

Alaska Medicaid DUR Committee Meeting Minutes

Friday, January 17th, 2020

Frontier Building, 3601 C Street; Room 896

1:00pm

Drug Utilization Review Committee Attendees

Members Present	Non-Members Present
Erin Narus, PharmD (DHSS)	Umang Patel, PharmD (Magellan)
Charles Semling, PharmD (DHSS)	Marti Padilla, PharmD, (Magellan)
Ryan Ruggles, PharmD	
Keri McCutcheon, RPh	
Jenna Heistand, MD	
Robert Carlson, MD	

Review of minutes from November 2019

- Minutes approved by Ryan Ruggles, 2nd: Keri McCutcheon
- No changes or issues with previous minutes.

Review of Agenda

Dr. Semling went over the DUR Agenda to the committee members for today's meeting and set up expectations of the committee.

Prospective Drug Utilization Review/Clinical Topic Areas

New Prescription Medications (Interim (Suspend) 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.

Motion to approve drugs on suspend list: 1st: Ryan Ruggles, 2nd Jenna Heistand

New Prior Authorizations, Quantity Limits, Edits

Dr. Charles Semling reviewed new medication criteria for prior authorizations.

Jynarque™ (tolvaptan)

FDA INDICATIONS AND USAGE¹

Jynarque™ (tolvaptan) is a selective vasopressin V2-receptor antagonist indicated to slow kidney function decline on adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).

APPROVAL CRITERIA^{1,2}

1. Patient is 18 years of age or older **AND**;
2. Patient has a diagnosis of autosomal dominant polycystic kidney disease and is at risk for kidney function decline **AND**;
3. Is being prescribed by or in consultation with a nephrologist **AND**;
4. The patient has had a liver function test, showing results deemed appropriate prior to treatment **AND**;
5. Prescriber agrees to check liver function at week 2, 4 and then monthly during the first 18 months of therapy.

DENIAL CRITERIA^{1,2}

1. Failure to meet approval criteria **OR**;
2. Patient has history of significant liver impairment or injury **OR**;
3. Patient has uncorrected abnormal blood serum level **OR**;
4. Patient is unable to sense or appropriately respond to thirst **OR**;
5. Patient is hypovolemic, anuric, or has an uncorrected urinary outflow obstruction **OR**;
6. Patient is concomitantly using a strong CYP 3A inhibitor.

CAUTIONS¹

- Serious liver injury has occurred in patients taking Jynarque™.
- Monitor for hypernatremia, dehydration, and hypovolemia.
- Dose reductions of Jynarque™ may be recommended for patients taking a moderate CYP 3A inducer.

DURATION OF APPROVAL

- Initial Approval: up to 90 days
- Reauthorization Approval: up to 12 months

QUANTITY LIMIT

- 45mg and 15mg kit - 56 tablets per 28 days

- 60mg and 30mg kit - 56 tablets per 28 days
- 90mg and 30mg kit - 56 tablets per 28 days
- 15 mg tablets – 30 per 30 days
- 30mg tablets – 30 per 30 days

REFERENCES / FOOTNOTES:

1. Jynarque™ [prescribing information]. Rockville, M: Otuska America Pharmaceutical Inc.; February 2019.
2. Torres VE, Chapman AB, Devuyst O, et al. for the Tempo 3:4 trial investigators. Tolvaptan in patients with autosomal dominant polycystic kidney disease. New England Journal of Medicine, 2012;367(25):2407-2418.

Motion to approve with changes (more specific on uncorrected abnormal blood serum): Kerri McCutcheon, Jenna Heistand

**Evenity™
(romosozumab-aqqg)**

FDA INDICATIONS AND USAGE¹

Evenity™ (romosozumab-aqqg) is a sclerostin inhibitor that is indicated for the treatment of osteoporosis in postmenopausal women at high risk of fracture, defined by a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other osteoporosis therapies. Duration of treatment should be limited to no more than 12 monthly doses, due to a waning anabolic effect over time.

APPROVAL CRITERIA^{1,2,3}

1. Patient is a postmenopausal woman at risk of fracture **AND**;
2. Patient has a diagnosis of osteoporosis defined by a bone mineral density T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 or a clinical diagnosis based on the history of a low trauma fracture and is at high risk for fracture **AND**;
3. Is being administered by a healthcare provider **AND**;
4. The patient has had a trial of an oral bisphosphonate (i.e. alendronate) for at least one year with less than optimal results, has a contraindication to their use, or the patient is unable to remain upright for at least 30 minutes **AND**;
5. The patient has failed a prior treatment with or is intolerant to an injectable osteoporosis therapy (i.e. zoledronic acid) **AND**;
6. The prescriber has counseled patients that calcium and vitamin D should be adequately supplemented throughout treatment.

DENIAL CRITERIA¹

7. Failure to meet approval criteria **OR**;
8. Patient has had myocardial infarction or stroke with in the preceding year **OR**;

9. Patient has hypocalcemia **OR**;
10. Treatment duration is for more than 12 monthly doses.

CAUTIONS¹

- Monitor for major adverse cardiac events.
- Calcium and Vitamin D should be adequately supplemented throughout treatment.
- Monitor for osteonecrosis of the jaw.
- Hypersensitivity reactions such as, angioedema, erythema multiforme, rash, and dermatitis have been observed.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to an additional 9 months (authorization for approval cannot exceed 12 monthly doses)

QUANTITY LIMIT

- 2- 105mg syringes per month (210mg total)

REFERENCES / FOOTNOTES:

1. Evenity [prescribing information]. Thousand Oaks, CA: Amgen Inc.; April 2019.
2. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists Medical Guidelines for clinical practice for the prevention and treatment of postmenopausal osteoporosis. Endocrine Practice. September 2016;22(4):1-42.
3. Cosman F, de Beur SJ, Leboff MS, et al. National Osteoporosis Foundation. Clinician's Guide to Prevention and Treatment of Osteoporosis. Washington, DC: National Osteoporosis Foundation; 2014 Osteoporosis Int. October 2014;25(10):2359-81.

Motion to approve with changes (less than optimal results should be defined, and intolerant to 2 or more Bisphosphonates): 1st: Ryan Ruggles, 2nd Keri McCutcheon

Vumerity™ (diroximel fumerate)

FDA INDICATIONS AND USAGE¹

Vumerity™ (diroximel fumerate) is indicated for the treatment of relapsing forms of multiple sclerosis (MS), which includes clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults.

APPROVAL CRITERIA^{1,2,3}

1. Patient is 18 years of age or older **AND**;
2. Patient has a diagnosis multiple sclerosis (MS) to include one of the following,
 - a. clinically isolated syndrome **OR**;
 - b. relapsing-remitting disease **OR**;

- c. active secondary progressive disease **AND**;
3. Is being prescribed by or in consultation with a neurologist or a provider that specializes in multiple sclerosis **AND**;
4. The patient has had a complete blood cell count and liver function testing, showing results deemed appropriate for treatment **AND**;
5. Serum aminotransferase, alkaline phosphatase, and total bilirubin levels must be documented **AND**;
6. The prescriber has counseled patients of reproductive potential to use effective contraception during and for 6 months after the last dose **AND**;
7. The patient has had an adequate trial and failure of at least one drug indicated for MS.

DENIAL CRITERIA¹

08. Failure to meet approval criteria **OR**;
09. Patient has moderate to severe renal impairment **OR**;
10. Patient is taking dimethyl fumarate.

CAUTIONS¹

- Monitor for anaphylaxis and angioedema after the first dosage and throughout treatment.
- Progressive multifocal leukoencephalopathy has occurred in patient being treated with dimethyl fumarate.
- Lymphocyte counts may decrease with the use of Vumerity™.
- Liver injury has been reported and should be monitored.
- Patients should avoid alcohol.
- Administration with a high-fat, high-calorie meal or snack should be avoided.

DURATION OF APPROVAL

- Initial Approval: up to 30 days
- Reauthorization Approval: up to 12 months

QUANTITY LIMIT

- 120 – 231mg capsules per month

REFERENCES / FOOTNOTES:

1. Vumerity™ [prescribing information]. Waltham, MA: Alkermes, Inc.; October 2019. Accessed on 12/6/2019 at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5532591/>
2. Dargahi N, Katsara M, Tselios T, Androutsou ME, de Courten M, Matsoukas J, et al. Multiple sclerosis: Immunopathology and treatment update. Brain Sciences July 2017; 7. Accessed on 12/6/2019 at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5532591/>
3. Tintore, M, Vidal-Jordana, A, Sastre-Garriga, J. Treatment of multiple sclerosis: success from bench to bedside. Nat Rev Neurol. January 15, 2019:53-58.

Motion to approve Keri McCutcheon, Ryan Ruggles

**Tecfidera™
(dimethyl fumarate)**

Indications:

“Tecfidera is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS).”¹

Dosage Form/Strength:

- Delayed-Release Capsules: 120mg, 240mg
- Delayed-Release Capsules: 120mg and 240mg 30-Day Starter Pack

Criteria for Approval: 1

- Patient has a diagnosis of a relapsing form of multiple sclerosis (for example: Relapsing-remitting MS, secondary-progressive MS with relapses, or progressive-relapsing MS); **AND**,
- Tecfidera is prescribed by, or in consultation with, a neurologist or a prescriber who specializes in the treatment of MS; **AND**,
- Baseline CBC with differential indicates a clinically sufficient lymphocyte count.
- Patient is ≥18 years of age; **AND**,
- Either the patient is unable to administer injections due to dexterity issues or visual impairment,

OR

o the patient has tried and failed at least one of the following: Avonex®, Copaxone®, Extavia®, or Rebif®.

Criteria for Reauthorization Approval:

- Patient meets all of the criteria for the initial authorization; **AND**,
- There is documented evidence of a positive clinical response to Tecfidera therapy, characterized by improved disease activity (i.e. improved annualized relapse rate, decreased occurrence rate of formation of gadolinium positive [GD+] lesions on MRI, or decreased rate of formation of lesions on MRI); **AND**,
- A current CBC with differential indicates a clinically sufficient lymphocyte count.

Criteria for Denial:

- The patient has a diagnosis of a non-relapsing form of MS (for example: primary progressive MS); **OR**,
- The patient has any diagnosis other than a relapsing form of MS; **OR**,
- Tecfidera is not prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of MS; **OR**,
- Patient is <18 years of age; **OR**,
- Tecfidera will be used concurrently with other MS disease-modifying agents (for example: Aubagio®, Avonex®, Betaseron®, Copaxone®, Extavia®, Gilenya®, Glatopa™, Lemtrada™, Plegridy®, Rebif®, or Tysabri®); **OR**,
- Patient does not have difficulty with dexterity or visual impairment that would preclude a trial with at least one of the following: Avonex, Rebif, Extavia, or Copaxone; **OR**, o The patient has not previously tried and failed at least one of the following: Avonex, Rebif, Extavia, or Copaxone.

Length of Authorization – Initial coverage:

- May be authorized for up to 1 year

Length of Authorization – Reauthorization:

- May be reauthorized for up to 1 year

Quantity Limit:

- Maximum of 2 capsules per day

Mechanism of Action:

“The mechanism by which dimethyl fumarate (DMF) exerts its therapeutic effect in multiple sclerosis is unknown. DMF and the metabolite, monomethyl fumarate (MMF), have been shown to activate the Nuclear factor (erythroid-derived 2)-like 2 (Nrf2) pathway in vitro and in vivo in animals and humans. The Nrf2 pathway is involved in the cellular response to oxidative stress. MMF has been identified as a nicotinic acid receptor agonist in vitro.” 1

References / Footnotes:

1 Tecfidera® package insert: Biogen, Inc. Cambridge, MA. February 2016. <http://www.tecfidera.com/pdfs/full-prescribing-info.pdf>. Accessed 4/8/2016

Motion to retire: no members had any objection to retire criteria

Cosentyx®
(secukinumab)

150mg/mL Sensoready pen, prefilled syringe, and lyophilized powder in vial for reconstitution
For subcutaneous administration

Indication:

“COSENTYX is a human interleukin-17A antagonist indicated for the treatment of moderate to severe plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis in adult patients who are candidates for systemic therapy or phototherapy, adults with active psoriatic arthritis (PsA) , and adults with active ankylosing spondylitis (AS).”1

Dosage Form/Strength:

- Injection: 150 mg/mL solution in a single-use Sensoready® pen.
- Injection: 150 mg/mL solution in a single-use prefilled syringe.
- For Injection: 150 mg, lyophilized powder in a single-use vial for reconstitution for healthcare professional use only.

Criteria for Approval:

1. Initial Authorization Request must include:

- * Monitoring plan
- * Previous therapies trialed and the nature of the failure
- * Complete medication regimen

2. The patient has had a negative tuberculosis test; **AND,**

3. The patient is greater than or equal to 18 years old; **AND,**

4. The patient has a diagnosis of moderate to severe plaque psoriasis, psoriatic arthritis, or ankylosing spondylitis; **AND,**

5. Has one of the following scores 2, 3, 4

o Plaque Psoriasis: Psoriasis Area and Severity Index (PASI) score of greater than or equal to 12 (or equivalent);
or

o Psoriatic Arthritis: Health Assessment Questionnaire-Disability Index (HAQ-DI) score ≥ 2 (or equivalent); or

o Ankylosing Spondylitis: Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) \geq 4 and Bath Ankylosing Spondylitis Functional Index (BASFI) \geq 4 (or equivalent); **AND**,

6. The patient has previously tried and failed, or has a contraindication to, a TNF blocker (i.e. Humira or Enbrel), and at least one other therapy.

Criteria for Reauthorization Approval:

1. A letter of medical necessity is submitted with chart notes demonstrating therapeutic benefit.
2. Baseline and current PASI score (for plaque psoriasis), HAQ-DI (for psoriatic arthritis), or BASDAI/BASFI (for ankylosing spondylitis) or equivalents are submitted.
3. Documentation of tolerance and absence of adverse events are submitted.

Criteria for Denial:

1. Known hypersensitivity to Cosentyx or any of its excipients; **OR**,
2. Patient is less than 18 years old; **OR**,
3. Has active tuberculosis or a positive tuberculosis test; **OR**,
4. The patient has a current active severe infection, has chronic or recurrent infections; **OR**,
5. The patient will be using concurrent therapy with a TNF blocker; **OR**,
6. One of the following for patients initiating therapy (depending on applicable diagnosis):
 - o PASI score of less than 12 (or equivalent); or
 - o Health Assessment Questionnaire-Disability Index (HAQ-DI) score $<$ 2 (or equivalent); or
 - o Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) $<$ 4 and Bath Ankylosing Spondylitis Functional Index (BASFI) $<$ 4;

7. If the Sensoready pen is being requested, the patient has a latex allergy

Length of Authorization:

1. Initial coverage may be approved for up to 3 months (7 doses total - Injections at Weeks 0, 1, 2, 3, 4, 8, and 12).
2. Subsequent re-authorizations may be approved for 12 months (Injections at Weeks 16 and thereafter at 4-week intervals).

Quantity Limit:

1. The dispensing limit is two vials, syringes, or pens per 30 days.
2. 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.

CAUTIONS:

- While approved for subcutaneous administration, initial Cosentyx doses should only be administered under the supervision of a physician. Cosentyx is intended for use under the guidance and supervision of a physician. Patients may self-inject after proper training in subcutaneous injection technique using the Sensoready pen or prefilled syringe and when deemed appropriate. The lyophilized powder for reconstitution is for healthcare provider use only. Administration of Cosentyx in the upper, outer arm may be performed by a caregiver or healthcare provider. Close monitoring and adequate follow-up are required in both circumstances for the safety of the patient.

Cosentyx criteria Version 1 Last updated: 3/25/2016 Approved: 3/25/2016

- Live vaccines should not be administered while patients are receiving Cosentyx unless determined that the benefit outweighs the risk.
- The removable cap of the Sensoready pen and the prefilled syringe contains natural rubber latex.

Mechanism of Action:

“Secukinumab is a human IgG1 monoclonal antibody that selectively binds to the interleukin-17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine that is

involved in normal inflammatory and immune responses. Secukinumab inhibits the release of proinflammatory cytokines and chemokines.”¹

References / Footnotes:

¹ Cosentyx™ Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. January 2016.

² Calin A, Garrett S, Whitelock H, Kennedy LG, O’Hea J, Mallorie P, Jenkinson T. “A new approach to defining functional ability in ankylosing spondylitis: the development of the Bath Ankylosing Spondylitis Functional Index.” *J. Rheumatol.* 1994 Dec;21(12):2281-5.

³ Garrett S, Jenkinson T, Kennedy LG, Whitelock H, Gaisford P, Calin A. “A new approach to defining disease status in ankylosing spondylitis: The Bath Ankylosing Spondylitis Disease Activity Index.” *J Rheumatol.* 1994 Dec;21(12):2286-91.

⁴ BASFAI, Bath ankylosing spondylitis functional index. <http://basdai.com/BASFI.php>. 2005. Accessed 01/15/2016.

Motion to retire: no members had any objection to retire criteria. Let PDL manage

C-II CNS Stimulants

Stimulant medications are FDA approved for the use in treating patients with the diagnosis of ADHD, narcolepsy, binge eating disorder and an adjunct therapy for obstructive sleep apnea. Not all stimulants are approved for all conditions listed. Stimulants are thought to work by increasing the neurotransmission of norepinephrine and dopamine.

Dr. Semling reviewed the utilization for the C-II CNS stimulants with the committee to discuss.

Upon discussion among the committee members, the decision is to require an ICD10 diagnosis codes submitted with the prescription for anyone 21 years of age and older.

After all the motions were determined, the committee reviewed and discussed the 4th quarter opioid utilization, including interacting drugs benzodiazepines and antipsychotics, report to comply with the Support Act. Trend is going downward.

The committee also reviewed the GINA guidelines and claims for the utilization of the Short Acting Beta Agonists in combination with and without controller medications, such as Inhaled glucocorticoids. No edits needed at this time.

End of Public Meeting

Adjournment 4:05 p.m.

Next meeting date April 17th, 2020.