Alaska Medicaid Drug Utilization Review Committee
March 25th 2016

Members Present
Jenny Love, MD
Ryan Ruggles, PharmD
Chuck Semling, PharmD
Maggie Rader, ANP
Rebecca Wall, PharmD (DHSS

Members Absent
John Pappenheim, MD
Trish White, RPh

Non Members Present
Jay Butler MD
John McCall RPh (Magellan)
Erin Narus, PharmD (DHSS)

Meeting started at approximately 1:20 PM

Welcome

Review of Minutes from January 22nd, 2016

- Motion for approval by Ryan Ruggles PharmD ,seconded by Dr Jenny Love MD
- Approved unanimously without modification

Review of Agenda

- Approved unanimously with modification

Open floor to members for comments, questions, concerns

- No issues were brought forward

Prospective Drug Utilization Review / Clinical Topic Areas

- New Prescription Medications (Interim PA List – 6 month review)
  - Butrans
    - The Committee decided to add Butrans to the PDL with open access and the following parameters:
      - Qty Limits: 4 patches per 28 days
      - Patients may not receive more than one extended-release/long-acting opioid product without a second-level review prior authorization.
      - Authorization for lost, stolen or destroyed opioid medications will not be permitted
    - The committee will trend usage for 6 months and review in September 2016.

The motion was made by Dr Jenny Love MD to add Butrans to the PDL with open access as described above. It was seconded by Maggie Rader CNM. Motion was approved unanimously by the committee.

- Review of existing Prior Authorizations, Quantity Limits, Edits
  - Direct Acting Antivirals for Hepatitis C (HCV) Genotypes 1a & 1b (Periodic Review)
    - Daklinza was added to the criteria for treatment experienced patients genotypes 1a & 1b. Metavir F2-F4
      - Qty Limits: One tablet once per day in combination with sofosbuvir (28 tablets /28 days)
      - Criteria for patients previously treated with Incivek/Victrelis + PegIFN + ribavirin
        - Daklinza + Sovaldi + ribavirin for 12-24 weeks

- Criteria for patients previously treated with Direct Acting Anti-viral based regimens (e.g. NS5A-inhibitor or NS5B polymerase inhibitor based regimens.) Metavir F2-F4
    - Daklinza + Sovaldi + ribavirin for 12-24 weeks

- Zepatier was added to the criteria for Genotypes 1a & 1b, for treatment naïve patients or prior treatment with ribavirin and Interferon. Metavir score F2-F4.
    - Qty Limits: Zepatier – One tablet once per day (28 tablets /28 days)
    - GT 1a without NS5A polymorphisms or GT 1b, *Metavir F2-4*
        - Zepatier for 12 weeks
    - For GT 1a with NS5A polymorphisms, Metavir F2-F4
        - Zepatier with ribavirin for 16 weeks
        - A 16 week duration was added an as option for authorization duration due to the addition of Zepatier in the criteria.
    - Zepatier was added to the criteria for treatment experienced patients for Genotypes 1a & 1b . Metavir F2-F4
        - Zepatier + ribavirin for 12 to 24 weeks.

- Criteria for denial for Daklinza and Zepatier were added to criteria.
    - Daklinza will be denied for the following:
        - Concomitant use with a drug that strongly induces CYP3A
        - Genotype 1a: Lack of testing for the presence of NS5A resistance-associated polymorphisms.
        - The patient has genotype 2, 4, 5 or 6.
    - Zepatier will be denied for the following:
        - Moderate to severe hepatic impairment: Child-Pugh score >6 [class B or C]
        - Concomitant use with OATP1B1/3 inhibitors, strong CYP3A inducers, or efavirenz.
        - Genotype 1a: Lack of testing for the presence of NS5A resistance-associated polymorphisms
        - The patient has genotype 2, 3, 5 or 6.

    - Approved regimens for the treatment of treatment experienced patients was clarified and expanded to address prior treatment with Direct Acting Anti-viral based regimens (e.g. NS5A-inhibitor or NS5B polymerase inhibitor based regimens) Metavir F2-F4
        - Harvoni + ribavirin for 12-24 weeks
        - Viekira + ribavirin for 12-24 weeks
        - Zepatier + ribavirin for 12-24 weeks
        - Sovaldi + Daklinza + ribavirin for 12-24 weeks

- Recommendations for Changes to Criteria for Approval for both treatment naïve and experienced treatment patients were presented as follows:
    - APRI and FIB4 will not be accepted to confirm the Metavir Fibrosis stage.
    - The Hepatitis C disease activity score must be submitted with the authorization request.
    - Requirement for patient abstinence of unlawful drugs or alcohol was modified. The patient must have a negative urine confirmation test within the previous 90 days or positive results explained by prescriber with documentation of attendance in a substance abuse program.
    - For all criteria that indicate the usage of ribavirin: if ribavirin is not used Alaska Medicaid reserves the right to not extend treatment duration beyond what was initially authorized.

The motion was made by Dr Jenny Love MD approve changes to Hepatitis C 1a and 1b criteria and It was seconded by Maggie Rader CNM. Motion was approved unanimously by the committee.

- Direct Acting Antivirals for Hepatitis C (HCV) Genotype 4 (Periodic Review)
  - Harvoni, Olyiso, Zepatier were added with the following quantity limits
    - Harvoni – One tablet once per day (28 tablets /28 days)
    - Olysio – One capsule once per day (28 capsules /28 days)
    - Zepatier – One tablet once per day (28 tablets /28 days)

  - Changes to Criteria for Treatment Naïve or prior treatment with PegIFN and ribavirin, Genotype 4
    - A 16 week regimen was added an as option for authorization duration due to the addition of Zepatier as a choice in the criteria.
    - Criteria
      - GT 4 Metavir F2-4
        - Harvoni 12 weeks
        - Zepatier 12 to 16 weeks
          - Duration depends on clinical situation and whether treatment naïve or PegIFN + ribavirin experienced.
      - GT 4 Metavir F2-3
        - Sovaldi + PegIFN + ribavirin for 12 weeks
        - Technivie + ribavirin for 12 weeks
      - GT 4 Hepatocellular carcinoma awaiting liver transplantation AND meets Milan Criteria
        - Sovaldi + ribavirin 48 weeks or until liver transplant
      - GT 4 with decompensated cirrhosis [Child-Pugh B or C]
        - Restricted to specialist
      - Mixed Genotype
        - Restricted to specialist

    - Approved regimens for the treatment of treatment experienced patients
      - Prior treatment with Direct Acting Antiviral based regimens (e.g. NS5A-inhibitor or NS5B polymerase inhibitor based regimens) Metavir F2-F4
        - Harvoni + ribavirin for 12-24 weeks
      - Prior treatment with Sovaldi ± ribavirin ± PegIFN , Metavir F2-F3 only
        - Technivie + ribavirin for 12-24 weeks

  - Changes to Criteria for Denial
    - Criteria for denial was added for Harvoni
      - Severe Renal Disease
      - Drugs that are contraindicated or have significant clinical interactions
      - Patient has genotye 2 or 3 infection
    - Criteria for denial was added for Zepatier:
      - Moderate to severe hepatic impairment: Child-Pugh score >6 [class B or C]
      - Concomitant use with OATP1B1/3 inhibitors and a strong CYP3A inducers, or efavirenz.

- The patient has genotype 2, 3, 5 or 6.

- Recommendations for Changes to Criteria for Approval for both treatment naïve and experienced treatment patients were presented as follows:
  - APRI AND FIB4 will not be accepted to confirm the Metavir Fibrosis stage.
  - The Hepatitis C disease activity score must be submitted with the authorization request.
  - Requirement for patient abstinence of unlawful drugs or alcohol was modified. The patient must have a negative urine confirmation test within the previous 90 days or positive results explained by prescriber with documentation of attendance in a substance abuse program.
  - For all criteria that indicate the usage of ribavirin if ribavirin is not used Alaska Medicaid reserves the right to not extend treatment duration beyond what was initially authorized.

The motion was made by Dr Jenny Love MD to approve changes to Hepatitis C genotype 4 criteria and it was seconded by Ryan Ruggles PharmD. Motion was approved unanimously by the committee.

- Changes to criteria for Direct Acting Antivirals for Hepatitis C (HCV) Genotypes 2, 3, 5, 6. (Periodic Review)
  - Harvoni was added to criteria for Genotype 5 and 6 in treatment naïve patients and patients with treatment experience limited to PegIFN and ribavirin. Metavir F2-F4
    - Quantity limit of 28 tablets for 28 days.
    - 12 week duration.
  - Harvoni will not be used in severe renal impairment, CrCl<30ml/min or end stage renal disease.
  - Harvoni will not be used when taking a concomitant drug that has significant clinical interactions or is contraindicated.
  - Criteria was clarified and updated for patients with treatment experience for Genotypes 2,3,5,6.
    - Regimens for patients previously treated with Direct Acting Agents for Hepatitis C, Metavir F2-F4
      - Genotype 3: Sovaldi + Daklinza + ribavirin for 12-24 weeks
      - Genotype 5 or 6: Harvoni + ribavirin for 12-24 weeks
  - Recommendations for Changes to Criteria for Approval for both treatment naïve and experienced treatment patients were presented as follows:
    - APRI AND FIB4 will not be accepted to confirm the Metavir Fibrosis stage.
    - The Hepatitis C disease activity score must be submitted with the authorization request.
    - Requirement for patient abstinence of unlawful drugs or alcohol was modified. The patient must have a negative urine confirmation test within the previous 90 days or positive results explained by prescriber with documentation of attendance in a substance abuse program.
    - For all criteria that indicate the usage of ribavirin if ribavirin is not used Alaska Medicaid reserves the right to not extend treatment duration beyond what was initially authorized.

The motion was made by Ryan Ruggles PharmD to approve changes to Hepatitis C genotype 2,3,5,6 criteria and it was seconded by Dr Jenny Love MD. Motion was approved unanimously by the committee.

- Criteria for prior authorization for Cosentyx were presented to the committee.
    - Indication restricted to:
        - Moderate to severe plaque psoriasis, psoriatic arthritis, ankylosing spondylitis
        - Plaque Psoriasis: PASI score of greater than or equal to 12 (or equivalent)
        - Psoriatic Arthritis: HAQ-DI score ≥ 2 (or equivalent)
        - Ankylosing Spondylitis: BASDAI ≥ 4 and BASFI ≥ 4
    - Further Requirements
        - J Code is submitted with the request
        - Age > 18 years of age
        - Has had a negative tuberculosis (TB) test
        - Has previously tried and failed, or has a contraindication to, a TNF blocker (i.e., Humira or Enbrel), and at least one other therapy
    - Denial
        - Patients with active TB or a positive TB test
        - Current active severe infection, or chronic or recurrent infections
        - Will be using concurrent therapy with a TNF blocker;
        - A PASI score of less than 12 or equivalent for patients initiating therapy
        - Known hypersensitivity to Cosentyx or any of its excipients or a latex allergy if the Sensoready pen is being requested
    - Reauthorization criteria
        - A letter of medical necessity is submitted with chart
        - Notes demonstrating therapeutic benefit
        - Baseline and current PASI/ HAQ-DI/ BASDAI/ or BASFI score (or equivalent) are submitted
        - Documentation of tolerance and absence of adverse events are submitted.
    - Quantity Limit:
        - Two vials, syringes, or pens per 30 days.
        - Quantity limit overrides are approvable for up to 5 doses (10 vials, syringes, or pens) per 28 days for a patient who is beginning therapy and has not reached the monthly maintenance dose.
    - Requirements for continuation of therapy after one year of therapy
        - Submittal of chart notes (within 3 months) if therapy has been utilized for more than one year.
        - Chart notes include appropriate diagnostic score (or equivalent), and document improvement, tolerance, and lack of adverse events, approve and allow continuation of therapy for additional year

The motion was made by Dr Jenny Love MD to approve criteria for Cosentyx and It was seconded by Ryan Ruggles PharmD. Motion was approved unanimously by the committee.

- Criteria for prior authorization for Lemtrada were presented to the committee.
    - Submitted JCode of J2020
    - Diagnosis of relapsing remitting multiple Sclerosis
    - Patient has had an inadequate response to at least 2 medications indicated for the treatment of MS.
    - Compliance with the requirements of the Lemtrada REMS program:
        - Prescriber has been certified with the program by enrolling and completing training.
        - Patient is enrolled in the program and complies with ongoing monitoring requirements including baseline labs and skin examination for melanoma.
        - Pharmacy is certified with the program and only dispenses to certified healthcare facilities that are authorized to receive Lemtrada.
        - Healthcare facility is enrolled in the program and verifies that patients are authorized before infusing Lemtrada.
        - Healthcare facility has on-site access to equipment and personnel trained to manage infusion reactions.
    - The provider administering Lemtrada must be enrolled with Alaska Medicaid as a Health Professional Group or Medical provider (physician or APRN).
    - Lemtrada is not being administered under the Alaska Medicaid Home Infusion Therapy program.
    - Patient will not be receiving Lemtrada in combination with another disease modifying agent (e.g., interferon beta preparations, glatiramer acetate, dimethyl fumarate).

- Patient has had a negative tuberculosis test prior to treatment.
- Criteria for Reauthorization Approval:
  - Patient meets all of the criteria for the initial authorization.
  - There is documented evidence of a positive clinical response to Lemtrada therapy.
  - Compliance with the REMs program for monitoring

The motion was made by Ryan Ruggles PharmD to approve criteria for Lemtrada and it was seconded by Chuck Semling PharmD. Motion was approved unanimously by the committee.

- Criteria for prior authorization for the PCSK-9 inhibitors were presented to the committee.
  - Praluent Criteria for Approval
    - The patient has not reached goal LDL-C level for the patient's risk category, as defined by generally accepted, evidence based guidelines.
    - The patient has a diagnosis of heterozygous familial hypercholesterolemia
    - The patient has a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD)
    - The patient will use the requested medication in conjunction with BOTH diet and maximally tolerated statin therapy unless the patient has a package labeled contraindication to all statins
      - muscle cramps/pain does not count as a contraindication
    - Patient is 18 years old or greater
    - Baseline (prior to treatment with a PCSK9 inhibitor) LDL and Total Cholesterol levels must be provided
    - Praluent is being prescribed by, or in consultation with, a specialist (e.g., cardiologist, lipidologist, endocrinologist).

  - Repatha Criteria for Approval:
    - The patient has not reached goal LDL-C level for the patient's risk category, as defined by generally accepted, evidence based guidelines.
    - The patient will use the requested medication in conjunction with diet.
    - Repatha is being prescribed by, or in consultation with, a specialist (e.g., cardiologist, lipidologist, endocrinologist).
    - The patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH)
      - For patients with a diagnosis of HoFH, the patient will be using Repatha in combination with other LDL lowering therapies, such as statins, Zetia (ezetimibe), or LDL apheresis.
      - For a diagnosis of HoFH, the patient is 13 years of age or older.
    - The patient has a diagnosis of heterozygous familial hypercholesterolemia (HeFH)
    - The patient has a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD)
    - For a diagnosis of ASCVD or HeFH, the patient will use the requested medication in conjunction with maximally tolerated statin therapy; unless the patient has a package labeled contraindication to all statins
      - muscle cramps/pain does not count as a contraindication
    - For a diagnosis of ASCVD or HeFH, the patient is 18 years of age or older
    - Baseline (prior to treatment with a PCSK9 inhibitor) LDL and Total Cholesterol levels must be submitted.
  - Criteria for Reauthorization Approval:
    - Patient meets all of the criteria for the initial authorization.
      - WITH THE EXCEPTION OF: "The patient has not reached his/her goal LDL-C level for the patient's risk category, as defined by generally accepted, evidence based guidelines"
    - There is documented evidence of a positive clinical response to therapy.

- Both baseline (prior to treatment with a PCSK9 inhibitor), and current LDL-C and Total Cholesterol levels must be submitted with any reauthorization request.
- Reauthorization approval may be issued for up to an additional 12 months

- .Praluent Criteria for Denial:
  - The patient does not have an approved diagnosis
    - heterozygous familial hypercholesterolemia
    - clinical atherosclerotic cardiovascular disease.
  - The patient will not be using Praluent in conjunction with BOTH diet and maximally tolerated statin therapy OR the patient does not have a package labeled contraindication to all statins
  - The patient is at goal LDL-C level
  - Patient is younger than 18 years old
  - Praluent will be used in combination with Juxtapid (lomitapide) or Kynamro (mipomersen)
  - Praluent is not being prescribed by, or in consultation with, a specialist
  - Baseline (prior to treatment with a PCSK9 inhibitor) LDL and Total Cholesterol levels have not been submitted.

- Repatha Criteria for Denial:
  - The patient does not have an approved diagnosis
    - homozygous or heterozygous familial hypercholesterolemia
    - clinical atherosclerotic cardiovascular disease
  - For a diagnosis of HoFH, the patient will not be using Repatha in combination with other LDL lowering therapies
  - For a diagnosis of ASCVD or HeFH, the patient will not be using Repatha in conjunction with maximally tolerated statin therapy, OR the patient does not have a package labeled contraindication to all statins
  - . The patient is at goal LDL-C level
  - For a diagnosis of HoFH, the patient is younger than 13 years old
  - For a diagnosis of HeFH or ASCVD, the patient is younger than 18 years old
  - Repatha will be used in combination with Juxtapid (lomitapide) or Kynamro (mipomersen)
  - Baseline (prior to treatment with a PCSK9 inhibitor) lipid levels have not been submitted
  - Repatha is not being prescribed by, or in consultation with, a specialist
  - The patient will not be using Repatha in conjunction with diet.
- Length of Authorization:
  - Initial coverage may be approved for up to three months.
  - Subsequent re-authorizations may be issued for up to a year.
- Quantity Limit:
  - The Praluent dispensing limit is 2 pens or syringes per 30 days.
  - The Repatha dispensing limit is 2 syringes or autoinjectors per 30 days for a diagnosis of heterozygous familial hypercholesterolemia (HeFH) (ASCVD).
  - The Repatha dispensing limit is 3 syringes or autoinjectors per 30 days for a diagnosis of homozygous familial hypercholesterolemia (HoFH).

The motion was made by Ryan Ruggles PharmD and It was seconded by Dr Jenny Love MD to revisit PCSK9 criteria during April DUR Meeting. Motion was approved unanimously by the committee.

The Committee Reviewed the Opioid Report for Long Acting and Short acting Opioids for the last quarter of 2015

- The Committee will continue to review trends, with a specific focus on opioid naïve patients
  - Data will be used to identify trends and develop strategies for prescriber education and public education
    - Specifically related to prescribed quantities and the use of Extended Release Products.

FDA Drug Communications Reviewed

- SGLT2 Inhibitors-In December 2015 the FDA added safety label changes for the SGLT2 Inhibitors warning of the risk of Ketoacidosis.

- Posaconazole- In December 2015 the FDA cautioned of dosing errors related to the 2 oral dosage forms of (Noxafil) posaconazole, an oral suspension and a delayed-release tablet. To help prevent additional medication errors, the drug labels were revised to indicate that the two oral formulations cannot be directly substituted for each other but require a change in dose.

- Roziglitazone-In December 2015 the FDA eliminated the Risk Evaluation and Mitigation Strategy for rosiglitazone-containing type 2 diabetes medicines, which are approved as Avandia, Avandamet, Avandaryl, and generics.

The motion was made by Ryan Ruggles PharmD to adjourn the meeting and It was seconded by Maggie Radar ANP. Motion was approved unanimously by the committee.