee discussed the quantity limit.

Dr. Semling discussed whether it should be after 3 courses and then prescriber would need to justify after 3 courses of therapy.
Committee decided on 3 courses of therapy per year (max of 14 days per month) 3 courses of treatment = 14 day treatments per year.

Approved motion with QL by Dr. Ruggles, second to motion: Keri McCutcheon. Approved unanimously.
Palanziq™

Approval criteria must meet all of the following:

FDA INDICATIONS AND USAGE

Palanziq™ is a phenylalanine-metabolizing enzyme indicated to reduce blood phenylalanine concentrations in adult patients with phenylketonuria who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management.

APPROVAL CRITERIA

1. Patient is 18 years of age or older AND;
2. Patient has a confirmed diagnosis of phenylketonuria AND;
3. Prescribed by or in consultation with a metabolic specialist and both prescriber and patient are enrolled in REMS program AND;
4. Baseline phenylalanine levels have been documented AND;
5. Patient is actively on a phenylalanine restricted diet AND;
6. Patient has uncontrolled blood phenylalanine concentrations >600 micromol/L on existing management (i.e., Kuvan agents) AND;
7. Phenylalanine levels are being monitored and recorded through therapy AND;
8. Patient has been prescribed an auto-injectable epi-in use device and has been trained on proper use.

DENIAL CRITERIA

1. Patient is less than 18 years of age OR;
2. Patient does not have a confirmed diagnosis of phenylketonuria OR;
3. Not being prescribed by or in consultation with a metabolic specialist and both prescriber and patient are not enrolled in REMS program OR;
4. Baseline phenylalanine levels have not been documented OR;
5. Patient is not actively on a phenylalanine restricted diet OR;
6. Patient does not have uncontrolled blood phenylalanine concentrations >600 micromol/L on existing management (i.e., Kuvan agents) OR;
7. Patient is concomitantly using Kuvan agents with Palanziq™ OR;
8. Phenylalanine levels are not being monitored and recorded through therapy OR;
9. Patient has not been prescribed an auto-injectable epinephrine device and has not been trained on proper use.

Approved as written, motion to approve by Dr. Hiestand, second to motion: Dr. Piromalli. Approved unanimously.

Neudexta™

Approval criteria must meet all of the following:

FDA INDICATIONS AND USAGE

Neudexta™ is a combination of dextromethorphan hydrobromide and quinidine sulfate indicated for the treatment of pseudobulbar affect (PBA). PBA is characterized by involuntary, sudden, and frequent episodes of laughing or crying secondary to unrelated neurologic conditions.

APPROVAL CRITERIA

1. Patient is 18 years of age or older AND;
2. Patient has a confirmed diagnosis of pseudobulbar affect associated with multiple sclerosis, amytrophic lateral sclerosis, stroke, Parkinson’s disease, Alzheimer’s disease or traumatic brain injury AND;
3. Being prescribed by or in consultation with a neurologist or psychiatrist AND;
4. Patient has tried and failed at a therapeutic dose of one SSRI (i.e., fluoxetine) and one TCA (i.e., amitriptyline) or has a contraindication to use OR;
5. Patient must have a baseline score of at least 13 on the Center for Neurologic Studies-Neurolability scale.

DENIAL CRITERIA

1. Patient is less than 18 years of age OR;
2. Patient does not have a confirmed diagnosis of pseudobulbar affect associated with multiple sclerosis, amytrophic lateral sclerosis, stroke, or traumatic brain injury OR;
3. Medication is not being prescribed by or in consultation with a neurologist or psychiatrist OR;
4. Patient has not tried and failed at a therapeutic dose of one SSRI (i.e., fluoxetine) and one TCA (i.e., amitriptyline) or has a contraindication to use OR;
5. Patient is taking quinidine, quinine, mefloquine, or other medications that prolong the QT interval and metabolized by CYP2D6 OR;
6. Concomitant use of MAOI within the last 14 days OR;
7. Patient has prolonged QT interval, heart failure, or complete atrioventricular block without an implanted pacemaker.

Approved as written: motion to approve by Dr. Ruggles, second to motion: Dr. Piromalli. Approved unanimously.
Hetlioz®

Approval criteria must meet all of the following:

**FDA INDICATIONS AND USAGE**

Hetlioz® is a melatonin receptor agonist indicated in the treatment of Non-24 Hour Sleep-Wake Disorder (Non-24). Non-24 is a chronic problem associated with the circadian rhythm in people that are deprived of light. Total blindness affects the ability to fall asleep, stay asleep, and wake up feeling as though they need more sleep. The body cannot recognize the 24 hour light-dark cycle, which is needed to synchronize one’s internal clock.

**APPROVAL CRITERIA**

1. Patient is 18 years of age or older AND;
2. Patient has a confirmed diagnosis of Non-24-hour Sleep-Wake disorder AND;
3. Patient is completely blind (i.e., not light perception) AND;
4. Prescribed by or in consultation with a sleep specialist AND;
5. Patient has tried and failed the use of melatonin under the guidance of a sleep specialist for at least 3 months or has an intolerance or contraindication to melatonin use AND;
6. Prescriber must submit chart notes showing a trial and failure of a prescribed sleep-wake schedule.

**DENIAL CRITERIA**

1. Patient is less than 18 years of age OR;
2. Patient does not have a confirmed diagnosis of Non-24-hour Sleep-Wake disorder OR;
3. Patient is not completely blind (i.e., not light perception) OR;
4. Not being prescribed by or in consultation with a sleep specialist OR;
5. Patient has not tried and failed the use of melatonin under the guidance of a sleep specialist for at least 3 months or does not have an intolerance or contraindication to melatonin use OR;
6. Prescriber has not submitted chart notes showing a trial and failure of a prescribed sleep-wake schedule.

Approved as written: motion to approve by Keri McCutcheon, Dr. Ruggles to second motion. Approved unanimously.

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

Review of current quantity limits –
Tabled and will vote through email or will bring back to next meeting.

**Opioid Reports For Dental Prescribing – New Edits Day Supply**

Dental analgesia update:

Dr. Semling discussed the documents presented. The committee discussed having a Maximum day supply of 4 days or less since the majority are getting 4 days supply. Dr. Semling, will look at the 4 days maximum day supply and look at specific provider type with blessing of committee will put a 4 day supply limit.

**Intervention Informational Updates**

**ICD-10 Requirement for Opioid Prescriptions**:

ICD-10 compliance summary report was provided
The committee discussed including the ICD10 codes on opioid prescriptions in order for it to pay. However, the pharmacists can typically put a 2 to override this edit.
Committee opened up the conversation, but it will continue to be discussed

End of Public Meeting

**Adjournment 4:34 p.m.**

Next meeting date April 19th, 2019.