Umpqua Health Alliance

Pharmacy Utilization Management Guidelines

Effective July 1, 2020

Contents

General Utilization Management Criteria

Policy Number: Rx001

I. MEDICATION NAME(S):

- Multiple

II. LENGTH OF AUTHORIZATION:

- Variable

III. QUANTITY LIMITS:

- Multiple (see formulary)

IV. INITIAL CRITERIA:

1. Is the drug prescribed for a condition funded by the Oregon Health Plan (OHP) in a manner consistent with the Health Evidence Review Commission (HERC) Prioritized List of Health Services?
    a. Yes (go to #3)
    b. No (go to #2)
2. Is there a comorbid condition for which coverage would be allowed?
    a. Yes (go to #3)
    b. No (forward to pharmacist for review [deny 3a/3c])
3. Is the drug used for an FDA-approved indication or a medically appropriate off-label use with strong evidence supporting safety and efficacy? (Refer to Table 1 in 'Additional Information' for recommendation, evidence and efficacy ratings: the strength of recommendation must be class IIa or higher; the strength of evidence must be category B or higher; and the efficacy must be IIa or higher.)
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 12a if drug not FDA-approved, or 8a if indication not FDA-approved])
4. Is the drug prescribed at the appropriate FDA-approved dose to treat the covered condition?
    a. Yes (go to #5)
    b. No (forward to pharmacist for review)
5. Is the prescribed dose within UHA's quantity limits?
    a. Yes (go to #6)
    b. No (forward to pharmacist for review)
6. Is the medication prescribed by or in consultation with an appropriate health care provider with expertise in treating this condition?
    a. Yes (go to #7)
    b. No (forward to pharmacist for review)

7. Does the member have any contraindications to therapy according to FDA-approved labeling?
    a. Yes (deny)
    b. No (go to #8)
8. If FDA-approved labeling or national clinical guidelines categorize this drug as a second line therapy, has there been trial and failure of or contraindication to the first-line therapies?
    a. Yes or N/A (go to #9)
    b. No (forward to pharmacist for review)
9. Has the member tried and failed all less-costly alternative therapies that are similar or identical to the requested therapy (within the same drug class, therapeutic class, or used to treat the member's condition according to UpToDate)?
    a. Yes (go to #10)
    b. No (forward to pharmacist for review [deny 7a, or deny 5k for formulary exception requests])
10. Has documentation been submitted to support medical necessity, including chart notes, a treatment plan, monitoring parameters, and laboratory values (if applicable)?
    a. Yes or N/A (go to #11)
    b. No (forward to pharmacist for review [deny 5a])
11. Has the member been adherent to first-line therapies used to treat this condition? (Adherent is defined as a MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes or N/A (go to #12)
    b. No (forward to pharmacist for review [deny 5u])
12. Is the drug requested primarily for the convenience of the member and not medically necessary?
    a. Yes (deny 5o)
    b. No (approve)

V. RENEWAL CRITERIA:

1. Is the requested drug being used outside of the FDA-approved treatment duration?
    a. Yes (deny 5a)
    b. No (go to #2)
2. Has documentation been submitted to support the continued medical necessity and safety, including chart notes, a treatment plan, monitoring parameters, and laboratory values (if applicable)?
    a. Yes or N/A (go to #3)
    b. No (forward to pharmacist for review [deny 5a])
3. When appropriate, has the member been non-adherent to therapy and unlikely to benefit from additional therapy? (Non-adherent is defined as a MPR less than 80% or gaps between fills that exceed 5 days.)
    a. Yes (deny 5u)
    b. No or N/A (approve)

VI. ADDITIONAL INFORMATION:

- Table 1. Recommendation, Evidence and Efficacy Ratings

1. Strength Of Recommendation		
Class I	Recommended	The given test or treatment has been proven to be useful, and should be performed or administered.
Class IIa	Recommended, In Most Cases	The given test, or treatment is generally considered to be useful, and is indicated in most cases.
Class IIb	Recommended, In Some Cases	The given test, or treatment may be useful, and is indicated in some, but not most, cases.
Class III	Not Recommended	The given test, or treatment is not useful, and should be avoided.
Class Indeterminate	Evidence Inconclusive	
2. Strength Of Evidence		
Category A	Category A evidence is based on data derived from: Meta-analyses of randomized controlled trials with homogeneity with regard to the directions and degrees of results between individual studies. Multiple, well-done randomized clinical trials involving large numbers of patients.	
Category B	Category B evidence is based on data derived from: Meta-analyses of randomized controlled trials with conflicting conclusions with regard to the directions and degrees of results between individual studies. Randomized controlled trials that involved small numbers of patients or had significant methodological flaws (e.g., bias, drop-out rate, flawed analysis, etc.). Nonrandomized studies (e.g., cohort studies, case-control studies, observational studies).	
Category C	Category C evidence is based on data derived from: Expert opinion or consensus, case reports or case series.	
No Evidence		
3. Efficacy		
Class I	Effective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is effective.
Class IIa	Evidence Favors Efficacy	Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion favors efficacy.
Class IIb	Evidence is Inconclusive	Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion argues against efficacy.
Class III	Ineffective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is ineffective.

VII. REVISION HISTORY:

- **P&T Review Date:** 3/2018
- **Implementation Date:** 3/8/2018

Stimulants

Policy Number: Rx002

I. MEDICATION NAME(S):

- dexmethylphenidate HCl
- dexmethylphenidate HCl ER
- dextroamphetamine sulfate ER
- dextroamphetamine sulfate
- Zenzedi (dextroamphetamine sulfate)
- dextroamphetamine-amphet ER
- dextroamphetamine-amphetamine
- Vyvanse (lisdexamfetamine dimesylate)
- methylphenidate LA
- methylphenidate HCl CD
- methylphenidate ER
- methylphenidate HCl
- methylphenidate HCl ER
- Metadate ER (methylphenidate HCl ER)

II. LENGTH OF AUTHORIZATION:

- Initial, members age 19 and older: six months
- Initial, members age 18 and younger: one year
- Renewal, members age 19 and older: six months
- Renewal, members age 18 and younger: one year

III. QUANTITY LIMITS:

- Multiple (see formulary)

IV. INITIAL CRITERIA:

1. Is the drug prescribed for a diagnosis of ADD/ADHD by a licensed mental health provider?
    a. Yes (go to #8)
    b. No (go to #2)
2. Is the drug prescribed for a diagnosis of ADD/ADHD by the member's primary care provider using a validated symptom checklist? (See Additional Information section for validated symptom checklists.)
    a. Yes (go to #4)
    b. No (go to #3)
3. Does the member have an established diagnosis of narcolepsy from a neurologist or pulmonologist?
    a. Yes (go to #8)
    b. No (forward to pharmacist for review [deny 5z])
4. Is the member using any medications or substances that have the potential to cause sedation or lack of focus including opiates (with the exception of buprenorphine for SUD), benzodiazepines, marijuana, and alcohol?

    a. Yes (forward to pharmacist for review [deny 5z])
    b. No (go to #5)
5. Is the member age 19 or older?
    a. Yes (go to #6)
    b. No (go to #7)
6. Has the requesting provider performed a urine drug screen and provided appropriate results at the initial visit when the stimulant was initially prescribed? (Appropriate results would include the absence of THC, opiates, benzodiazepines, cocaine.)
    a. Yes (go to #8)
    b. No (forward to pharmacist for review [deny 5z])
7. Is the member age 5 or older for dextroamphetamine/amphetamine (generic Adderall) or age 6 or older for all other medications?
    a. Yes (go to #8)
    b. No (forward to pharmacist for review [deny GLN 20, 8a])
8. Is the medication being prescribing in a manner that is supported by the FDA approved package insert indications and dosing recommendations?
    a. Yes (go to #9)
    b. No (forward to pharmacist for review)
9. Does the member have any co-morbid conditions such as uncontrolled hypertension, cardiac arrhythmias, untreated or uncontrolled anxiety or agitation, or hyperthyroidism? (Note: uncontrolled anxiety or agitation is allowed when the medication is managed by a liscensed mental health provider.)
    a. Yes (forward to pharmacist for review)
    b. No (go to #10)
10. Are there cheaper alternatives available?
    a. Yes (forward to pharmacist for review [deny 7a or 5k])
    b. No (for members age 19 and older: approve for six months; for members age 18 and younger: approve for one year)

V. RENEWAL CRITERIA:

1. Is the drug prescribed by a licensed mental health provider?
    a. Yes (approve for one year)
    b. No (go to #2)
2. Is the member currently using any medications or substances that have the potential to cause sedation or lack of focus including opiates (with the exception of buprenorphine for SUD), benzodiazepines, marijuana, and alcohol?
    a. Yes (forward to pharmacist for review [deny 5z])
    b. No (go to #3)
3. Is the member age 19 or older?
    a. Yes (go to #4)
    b. No (approve for one year)
4. Is the requesting provider performing random urine drug screens at least every six months and has the provider included documentation of an appropriate UDS within the last three months? (Appropriate results would include the absence of THC, opiates, benzodiazepines, cocaine, and presence of the prescribed stimulant if applicable.)
    a. Yes (approve for six months)

b. No (forward to pharmacist for review [deny 5z])

VI. ADDITIONAL INFORMATION:

- Accepted validated symptom checklists, Adults: Adult ADHD Self-Report Scale (ASRS-v1.1); Copeland Symptom List for Adult Attention Deficit Disorder; Conners' Adult ADHD Rating Scale (CAARS)
- Accepted validated symptom checklists, Children: Conners 3rd Edition; Behavior Assessment System for Children (BASC); Child Behavior Checklist/Teacher Report Form; ADHD Comprehensive Teacher's Rating Scale (ACTeRS); ADHD Rating Scale; Childhood Attention Problem Scale; Vanderbilt Assessment Scales
- If the member has ever had a history of substance abuse, we recommend considering use of an alternative medication: TCA (desipramine, nortriptyline), Strattera, or bupropion if a TCA is not tolerated. However, this is not a requirement.

VII. REVISION HISTORY:

- **P&T Review Date:** 3/2020, 12/2019, 12/2018, 6/2018, 6/2016, 5/2016, 6/2012, 10/2011, 8/2009, 10/2007, 6/2006, 10/2005
- **Implementation Date:** 3/25/2020, 2/17/2020, 12/11/2019, 12/6/2018, 6/21/2018, 6/2/2016, 9/14/2005

Opiate Agonists

Policy Number: Rx005

I. MEDICATION NAME(S):

- acetaminophen with codeine
- Capital W-Codeine (acetaminophen with codeine)
- butalbital/acetaminophen/caffeine/codeine
- codeine sulfate
- codeine/butalbital/aspirin/caffeine
- Ascomp With Codeine (codeine/butalbital/aspirin/caffeine)
- fentanyl
- fentanyl citrate
- Vicodin HP (hydrocodone/acetaminophen)
- hydrocodone/acetaminophen
- Co-Gesic (hydrocodone/acetaminophen)
- Lorcet (hydrocodone/acetaminophen)
- Lorcet Plus (hydrocodone/acetaminophen)
- Lorcet HD (hydrocodone/acetaminophen)
- Stagesic (hydrocodone/acetaminophen)
- Zydone (hydrocodone/acetaminophen)
- hydrocodone/ibuprofen
- hydromorphone HCl
- meperidine HCl
- methadone HCl
- morphine sulfate
- morphine sulfate ER
- oxycodone HCl
- oxycodone HCl ER
- Oxycontin (oxycodone HCl ER)
- oxycodone HCl/acetaminophen
- Roxicet (oxycodone HCl/acetaminophen)
- Endocet (oxycodone HCl/acetaminophen)
- oxycodone HCl/aspirin
- Endodan (oxycodone HCl/aspirin)
- oxymorphone HCl
- tramadol HCl
- Multiple Non-Formulary Opiates

II. LENGTH OF AUTHORIZATION:

- Initial and renewal: six weeks up to 90 days for conditions of the spine and back, six months for cancer pain or palliative care, and three months for all other diagnoses

III. QUANTITY LIMITS:

- 30 days every 180 days, cummulative 90 MED limit

IV. INITIAL CRITERIA:

1. Is the drug prescribed for a condition funded by the Oregon Health Plan (OHP) in a manner consistent with the Health Evidence Review Commission (HERC) Prioritized List of Health Services?
    a. Yes (go to #2)

    b. No (forward to pharmacist review [deny 3a])
2. Does Prioritized List of Health Services Guideline Note 60 apply (opioid prescribing for conditions of the back and spine)?
    a. Yes (go to #3)
    b. No (go to #4)
3. Does the request meet Guideline Note #60, Opioid for Conditions of the Back and Spine? For acute use, the following provisions must be met: Immediate-Release opiates only; trial and failure of non-opiates such as NSAIDs, APAP, muscle relaxants; use of other interventions such as physical therapy; no current or history of opiate abuse and documented verification that the patient is not high risk for opioid misuse or abuse. For acute use greater than 6 weeks and less than 90 days post injury or flare, there must be documented evidence of improvement of function of at least thirty percent as compared to baseline based on a validated tool (e.g. Oswestry, Neck Disability Index, SF-MPQ, and MSPQ). Chronic use (greater than 90 days) requires an individual treatment plan with a taper plan.
    a. Yes (go to #4)
    b. No (forward to pharmacist review [deny GLN 60 #1 or #2])
4. Is the drug prescribed for migraine headache?
    a. Yes (forward to pharmacist review [deny 5a])
    b. No (go to #5)
5. Has the member failed less costly alternative opioids? (For example, Morphine ER must be tried and failed before Fentanyl or Oxycodone ER.)
    a. Yes (go to #6)
    b. No (forward to pharmacist review [deny 7a])
6. Is the drug prescribed for cancer pain, or is the patient receiving hospice or end-or-life care?
    a. Yes (approve for six months)
    b. No (go to #7)
7. Does the patient have a history of diversion, history of opioid abuse, active substance abuse as defined as any illicit or non-prescribed substance (including alcohol and marijuana) within the past year?
    a. Yes (forward to pharmacist review [deny 5a])
    b. No (go to #8)
8. Is there a pain contract in place limiting the patient to one provider and one pharmacy?
    a. Yes (go to #9)
    b. No (forward to pharmacist review [deny 5g])
9. Has the prescriber submitted a written treatment plan stating goals used to determine treatment successes such as pain relief and improved physical and psychosocial function?
    a. Yes (go to #10)
    b. No (forward to pharmacist review [deny 5g])
10. Has the member had a mental health screening within the last year?
    a. Yes (go to #11)
    b. No (forward to pharmacist review [deny 5g])
11. Has the requesting provider performed a urine drug screen and provided appropriate results? (Appropriate results would include the absence of THC, cocaine,

benzodiazepines, and any non-prescribed substances. Concurrent opioid and benzodiazepine use will not be approved due to risk of respiratory depression.)
    a. Yes (go to #12)
    b. No (forward to pharmacist review [deny 5g])
12. Has the provider reviewed the Oregon Prescription Monitoring Program registry and documented appropriate results?
    a. Yes (go to #13)
    b. No (forward to pharmacist review [deny 5g])
13. Is the member taking greater than 90 MED per day?
    a. Yes (forward to pharmacist review [deny for QL over 90 MED])
    b. No (approve for six weeks for back pain and three months for all other conditions)

V. RENEWAL CRITERIA:

1. Is the drug prescribed for cancer pain, or is the patient receiving hospice or end-or-life care?
    a. Yes (approve for six months)
    b. No (go to #2)
2. Does Prioritized List of Health Services Guideline Note 60 apply (opioid prescribing for conditions of the back and spine)?
    a. Yes (go to #3)
    b. No (go to #4)
3. Does the request meet Guideline Note #60, Opioid for Conditions of the Back and Spine? For acute use greater than 6 weeks and less than 90 days post injury or flare, there must be documented evidence of improvement of function of at least thirty percent as compared to baseline based on a validated tool (e.g. Oswestry, Neck Disability Index, SF-MPQ, and MSPQ). Chronic use (greater than 90 days) is not covered.
    a. Yes (go to #4)
    b. No (forward to pharmacist review [deny GLN 60 #2])
4. Has the requesting provider performed a urine drug screen within the last six months and provided appropriate results? (Appropriate results would include the absence of THC, cocaine, benzodiazepines, and any non-prescribed substances.)
    a. Yes (go to #5)
    b. No (forward to pharmacist review [deny 5g])
5. Has the provider reviewed the Oregon Prescription Monitoring Program registry regularly, at least once since the last approval, and documented appropriate results?
    a. Yes (approve for six weeks for back pain and three months for all other conditions)
    b. No (forward to pharmacist review [deny 5g])

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 3/2020, 9/2018, 5/2012
- **Implementation Date:** 3/25/2020, 9/20/2018, 5/1/2018

Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Policy Number: Rx006

I. MEDICATION NAME(S):

- Alogliptin *preferred*
- Tradjenta (linagliptin)
- Onglyza (saxagliptin)
- Kombiglyze XR (saxagliptin HCl/metformin HCl)
- Januvia (sitagliptin phosphate)
- Janumet (sitagliptin phos/metformin HCl)

II. LENGTH OF AUTHORIZATION:

- Initial: six months
- Renewal: one year

III. QUANTITY LIMITS:

- Januvia: 1 per 1 day

IV. INITIAL CRITERIA:

1. Is the drug prescribed for Type 2 diabetes mellitus?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])
2. Has the member had an adequate trial and failure of, contraindication to, or intolerance to metformin dosed at 2,000 mg per day? (Adequate trial is defined as adherent to therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (go to #3)
    b. No (forward to pharmacist for review [deny 7a])
3. Has the member had an adequate trial and failure of or contraindication to a sulfonylurea or TZD?
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 7a])
4. Is the request for alogliptin?
    a. Yes (go to #9)
    b. No (go to #5)
5. Has the member had an adequate trial and failure of or contraindication to alogliptin?
    a. Yes (go to #6)
    b. No (deny 7a)
6. Has the member had an adequate trial and failure of, contraindication to, or intolerance to basal insulin at a dose of at least 80 units daily? (Adequate trial is defined as compliant with therapy for at least three consecutive months, MPR greater than or

equal to 80% or no gaps between fills that exceed 5 days, and an A1C of 7% or less after at least two dose increases. Contraindication or intolerance can include adverse reactions to insulin, like severe hypoglycemia, but does not include weight gain or concern about weight gain.)
    a. Yes (go to #7)
    b. No (forward to pharmacist for review [deny 7a])
7. Is the member's most recent A1c (within the last six months) greater than 9%?
    a. Yes (go to #8)
    b. No (go to #9)
8. Has the provider submitted an acceptable, medical rationale for why mealtime insulin cannot be used?
    a. Yes (approve for six months)
    b. No (forward to pharmacist for review [deny 5a/7a])
9. Is the member's most recent A1c (within the last six months) already at goal (at or below 7% for most members)?
    a. Yes (forward to pharmacist for review [deny 5a])
    b. No (approve for six months)

V. RENEWAL CRITERIA:

1. Is the member adherent to therapy? (Adherence defined as a MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 5u])
2. Has the member had at least a 10% reduction in A1c or A1c is at goal (at or below 7%)? (A1c value must be recently measured within the last six months.)
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 5a])

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 3/2020, 12/2018, 6/2018
- **Implementation Date:** 12/6/2018, 6/21/2018

UMPQUA HEALTH ALLIANCE
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ROSEBURG, OR 97470

Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists (i.e. Incretin Mimetics)

Policy Number: Rx007

I. MEDICATION NAME(S):

- Byetta (exenatide) *preferred*
- Bydureon (exenatide microspheres) *preferred*
- Adlyxin (lixisenatide) *preferred*
- Rybelsus (semaglutide) *preferred*
- Tanzeum (albiglutide)
- Trulicity (dulaglutide)
- Saxenda (liraglutide)
- Victoza (liraglutide)
- Ozempic (semaglutide)

II. LENGTH OF AUTHORIZATION:

- Initial: six months
- Renewal: one year

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug prescribed for Type 2 diabetes mellitus?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])
2. Has the member had an adequate trial and failure of, contraindication to, or intolerance to metformin dosed at 2,000mg per day? (Adequate trial is defined as adherent to therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (go to #3)
    b. No (forward to pharmacist for review [deny 7a])
3. Does the member have either (1) established atherosclerotic cardiovascular disease (ASCVD) defined as ischemic heart disease, ischemic cerebrovascular disease, or peripheral artery disease; OR (2) high risk for ASCVD defined as age 55 years or older for men or 60 years or older for women, AND one or more traditional risk factors including hypertension, dyslipidemia (LDL > 130 mg/dL or taking lipid-lowering therapies), or tobacco use?
    a. Yes (go to #10)
    b. No (go to #4)
4. Has the member had an adequate trial and failure of or contraindication to a sulfonylurea or TZD?
    a. Yes (go to #5)
    b. No (forward to pharmacist for review [deny 7a])

5. Has the member had an adequate trial and failure of, contraindication to, or intolerance to basal insulin at a dose of at least 80 units daily? (Adequate trial is defined as compliant with therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days, and an A1C of 7% or less after at least two dose increases. Contraindication or intolerance can include adverse reactions to insulin, like severe hypoglycemia, but does not include weight gain or concern about weight gain.)
    a. Yes (go to #6)
    b. No (forward to pharmacist for review [deny 7a])
6. Is the member's most recent A1c (within the last six months) greater than 9%?
    a. Yes (go to #7)
    b. No (go to #8)
7. Has the provider submitted an acceptable, medical rationale for why mealtime insulin cannot be used?
    a. Yes (go to #8)
    b. No (forward to pharmacist for review [deny 5a/7a])
8. Is the member's most recent A1c (within the last six months) already at goal (at or below 7% for most members)?
    a. Yes (forward to pharmacist for review [deny 5a])
    b. No (go to #9)
9. Has the member had an adequate trial and failure of or contraindication to a dipeptidyl peptidase-4 (DPP-4) inhibitor?
    a. Yes (go to #10)
    b. No (forward to pharmacist for review [deny 7a])
10. Has the member had an adequate trial and failure of, contraindication to, or intolerance to an SGLT2 inhibitor (Steglatro [preferred], Invokana, Farxiga, or Jardiance)?
    a. Yes (go to #11)
    b. No (forward to pharmacist for review [deny 7a])
11. Is the requested medication on formulary?
    a. Yes (approve for six months)
    b. No (go to #12)
12. Has the member tried and failed the formulary alternative medications?
    a. Yes (approve for six months)
    b. No (forward to pharmacist review [deny 5k])

V. RENEWAL CRITERIA:

1. Is the member adherent to therapy? (Adherence defined as a MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 5u])
2. Has the member had at least a 10% reduction in A1c or A1c is at goal (at or below 7%)? (A1c value must be recently measured within the last six months.)
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 5a])

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 3/2020, 12/2018, 6/2018
- **Implementation Date:** 3/25/2020, 12/6/2018, 6/21/2018

Sodium-Glucose Cotransporter-2 (SGLT2) Inhibitors

Policy Number: Rx008

I. MEDICATION NAME(S):

- Steglatro (ertugliflozin) *preferred*
- Invokana (canagliflozin)
- Farxiga (dapagliflozin propanediol)
- Jardiance (empagliflozin)

II. LENGTH OF AUTHORIZATION:

- Initial: six months
- Renewal: one year

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug prescribed for Type 2 diabetes mellitus?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])
2. Has the member had an adequate trial and failure of, contraindication to, or intolerance to metformin dosed at 2,000mg per day? (Adequate trial is defined as adherent to therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (go to #3)
    b. No (forward to pharmacist for review [deny 7a])
3. Does the member have any of the following: (1) established atherosclerotic cardiovascular disease (ASCVD) defined as ischemic heart disease, ischemic cerebrovascular disease, or peripheral artery disease; OR (2) high risk for ASCVD defined as age 55 years or older for men or 60 years or older for women, AND one or more traditional risk factors including hypertension, dyslipidemia (LDL > 130 mg/dL or taking lipid-lowering therapies), or tobacco use; OR (3) heart failure with a LVEF < 45%; OR (4) chronic kidney disease (CKD) with an eGFR 30-60 mL/min?
    a. Yes (go to #10)
    b. No (go to #4)
4. Has the member had an adequate trial and failure of or contraindication to a sulfonylurea or TZD?
    a. Yes (go to #5)
    b. No (forward to pharmacist for review [deny 7a])
5. Has the member had an adequate trial and failure of, contraindication to, or intolerance to basal insulin at a dose of at least 80 units daily? (Adequate trial is defined as compliant with therapy for at least three consecutive months, MPR greater than or

equal to 80% or no gaps between fills that exceed 5 days, and an A1C of 7% or less after at least two dose increases. Contraindication or intolerance can include adverse reactions to insulin, like severe hypoglycemia, but does not include weight gain or concern about weight gain.)
    a. Yes (go to #6)
    b. No (forward to pharmacist for review [deny 7a])
6. Is the member's most recent A1c (within the last six months) greater than 9%?
    a. Yes (go to #7)
    b. No (go to #8)
7. Has the provider submitted an acceptable, medical rationale for why mealtime insulin cannot be used?
    a. Yes (go to #9)
    b. No (forward to pharmacist for review [deny 5a/7a])
8. Is the member's most recent A1c (within the last six months) already at goal (at or below 7% for most members)?
    a. Yes (forward to pharmacist for review [deny 5a])
    b. No (go to #9)
9. Has the member had an adequate trial and failure of or contraindication to a dipeptidyl peptidase-4 (DPP-4) inhibitor?
    a. Yes (go to #10)
    b. No (forward to pharmacist for review [deny 7a])
10. Is the requested medication Steglatro (ertugliflozin)?
    a. Yes (approve for six months)
    b. No (go to #11)
11. Has the member had an adequate trial and failure of, contraindication to, or intolerance to Steglatro? (The UHA Pharmacy and Therapeutics Committee has determined the cardiovascular and renal benefits are likely a class effect.)
    a. Yes (approve for six months)
    b. No (forward to pharmacist for review [deny 5k])

V. RENEWAL CRITERIA:

1. Is the member adherent to therapy? (Adherence defined as a MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 5u])
2. Has the member had at least a 10% reduction in A1c or A1c is at goal (at or below 7%)? (A1c value must be recently measured within the last six months.)
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 5a])

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 3/2020, 12/2018, 6/2018
- **Implementation Date:** 3/25/2020, 12/6/2018, 6/21/2018

Insulins

Policy Number: Rx009

I. MEDICATION NAME(S):

- Novolog (insulin aspart) cartridge
- Novolog Flexpen (insulin aspart) pen
- Novolog Mix 70-30 Flexpen (insulin aspart protamine/insulin aspart) pen
- Levemir (insulin detemir) vial
- Levemir Flextouch (insulin detemir) pen
- Lantus (insulin glargine)
- Lantus Solostar (insulin glargine) pen
- Toujeo Solostar (insulin glargine) pen
- Admelog Solostar (insulin lispro) pen
- Humalog (insulin lispro) cartridge
- Humalog Mix 50-50 Kwikpen (insulin lispro protamine/lispro) pen
- Humalog Mix 75-25 Kwikpen (insulin lispro protamine/lispro) pen
- Humulin 70-30 Kwikpen (insulin NPH/insulin regular) pen
- Novolin 70-30 Flexpen (insulin NPH/insulin regular) pen
- Humulin N Kwikpen (insulin NPH) pen
- Humulin R U-500 (insulin regular) pen
- Humulin R U-500 Kwikpen (insulin regular) pen

II. LENGTH OF AUTHORIZATION:

- Initial: length of benefit (LOB)

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug prescribed for diabetes mellitus (type 1 or 2)?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 5a])
2. Is the request for Lantus, Levemir or Toujeo?
    a. Yes (go to #3)
    b. No (go to #7)
3. Has the member had an adequate trial and failure of or contraindication to UHA's preferred long-acting insulin, Basaglar? (Adequate trial is defined as adherent to therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 7a])
4. Is the request for Toujeo?
    a. Yes (go to #5)
    b. No (approve for LOB)

5. Does the member require greater than 80 units per day, but less than or equal to 200 units per day of basal insulin? (Toujeo was not studied in patients with insulin resistance (total daily insulin dose >200 units/day) and is not intended to be a replacement for those requiring U-500 insulin.)
    a. Yes (approve for LOB)
    b. No (go to #6)
6. Does the member have nocturnal hypoglycemia after other inventions have been made to address hypoglycemia?
    a. Yes (approve for LOB)
    b. No (forward to pharmacist for review [deny 5a])
7. Is the request for Admelog, Novolog or Humalog?
    a. Yes (go to #8)
    b. No (go to #9)
8. Has the member had an adequate trial and failure of or contraindication to UHA's preferred rapid-acting insulin, insulin lispro? (Adequate trial is defined as adherent to therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (go to #11)
    b. No (forward to pharmacist for review [deny 7a])
9. Is the request for Humulin R U-500?
    a. Yes (go to #10)
    b. No (go to #11)
10. Does the member have insulin resistance requiring greater than 200 units per day?
    a. Yes (go to #11)
    b. No (forward to pharmacist for review [deny 5a]))
11. Is the request for an insulin pen or cartridge?
    a. Yes (go to #12)
    b. No (approve for LOB)
12. Does the member meet ANY of the following criteria: (1) Age 18 years or younger (approve until age 19); (2) Member demonstrates an inability to draw insulin from a multidose vial into a syringe documented by provider; (3) Use short-acting insulin in intensive multi-dose therapy (i.e. greater than 4 times a day injections); OR (4) Member has uncontrolled diabetes due to poor compliance evident by claims history?
    a. Yes (approve for LOB)
    b. No (forward to pharmacist for review [deny 5a])

V. RENEWAL CRITERIA:

VI. ADDITIONAL INFORMATION:

- For members already started and stabilized on a non-preferred insulin, UHA will allow a transition fill to allow time to switch to the preferred insulin.

VII. REVISION HISTORY:

- **P&T Review Date:** 12/2019, 6/2018
- **Implementation Date:** 12/11/2019, 6/21/2018

Topical Antifungals

Policy Number: Rx010

I. MEDICATION NAME(S):

- ciclopirox
- clotrimazole/betamethasone dip
- ketoconazole
- miconazole nitrate (Antifungal Cream, Baza Antifungal, Inzo Antifungal, Micatin, Miconazole Nitrate, Remedy Antifungal, Secura Antifungal)
- naftifine HCl
- Naftin (naftifine HCl)
- nystatin (Nyamyc, Nystop)
- nystatin/triamcinolone
- Exelderm (sulconazole nitrate)
- Lamisil (terbinafine HCl)

II. LENGTH OF AUTHORIZATION:

- Initial: three to six months
- Renewal: six months

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug used for an FDA-approved indication or a medically appropriate off-label use with strong evidence supporting safety and efficacy?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])
2. Is the drug prescribed for a condition funded by the Oregon Health Plan (OHP) in a manner consistent with the Health Evidence Review Commission (HERC) Prioritized List of Health Services? (Fungal infections of the skin, scalp, groin and nails are not funded for most members. Some conditions are covered if the member is immunocompromised, like those with AIDS or cancer.)
    a. Yes (go to #4)
    b. No (go to #3)
3. Is there a comorbid condition for which coverage would be allowed? For example, type 2 diabetes or other conditions that may increase the risk of serious secondary skin infections.
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 3a/3c])
4. Has the member tried and failed clotrimazole 1% cream (on formulary without PA) or is this medication not appropriate to treat the member's condition?
    a. Yes (go to #5)
    b. No (forward to pharmacist review [deny 7a])

5. Is the requested medication on formulary?
    a. Yes (approve for six months)
    b. No (go to #6)
6. Has the member tried and failed all less-costly formulary alternative medications?
    a. Yes (approve for six months)
    b. No (forward to pharmacist review [deny 5k])

V. RENEWAL CRITERIA:

1. Is the drug used for an FDA-approved indication or a medically appropriate off-label use with strong evidence supporting safety and efficacy?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])
2. Is the drug prescribed for a condition funded by the Oregon Health Plan (OHP) in a manner consistent with the Health Evidence Review Commission (HERC) Prioritized List of Health Services? (Fungal infections of the skin, scalp, groin and nails are not fund
    a. Yes (approve for six months)
    b. No (go to #3)
3. Is there a comorbid condition for which coverage would be allowed? For example, type 2 diabetes or other conditions that may increase the risk of serious secondary skin infections.
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 3a/3c])
4. Has documentation been submitted to support the continued use of this medication in accordance with clinical guidelines? (Refer to UpToDate or product labeling for appropriate treatment duration.)
    a. Yes (approve for six months)
    b. No (forward to pharmacist for review [deny 5a])

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 6/2018
- **Implementation Date:** 6/21/2018

Nasal Corticosteroids

Policy Number: Rx011

I. MEDICATION NAME(S):

- flunisolide
- fluticasone propionate (No PA required, QL only)
- mometasone furoate

II. LENGTH OF AUTHORIZATION:

- Initial: one year
- Renewal: one year

III. QUANTITY LIMITS:

- Fluticasone: 1 fill per 1 year, 16 mLs per 30 days

IV. INITIAL CRITERIA:

1. Is the drug used for a diagnosis of allergic rhinitis, non-allergic rhinitis, or nasal polyps?
    a. Yes (go to #2)
    b. No (go to #3)
2. Is there a comorbid condition for which coverage would be allowed (i.e. asthma, COPD, obstructive sleep apnea or other respiratory conditions exacerbated by limited air flow)?
    a. Yes (go to #4)
    b. No (forward to pharmacist review [deny 3a/3c])
3. Is the drug used for a diagnosis of chronic sinusitis defined as 12 weeks of continuous symptoms without improvement?
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 8a])
4. Is the request for fluticasone or flunisolide?
    a. Yes (approve for six months)
    b. No (go to #5)
5. Has the member failed an adequate trial of fluticasone and flunisolide (and other less costly alternative agents)?
    a. Yes (approve for one year)
    b. No (forward to pharmacist review, [deny 7a, or 5k for non-formulary agents])

V. RENEWAL CRITERIA:

1. Has the prescriber submitted documentation of continued medical necessity in accordance with initial criteria?
    a. Yes (approve for one year)

b. No (forward to pharmacist for review [deny 5a])

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 12/2018, 6/2018
- **Implementation Date:** 12/6/2018, 6/21/2018

Clonazepam

Policy Number: Rx013

I. MEDICATION NAME(S):

- clonazepam

II. LENGTH OF AUTHORIZATION:

- Initial: one to six months (one year for seizures, oncology, or palliative care)
- Renewal: up to six months (one year for seizures, oncology, or palliative care)

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug used for a member with a malignant neoplasm or other end-of-life diagnosis?
    a. Yes (approve for one year)
    b. No (go to #2)
2. Is the drug used for a member with a diagnosed seizure disorder?
    a. Yes (approve for length of benefit)
    b. No (go to #3)
3. Is the drug used for an FDA-approved indication or a medically appropriate off-label use with strong evidence supporting safety and efficacy?
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 8a])
4. Is the drug prescribed for a condition funded by the Oregon Health Plan (OHP) in a manner consistent with the Health Evidence Review Commission (HERC) Prioritized List of Health Services?
    a. Yes (go to #5)
    b. No (forward to pharmacist review [deny 3a/3c])
5. Is the member taking a concurrent sedative, hypnotic or opioid?
    a. Yes (forward to pharmacist review [deny 5a]
    b. No (go to #6)
6. Is this a new start request for short-term use (less than 4 weeks)?
    a. Yes (approve for one month)
    b. No (go to #7)
7. Is there appropriate rationale to support long-term benzodiazepine use for this indication?
    a. Yes (approve for six months)
    b. No (forward to pharmacist review [deny 5a])

V. RENEWAL CRITERIA:

1. Is the drug used for a member with a malignant neoplasm or other end-of-life diagnosis?
    a. Yes (approve for one year)
    b. No (go to #2)
2. Is the drug used for a member with a diagnosed seizure disorder?
    a. Yes (approve for length of benefit)
    b. No (go to #3)
3. Is the member taking a concurrent sedative, hypnotic or opioid?
    a. Yes (forward to pharmacist review [deny 5a]
    b. No (go to #4)
4. Is there appropriate rationale to support long-term benzodiazepine use for this indication? (Exceptions may be made to allow time to taper off of medication.)
    a. Yes (approve for up to six months)
    b. No (forward to pharmacist review [deny 5a])

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 6/2018
- **Implementation Date:** 6/21/2018

Direct Oral Anticoagulants

Policy Number: Rx014

I. MEDICATION NAME(S):

- Eliquis (apixaban)
- Bevyxxa (betrixaban maleate)
- Pradaxa (dabigatran etexilate mesylate)
- Savaysa (edoxaban tosylate)
- Xarelto (rivaroxaban)

II. LENGTH OF AUTHORIZATION:

- Initial:
  - Atrial fibrillation: one year
  - Coronary artery disease (CAD) (stable) or peripheral artery disease (PAD): one year
  - Provoked DVT/PE treatment: three months
  - Unprovoked DVT/PE treatment: six months
  - Knee replacement: 14 days
  - Hip replacement: 35 days
  - VTE prophylaxis in patients with restricted mobility: 42 days for Bevyxxa (betrixaban), 39 days for Xarelto (rivaroxaban)
- Renewal: one year
  - Atrial fibrillation: one year
  - CAD or PAD: one year
  - Unprovoked DVT/PE treatment; secondary DVT/PE prophylaxis: one year
  - All other indications should not require renewal

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug prescribed for a condition funded by the Oregon Health Plan (OHP) in a manner consistent with the Health Evidence Review Commission (HERC) Prioritized List of Health Services?
   a. Yes (go to #2)
   b. No (forward to pharmacist review [deny 3a])
2. Is the drug prescribed for an FDA-approved indication AND is the appropriate dose and duration being prescribed consistent with the FDA approved prescribing information? (Refer to Table 1. Indications and Dosing in 'Additional Information' section.)
   a. Yes (go to #3)
   b. No (forward to pharmacist review [deny 8a])

3. Does the member have any of the following conditions: liver disease (LMWH preferred), renal disease with CrCl less than 30 ml/min (warfarin preferred), thrombolytic therapy use (UFH infusion preferred), pregnancy or pregnancy risk (LMWH preferred), valvular disease including mechanical heart valves or moderate to severe mitral stenosis (warfarin preferred), left ventricular thrombi (warfarin preferred), antiphospholipid syndrome (warfarin preferred), or antithrombin deficiency (warfarin preferred)?
    a. Yes (forward to pharmacist review [deny 5a, comorbid])
    b. No (go to #4)
4. Is the drug prescribed for non-valvular atrial fibrillation?
    a. Yes (go to #5)
    b. No (approve for the appropriate initial duration for the diagnosis as listed above)
5. Does the member have a CHA2DS2-VASc score greater than or equal to 2, OR does member have a CHA2DS2-VASc score of 1 and the provider provided rationale explaining the medical necessity of anticoagulation? (CHA2DS2-VASc: CHF = 1; hypertension = 1; age 75 years or greater = 2; diabetes = 1; stroke/TIA/thromboembolism = 2; vascular disease = 1; age 65-74 years = 1; female = 1)
    a. Yes (approve for one year)
    b. No (forward to pharmacist review [deny 5a, CHA2DS2-VASc])

V. RENEWAL CRITERIA:

1. Is the drug prescribed for non-valvular atrial fibrillation, CAD or PAD, secondary prophylaxis for unprovoked DVT/PE with low to moderate bleeding risk (0-1 risk factors)? (Bleeding risk factors include: hypertension, abnormal liver function, abnormal renal function, stroke, bleeding tendency or predisposition, labile INRs in patients taking warfarin, age greater than 65 years, concomitant antiplatelet agents [e.g., aspirin, clopidogrel, ticlopidine, NSAIDS], and concomitant excess alcohol use.)
    a. Yes (go to #2)
    b. No (forward to pharmacist review [deny 8a, over the max FDA-approved duration])
2. Is the member adherent to therapy? (Adherence defined as a MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (approve for one year)
    b. No (forward to pharmacist review [deny 5u])

VI. ADDITIONAL INFORMATION:

- Table 1. Indications and Dosing (note: price quotes completed on 6/22/2020)

	Eliquis (apixaban)	Bevyxxa (betrixaban)	**Pradaxa (dabigatran)**	**Savaysa (edoxaban)**	**Xarelto (rivaroxaban)**
Deep vein thrombosis (DVT) or pulmonary embolism (PE) treatment	**10 mg twice daily for 7 days followed by 5 mg twice daily ($560 for first 30 days, then $454/30 days) DURATION*: •Provoked*: 3 months (provided provoking risk factor is no longer**	Not indicated	**150 mg twice daily following 5-10 days of parenteral anticoagulation ($442/30 days) DURATION*: •Provoked*: 3 months (provided provoking risk factor is no longer present).**	**Weight-based dose once daily following 5-10 days of parenteral anticoagulation: •Patient weight >60 kg: 60 mg once daily ($375/30 days) •Patient weight ≤60 kg: 30 mg once**	**15 mg twice daily for 21 days followed by 20 mg once daily ($770 for first 30 days, then $453/30 days) DURATION*: •Provoked*: 3 months (provided provoking risk factor is no longer**

	present). •Unprovoked*: ≥3 months depending on risk of venous thromboembolism recurrence and bleeding. (Note: can be used in patients with active cancer.)		**•Unprovoked*: ≥3 months depending on risk of venous thromboembolism recurrence and bleeding.**	**daily ($375/30 days) DURATION*: •Provoked*: 3 months (provided provoking risk factor is no longer present). •Unprovoked*: ≥3 months depending on risk of venous thromboembolism recurrence and bleeding. (Note: can be used in patients with active cancer, except GI cancer [LMWH preferred].)**	**present). •Unprovoked*: ≥3 months depending on risk of venous thromboembolism recurrence and bleeding. (Note: can be used in patients with active cancer, except GI cancer [LMWH preferred].)**
Secondary DVT/PE prophylaxis	**2.5 mg twice daily (indefinite) after initial 6 months of therapy ($454/30 days)**	Not indicated	**150 mg twice daily (indefinite) ($442/30 days)**	**Not indicated**	**10 mg once daily (indefinite) after initial 6 months of therapy ($453/30 days)**
Non-valvular atrial fibrillation	**5 mg twice daily indefinitely ($454/30 days)**	Not indicated	**150 mg twice daily indefinitely ($442/30 days)**	**60 mg once daily ($375/30 days)**	**20 mg once daily indefinitely ($453/30 days) (Note: PCI with stent placement is off-label, dosed at 15 mg once daily)**
Postoperative DVT prophylaxis (hip and knee replacement surgery)	**2.5 mg twice daily DURATION: •Knee: 10-14 days ($212) •Hip: up to 35 days ($529)**	Not indicated	**110 mg on day 1 then 220 mg once daily (hip replacement only; use in knee replacement is off-label) DURATION: •Knee (off-label): 10-14 days ($199) •Hip: up to 35 days ($508)**	**Not indicated**	**10 mg once daily •Knee: 10-14 days ($212) •Hip: up to 35 days ($528)**
VTE prophylaxis in patients with restricted mobility from acute illness (heart failure, respiratory failure, infectious disease, rheumatic disease, or ischemic stroke) and other VTE risk factors (age ≥75 years; age 60 to 74 years with D-dimer at least 2 times the upper limit of normal (ULN); or age 40 to 59 years with D-dimer at	**Not indicated**	160 mg for one dose, then 80 mg daily for 35 to 42 days ($622)	**Not indicated**	**Not indicated**	**10 mg once daily for 31 to 39 days ($589)**

least 2 times the ULN and a history or either VTE or cancer)					
Coronary artery disease (CAD) (stable) or peripheral artery disease (PAD) (May consider use in carefully selected patients who are at high risk of cardiovascular events and low risk of bleeding if therapeutic anticoagulation or dual antiplatelet therapy is not required for another indication.)	**Not indicated**	Not indicated	**Not indicated**	**Not indicated**	**2.5 mg twice daily with low dose aspirin ($453/30 days)**

** For provoked DVT/PE (surgery, estrogen therapy, pregnancy, leg injury, flight greater than 8 hours), the duration of therapy is three months. For unprovoked DVT/PE with low to moderate bleeding risk (0-1 risk factors), the prescriber may use extended anticoagulation therapy (no stop date). For unprovoked DVT/PE with high bleeding risk (2 or more risk factors), the duration of therapy is three months. (Bleeding risk factors include: hypertension, abnormal liver function, abnormal renal function, stroke, bleeding tendency or predisposition, labile INRs in patients taking warfarin, age greater than 65 years, concomitant antiplatelet agents [e.g., aspirin, clopidogrel, ticlopidine, NSAIDS], and concomitant excess alcohol use.)*

VII. REVISION HISTORY:

- **P&T Review Date:** 6/2020, 9/2018
- **Implementation Date:** 6/24/2020, 9/20/2018

Topical Corticosteroids

Policy Number: Rx015

I. MEDICATION NAME(S):

- amcinonide
- betamethasone dipropionate
- betamethasone valerate
- clobetasol propionate
- clobetasol emollient
- clobetasol emulsion
- clocortolone pivalate
- Apexicon E (diflorasone diacetate/emoll)
- fluocinolone acetonide
- fluocinonide
- Scalacort DK (hydrocort/sal acid/sulf/shamp1)
- hydrocortisone (Ala-Cort, Ala-Scalp, Anti-Itch, Cortaid, Cortisone, Cortizone-10, Cortizone-10 Plus, Eczema Anti-Itch, Hydrocream, Noble Formula HC, Preparation H, Procto-Pak, Scalp Relief, Scalpicin, Soothing Care)
- Texacort (hydrocortisone)
- Nucort (hydrocortisone acet/aloe vera)
- hydrocortisone acetate
- hydrocortisone butyrate
- Pandel (hydrocortisone probutate)
- hydrocortisone/aloe vera (Cortizone-10, Hydrocortisone Plus, Hydrocortisone-Aloe, Hydroskin)
- mometasone furoate
- triamcinolone acetonide (Trianex, Triderm)

II. LENGTH OF AUTHORIZATION:

- Initial: six months
- Renewal: one year

III. QUANTITY LIMITS:

- Multiple (see formulary)

IV. INITIAL CRITERIA:

1. Is the drug used for an FDA-approved indication or a medically appropriate off-label use with strong evidence supporting safety and efficacy?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])
2. Is the drug prescribed for a condition funded by the Oregon Health Plan (OHP) in a manner consistent with the Health Evidence Review Commission (HERC) Prioritized List of Health Services? (Mild to moderate inflammatory skin conditions are not funded. Refer to Guideline Note 21 for coverage of severe inflammatory skin disease: inability to use hands or feet for activities of daily living, or is on the face preventing normal social contact; and one of the following is present: more than 10% of the body is covered and/or the hands, feet, or mucous membranes are affected.)

a. Yes (go to #4)
b. No (go to #3)

3. Is there a comorbid condition for which coverage would be allowed?
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 3a/3c or 5a21 for mild/moderate skin conditions])
4. Has the member tried and failed triamcinolone 0.1% cream or ointment (on formulary without PA) or is this medication not appropriate to treat the member's condition?
    a. Yes (go to #5)
    b. No (forward to pharmacist review [deny 7a])
5. Has the member tried and failed all less-costly formulary alternative medications?
    a. Yes (approve for six months)
    b. No (forward to pharmacist review [deny 7a or 5k])

V. RENEWAL CRITERIA:

1. Is the drug used for an FDA-approved indication or a medically appropriate off-label use with strong evidence supporting safety and efficacy?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])
2. Is the drug prescribed for a condition funded by the Oregon Health Plan (OHP) in a manner consistent with the Health Evidence Review Commission (HERC) Prioritized List of Health Services? (Mild to moderate inflammatory skin conditions are not funded. Refer to Guideline Note 21 for coverage of severe inflammatory skin disease: inability to use hands or feet for activities of daily living, or is on the face preventing normal social contact; and one of the following is present: more than 10% of the body is covered and/or the hands, feet, or mucous membranes are affected.)
    a. Yes (approve for one year)
    b. No (go to #3)
3. Is there a comorbid condition for which coverage would be allowed? For example, type 2 diabetes or other conditions that may increase the risk of serious secondary skin infections.
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 3a/3c or 5a21 for mild/moderate skin conditions])
4. Has documentation been submitted to support the continued use of this medication in accordance with clinical guidelines? (Refer to UpToDate or product labeling for appropriate treatment duration.)
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 5a])

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 6/2018
- **Implementation Date:** 6/21/2018

Lidocaine Transdermal Patch

Policy Number: Rx017

I. MEDICATION NAME(S):

- Lidoderm (lidocaine)
- lidocaine transdermal patch

II. LENGTH OF AUTHORIZATION:

- Initial: six months
- Renewal: one year

III. QUANTITY LIMITS:

- Up to 3 patches per day

IV. INITIAL CRITERIA:

1. Is the drug prescribed for pain associated with postherpetic neuralgia (shingles pain), diabetic neuropathy, or cancer-related neuropathy?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])
2. Has the member tried and failed lidocaine 2% jelly (on formulary without PA)?
    a. Yes (approve for six months)
    b. No (forward to pharmacist review [deny 5k])

V. RENEWAL CRITERIA:

1. Is the member adherent to therapy? (Adherence defined as a MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 5u])
2. Has documentation been submitted stating this medication has been effective for reducing the members pain?
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 5a])

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 6/2018
- **Implementation Date:** 6/21/2018

Neoplastic Disease

Policy Number: Rx018

I. MEDICATION NAME(S):

- abiraterone acetate
- Hexalen (altretamine)
- azacitidine
- Treanda (bendamustine HCl)
- bexarotene
- Myleran (busulfan)
- Jevtana (cabazitaxel)
- capecitabine
- Erbitux (cetuximab)
- Leukeran (chlorambucil)
- cyclophosphamide
- dactinomycin
- Sprycel (dasatinib)
- Docefrez (docetaxel)
- docetaxel
- Tarceva (erlotinib HCl)
- Emcyt (estramustine phosphate sodium)
- Afinitor (everolimus)
- Iressa (gefitinib)
- gemcitabine HCl
- imatinib mesylate
- Camptosar (irinotecan HCl)
- Tykerb (lapatinib ditosylate)
- Revlimid (lenalidomide)
- Gleostine (lomustine)
- lomustine
- Lysodren (mitotane)
- Tasigna (nilotinib HCl)
- nilutamide
- oxaliplatin
- Votrient (pazopanib HCl)
- Sylatron (peginterferon alfa-2b)
- Sylatron 4-Pack (peginterferon alfa-2b)
- Folotyn (pralatrexate)
- Matulane (procarbazine HCl)
- romidepsin
- Nexavar (sorafenib tosylate)
- Sutent (sunitinib malate)
- temozolomide
- Tabloid (thioguanine)
- Hycamtin (topotecan HCl)
- topotecan HCl
- toremifene citrate
- tretinoin
- Caprelsa (vandetanib)
- Zolinza (vorinostat)
- Multiple non-formulary antineoplastics (must first try and fail formulary alternatives if applicable)

II. LENGTH OF AUTHORIZATION:

- Variable

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug used for an FDA-approved indication, a medically appropriate off-label use with strong evidence supporting safety and efficacy, or a NCCN supported indication with evidence level of 2A or better?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])
2. Is the drug prescribed for a condition funded by the Oregon Health Plan (OHP) in a manner consistent with the Health Evidence Review Commission (HERC) Prioritized List of Health Services?
    a. Yes (go to #4)
    b. No (go to #3)
3. Is there a comorbid condition for which coverage would be allowed?
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 3a/3c])
4. If applicable, does the request meet criteria for treatment coverage specified in Guideline Note 12 of the Health Evidence Review Commission (HERC) Prioritized List of Health Services, considering treatment of cancer with little or no benefit (see 'Additional Information' section for Guideline Note 12)?
    a. Yes (go to #5)
    b. No (forward to pharmacist for review [deny 3a])
5. Is the medication prescribed by or in consultation with a hematologist or oncologist, as appropriate, for the type of cancer?
    a. Yes (go to #6)
    b. No (forward to pharmacist for review)
6. Does the member have a Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater?
    a. Yes (forward to pharmacist for review)
    b. No (go to #7)
7. According to NCCN guidelines, are there alternative less-costly therapies recommended at the same or better evidence level?
    a. No (approve for three months or other appropriate duration based on indication, treatment regimen, and monitoring requirements)
    b. Yes (forward to pharmacist for review [deny 7a])

V. RENEWAL CRITERIA:

1. According to FDA labeling, or NCCN guidelines, is treatment still indicated?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 5a])
2. Has there been evidence of disease responsiveness to therapy?
    a. Yes (approve for appropriate duration up to one year)
    b. No (forward to pharmacist for review [deny 5a])

VI. ADDITIONAL INFORMATION:

Prioritized List of Health Services Guideline Note 12, Patient-Centered Care of Advanced Cancer:

- Cancer is a complex group of diseases with treatments that vary depending on the specific subtype of cancer and the patient's unique medical and social

situation. Goals of appropriate cancer therapy can vary from intent to cure, disease burden reduction, disease stabilization and control of symptoms. Cancer care must always take place in the context of the patient's support systems, overall heath, and core values. Patients should have access to appropriate peer-reviewed clinical trials of cancer therapies. A comprehensive multidisciplinary approach to treatment should be offered including palliative care services (see STATEMENT OF INTENT 1, PALLIATIVE CARE).

- Treatment with intent to prolong survival is not a covered service for patients who have progressive metastatic cancer with:
  - Severe co-morbidities unrelated to the cancer that result in significant impairment in two or more major organ systems which would affect efficacy and/or toxicity of therapy; OR
  - A continued decline in spite of best available therapy with a non reversible Karnofsky Performance Status or Palliative Performance score of <50% with ECOG performance status of 3 or higher which are not due to a pre-existing disability.
- Treatments with intent to relieve symptoms or improve quality of life are covered as defined in STATEMENT OF INTENT 1, PALLIATIVE CARE. Examples:
  - Single-dose radiation therapy for painful bone metastases with the intent to relieve pain and improve quality of life.
  - Surgical decompression for malignant bowel obstruction. Single fraction radiotherapy should be given strong consideration for use over multiple fraction radiotherapy when clinically appropriate (e.g., not contraindicated by risk of imminent pathologic fracture, worsening neurologic compromise or radioresistant histologies such as sarcoma, melanoma, and renal cell carcinoma).
  - Medication therapy such as chemotherapy with low toxicity/low side effect agents with the goal to decrease pain from bulky disease or other identified complications. Cost of chemotherapy and alternative medication(s) should also be considered.
- To qualify for treatment coverage, the cancer patient must have a documented discussion about treatment goals, treatment prognosis and the side effects, and knowledge of the realistic expectations of treatment efficacy. This discussion may take place with the patient's oncologist, primary care provider, or other health care provider, but preferably in a collaborative interdisciplinary care coordination discussion. Treatment must be provided via evidence-driven pathways (such as NCCN, ASCO, ASH, ASBMT, or NIH Guidelines) when available.

VII. REVISION HISTORY:

- **P&T Review Date:** 9/2019
- **Implementation Date:** 9/25/2019

Hepatitis C Direct Acting Antivirals

Policy Number: Rx019

I. MEDICATION NAME(S):

- Daklinza (daclatasvir dihydrochloride)
- Zepatier (elbasvir/grazoprevir)*
- Mavyret (glecaprevir/pibrentasvir)*
- Harvoni (ledipasvir/sofosbuvir)
- ledipasvir/sofosbuvir
- Viekira Pak (ombita/paritap/riton/dasabuvir)
- Sovaldi (sofosbuvir)
- Vosevi (sofosbuvir/velpatas/voxilaprev)*
- Epclusa (sofosbuvir/velpatasvir)*
- sofosbuvir/velpatasvir*

**preferred agents according to the Oregon Health Authority (OHA) fee-for-service (FFS) preferred drug list (PDL)*

II. LENGTH OF AUTHORIZATION:

- 8-16 weeks

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. See FFS Approval Criteria: https://www.orpdl.org/durm/PA_Docs/HepatitisC_DAAs.pdf

V. RENEWAL CRITERIA:

VI. ADDITIONAL INFORMATION:

- UHA aligns with the OHA FFS PDL and prior authorization criteria.

VII. REVISION HISTORY:

- **P&T Review Date:** 9/2019
- **Implementation Date:** 9/25/2019

HIV Antiretrovirals

Policy Number: Rx020

I. MEDICATION NAME(S):

- All HIV antiretrovirals

II. LENGTH OF AUTHORIZATION:

- Variable (see criteria)

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug prescribed for the treatment of HIV infection?
    a. Yes (go to #5)
    b. No (go to #2)
2. Is the drug prescribed for post-exposure prophylaxis (PEP) for HIV-uninfected individuals who have experienced a high-risk exposure to HIV within the past 72 hours (e.g. condomless receptive or insertive anal or vaginal intercourse, or percutaneous exposure to blood)?
    a. Yes (approve for 28 days)
    b. No (go to #3)
3. Is the request for tenofovir/emtricitabine prescribed for pre-exposure prophylaxis (PrEP) in combination with safer sex practices for HIV-uninfected individuals who are at high risk for acquiring HIV?
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 8a])
4. Has member been assessed for acute HIV infection and has a recent HIV screening confirmed member is HIV negative? Note: Patients with acute HIV infection may present with a viral syndrome (e.g., lymphadenopathy, fever, malaise, and/or a maculopapular eruption).
    a. Yes (approve for three months)
    b. No (forward to pharmacist for review [deny 5a])
5. Is the request for a product containing abacavir (e.g. abacavir, abacavir/lamivudine, abacavir/lamivudine/zidovudine, Epzicom, Triumeq, Trizivir or Ziagen)?
    a. Yes (go to #6)
    b. No (go to #7)
6. Has the provider submitted documentation that the member is HLA-B*5701 negative?
    a. Yes (go to #15)
    b. No (forward to pharmacist for review [deny 5a, abacavir])

7. Is the request for Selzentry (maraviroc)?
    a. Yes (go to #8)
    b. No (go to #9)
8. Has the provider submitted documentation that the member has CCR5-tropic HIV infection?
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 5a, miraviroc])
9. Is the request for Aptivus, Crixivan, Invirase, or Viracept?
    a. Yes (go to #10)
    b. No (go to #11)
10. Has the member tried and failed one of the following: darunavir, atazanavir, or lopinavir OR has the provider submitted documentation that the member has a genotype supporting use of the requested medication over the preferred medications?
    a. Yes (go to #15)
    b. No (forward for pharmacist review [deny 7a, darunavir, atazanavir, or lopinavir])
11. Is the request for stavudine, didanosine, or Videx powder for solution?
    a. Yes (go to #12)
    b. No (go to #13)
12. Has the member tried and failed one of the following: tenofovir, emtricitibine, lamivudine, or abacavir OR has the provider submitted documentation that the member has a genotype supporting use of the requested medication over the preferred medications?
    a. Yes (go to #15)
    b. No (forward to pharmacist for review [deny 7a, abacavir, tenofovir, emtricitibine, or lamivudine])
13. Is the request for Rescriptor, Viramune XR, or nevirapine?
    a. Yes (go to #14)
    b. No (go to #17)
14. Has the member had a previous trial of one of the following: efavirenz or rilpivirine OR has the provider submitted documentation that the member has a genotype supporting use of the requested medication over the preferred medications?
    a. Yes (go to #15)
    b. No (forward to pharmacist for review [deny 7a, efavirenze or rilpivirine])
15. Has the provider submitted a recent comprehensive metabolic panel (CMP) and complete blood count (CBC)? (Note: refer to the drug's 'Monitoring Parameters' section in UpToDate.)
    a. Yes (go to #16)
    b. No (forward to pharmacist for review [deny 5a, request a recent CMP and CBC])
16. Are the member's liver function tests (LFT) and pancreatic enzymes within normal limits with no evidence of neutropenia on the CBC?
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 5a or contact HIV Alliance for consult])
17. For other ART products that are restricted at point-of-sale: has the prescriber submitted documentation to support that the member is being treated in accordance with the FDA-approved labeling?

a. Yes (approve for one year)
b. No (go to #18)

18. Has the provider submitted documented rationale that supports off-label use of the medication?
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 5a or contact HIV Alliance for consult])

V. RENEWAL CRITERIA:

1. Is the member adherent to therapy? (Adherence defined as a MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 5u or send MonitorRx Report to provider])
2. Is the request for tenofovir/emtricitabine prescribed for pre-exposure prophylaxis (PrEP) in combination with safer sex practices?
    a. Yes (go to #3)
    b. No (go to #4)
3. Has documentation been submitted confirming the member is HIV-negative (tested within the past three months) and is still at high risk for acquiring HIV?
    a. Yes (approve for six months)
    b. No (forward to pharmacist for review [deny 5a])
4. Has documentation been submitted to demonstrate of efficacy (viral load suppression), and appropriate monitoring? (Refer to UpToDate or product labeling.)
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 5a or contact HIV Alliance for consult])

VI. ADDITIONAL INFORMATION:

- If members come onto plan and are started an stabilized on antiretroviral therapy (ART), then UHA will allow continuation of the current regimen.

VII. REVISION HISTORY:

- **P&T Review Date:** 12/2019
- **Implementation Date:** 12/11/2019

UMPQUA HEALTH ALLIANCE
500 SE CASS AVENUE, SUITE 200
ROSEBURG, OR 97470

Skeletal Muscle Relaxants

Policy Number: Rx021

I. MEDICATION NAME(S):

- chlorzoxazone 500 mg tablet
- orphenadrine citrate ER 100 mg tablet
- multiple nonformulary medications

II. LENGTH OF AUTHORIZATION:

- Initial and renewal: three months

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug used for treatment of muscle spasm or pain associated with an acute musculoskeletal condition?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])
2. Is the request for a nonformulary medication?
    a. Yes (go to #4)
    b. No (go to #3)
3. Has the member tried and failed baclofen, cyclobenzaprine, methocarbamol, and tizanidine or are these medications not appropriate to treat the member's condition?
    a. Yes (approve for three months)
    b. No (forward to pharmacist review [deny 7a])
4. Has the member had an adequate trial and failure of, contraindication to, or intolerance to all formulary medications: baclofen, cyclobenzaprine, methocarbamol, tizanidine, chlorzoxazone (requires PA), and orphenadrine (requires PA)? (Adequate trial is defined as compliant with therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (approve for three months)
    b. No (forward to pharmacist review [deny 5k])

V. RENEWAL CRITERIA:

1. Has documentation been submitted to support the continued use of this medication in accordance with clinical guidelines? (Refer to UpToDate or product labeling for appropriate treatment duration.)
    a. Yes (approve for three months)
    b. No (forward to pharmacist for review [deny 5a])

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 12/2019
- **Implementation Date:** 12/11/2019

Celecoxib

Policy Number: Rx022

I. MEDICATION NAME(S):

- celecoxib

II. LENGTH OF AUTHORIZATION:

- Initial: length of benefit (LOB)

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug used for an FDA-approved indication or a medically appropriate off-label use with strong evidence supporting safety and efficacy?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])
2. Is the drug prescribed for a condition funded by the Oregon Health Plan (OHP) in a manner consistent with the Health Evidence Review Commission (HERC) Prioritized List of Health Services?
    a. Yes (go to #4)
    b. No (go to #3)
3. Is there a comorbid condition for which coverage would be allowed?
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 3a/3c])
4. Is the member at high-risk for developing gastrointestinal (GI) complications from long-term use of NSAIDs as defined by one of the following: (1) History of GI bleed; (2) Active peptic ulcer disease; or (3) High risk of GI bleed (at least 3 of the following) – history of peptic ulcer disease, age over 65 years, long-term use of oral steroids, long-term use of anticoagulants or antiplatelets (e.g. warfarin or clopidogrel), male gender, history of dyspepsia?
    a. Yes (go to #5)
    b. No (forward to pharmacist for review [deny 5a])
5. Has the member had an adequate trial and failure of, contraindication to, or intolerance to meloxicam? (Adequate trial is defined as compliant with therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (approve for LOB)
    b. No (forward to pharmacist for review [deny 7a, meloxicam])

V. RENEWAL CRITERIA:

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 6/2019
- **Implementation Date:** 6/12/2019

UMPQUA HEALTH
ALLIANCE
500 SE CASS AVENUE, SUITE 200
ROSEBURG, OR 97470

Triptans

Policy Number: Rx023

I. MEDICATION NAME(S):

- naratriptan HCl oral tablet (QL)
- rizatriptan oral tablet (QL)
- rizatriptan ODT (QL)
- sumatriptan oral tablet (QL)
- sumatriptan nasal spray (PA, QL)
- sumatriptan SQ pen (PA, QL)
- sumatriptan SQ cartridge (PA, QL)
- sumatriptan SQ vial (PA, QL)
- zolmitriptan oral tablet (QL)
- zolmitriptan ODT (QL)

II. LENGTH OF AUTHORIZATION:

- Initial: length of benefit (LOB)

III. QUANTITY LIMITS:

- Oral tablets and ODT: 9 tablets per 30 days
- sumatriptan nasal spray: 1 package (6 mL) per 30 days
- sumatriptan SQ pen and cartridge: 1 package (1 ml) per 30 days
- sumatriptan SQ vial: 1 vial (2.5 mL) per 30 days

IV. INITIAL CRITERIA:

1. Is the drug used for the treatment of migraine headaches?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])
2. Is the request for an oral formulary triptan (naratriptan, rizatriptan, sumatriptan, or zolmitriptan)?
    a. Yes (go to #4)
    b. No (go to #3)
3. Has the member tried and failed at least three oral formulary triptans (naratriptan, rizatriptan, sumatriptan, or zolmitriptan) or has the prescriber submitted documentation explaining why an oral formulation cannot be used?
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 7a])
4. Is the request for a quantity exception to exceed the quantity limit (QL)?
    a. Yes (forward to pharmacist for review [deny 5q])
    b. No (approve for one LOB)

V. RENEWAL CRITERIA:

VI. ADDITIONAL INFORMATION:

- Triptans should be used less than ten days per month to avoid medication overuse headaches. UHA will not exceed our quantity limits which are in alignment with these guidelines and product labeling.

VII. REVISION HISTORY:

- **P&T Review Date:** 12/2019
- **Implementation Date:** 12/11/2019

Ropinirole

Policy Number: Rx024

I. MEDICATION NAME(S):

- ropinirole ER
- ropinirole HCl

II. LENGTH OF AUTHORIZATION:

- Initial: length of benefit (LOB)

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug used for an FDA-approved indication or a medically appropriate off-label use with strong evidence supporting safety and efficacy?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])
2. Is the drug prescribed for a condition funded by the Oregon Health Plan (OHP) in a manner consistent with the Health Evidence Review Commission (HERC) Prioritized List of Health Services? (Restless legs syndrome is not a funded condition.)
    a. Yes (approve for LOB)
    b. No (go to #3)
3. Is there a comorbid condition for which coverage would be allowed?
    a. Yes (approve for LOB)
    b. No (forward to pharmacist for review [deny 3a, RLS])

V. RENEWAL CRITERIA:

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 6/2019
- **Implementation Date:** 6/12/2019

Interferon Beta-1a

Policy Number: Rx025

I. MEDICATION NAME(S):

- Avonex Kit (interferon beta-1a/albumin)
- Avonex Pen (interferon beta-1a)

II. LENGTH OF AUTHORIZATION:

- Initial: length of benefit (LOB)

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug used for the treatment of relapsing forms of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease?
    a. Yes (approve for LOB)
    b. No (forward to pharmacist for review [deny 8a])

V. RENEWAL CRITERIA:

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 12/2019
- **Implementation Date:** 12/11/2019

Dimethyl Fumarate

Policy Number: Rx026

I. MEDICATION NAME(S):

- Tecfidera (dimethyl fumarate)

II. LENGTH OF AUTHORIZATION:

- Initial: length of benefit (LOB)

III. QUANTITY LIMITS:

- 120-240 mg: 60 capsules in 30 days
- 120 mg: 14 capsules in 7 days
- 240 mg: 60 capsules in 30 days

IV. INITIAL CRITERIA:

1. Is the drug used for the treatment of relapsing forms of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])
2. Is the request for monotherapy and is not intended to be used in combination with other MS drugs?
    a. Yes (approve for LOB)
    b. No (forward to pharmacist for review [deny 5a])

V. RENEWAL CRITERIA:

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 12/2019
- **Implementation Date:** 12/11/2019

Doxycycline

Policy Number: Rx027

I. MEDICATION NAME(S):

- Doryx MPC (doxycycline hyclate)
- Doxycycline hyclate tablets and capsules
- Soloxide (doxycycline hyclate)
- doxycycline monohydrate tablets

II. LENGTH OF AUTHORIZATION:

- Initial and renewal: one month

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug used for an FDA-approved indication or a medically appropriate off-label use with strong evidence supporting safety and efficacy?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])
2. Is the drug prescribed for a condition funded by the Oregon Health Plan (OHP) in a manner consistent with the Health Evidence Review Commission (HERC) Prioritized List of Health Services? (Acne is not funded for most members.)
    a. Yes (go to #4)
    b. No (go to #3)
3. Is there a comorbid condition for which coverage would be allowed?
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 3a/3c])
4. Has the member had an adequate trial and failure of, contraindication to, or intolerance to doxycycline monohydrate capsules? (Adequate trial is defined as compliant with therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (approve for one month)
    b. No (forward to pharmacist for review [deny 7a, doxycycline monohydrate capsules])

V. RENEWAL CRITERIA:

1. Is the drug used for an FDA-approved indication or a medically appropriate off-label use with strong evidence supporting safety and efficacy?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])

2. Is the drug prescribed for a condition funded by the Oregon Health Plan (OHP) in a manner consistent with the Health Evidence Review Commission (HERC) Prioritized List of Health Services? (Acne is not funded for most members.)
    a. Yes (go to #4)
    b. No (go to #3)
3. Is there a comorbid condition for which coverage would be allowed?
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 3a/3c])
4. Has documentation been submitted to support the continued use of this medication in accordance with clinical guidelines? (Refer to UpToDate or product labeling for appropriate treatment duration.)
    a. Yes (approve for one month or the remainer of the treatment course)
    b. No (forward to pharmacist for review [deny 5a])

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 6/2019
- **Implementation Date:** 6/12/2019

Antineoplastic Gonadotropin Releasing Hormone Agonist

Policy Number: Rx028

I. MEDICATION NAME(S):

- Zoladex (goserelin acetate)
- Vantas (histrelin acetate)
- Eligard (leuprolide acetate)
- leuprolide acetate
- Lupron depot (leuprolide acetate)
- Lupaneta (leuprolide/norethindrone)
- Trelstar (triptorelin pamoate)

II. LENGTH OF AUTHORIZATION:

- Cancer: initial and renewal: one year
- Endometriosis: initial and renewal: six months (max duration is one year)
- Leiomyoma: initial: three months (max duration)
- Gender dysphoria: initial and renewal: one year (up to age 18 years)
- Precocious puberty: initial and renewal: one year (up to age 11 years for females and 12 years for males)

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug used for an FDA-approved indication or a medically appropriate off-label use with strong evidence supporting safety and efficacy (cancer, endometriosis, gender dysphoria, leiomyoma, precocious puberty)?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])
2. Is the treatment appropriate for the member's age and condition according to product labeling?
    a. Yes (go to #3)
    b. No (forward to pharmacist for review [deny 5a])
3. Is the medication prescribed by or in consultation with an appropriate health care provider with expertise in treating this condition: hematologist/oncologist for cancer; obstetrician/gynecologist for endometriosis and leiomyoma; or pediatric endocrinologist for gender dysphoria and precocious puberty?
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 3a/3c])
4. Is the request for a leuprolide product?
    a. Yes (go to #6)
    b. No (go to #5)

5. Has the member had an adequate trial and failure of, contraindication to, or intolerance to a leuprolide product, or is leuprolide not indicated? (Adequate trial is defined as adherent to therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (go to #6)
    b. No (forward to pharmacist for review [deny 5k])
6. Is the drug prescribed for a diagnosis of cancer?
    a. Yes (go to #11)
    b. No (go to #7)
7. Is the drug prescribed for a diagnosis of endometriosis?
    a. Yes (go to #13)
    b. No (go to #8)
8. Is the drug prescribed for a diagnosis of leiomyoma?
    a. Yes (go to #15)
    b. No (go to #9)
9. Is the drug prescribed for a diagnosis of gender dysphoria?
    a. Yes (go to #16)
    b. No (go to #10)
10. Is the drug prescribed for a diagnosis of precocious puberty)?
    a. Yes (go to #18)
    b. No (forward to pharmacist for review [deny 8a])
11. Is the drug used for an FDA-approved indication, a medically appropriate off-label use with strong evidence supporting safety and efficacy, or a NCCN supported indication with evidence level of 2A or better?
    a. Yes (go to #12)
    b. No (forward to pharmacist for review [deny 8a])
12. If applicable, does the request meet criteria for treatment coverage specified in Guideline Note 12 of the Health Evidence Review Commission (HERC) Prioritized List of Health Services, considering treatment of cancer with little or no benefit (see 'Additional Information' section for Guideline Note 12)?
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 3a])
13. Has the endometriosis diagnosis been confirmed by laparoscopy?
    a. Yes (go to #14)
    b. No (forward to pharmacist for review [deny 5a])
14. Has the member had an adequate trial and failure of, contraindication to, or intolerance to hormonal therapies (combined oral contraceptives, progestins, or levonorgestrel IUD)? (Adequate trial is defined as adherent to therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (approve for six months)
    b. No (forward to pharmacist for review [deny 7a])
15. Is the request for preoperative treatment of anemia caused by fibroids (uterine leiomyoma)?
    a. Yes (approve for three months)
    b. No (forward to pharmacist for review [deny 8a])
16. Is the member's age less than 18 years?

a. Yes (go to #17)
b. No (forward to pharmacist for review [deny 5a])

17. Does the request meet Guideline Note 127 of the Oregon Health Plan (OHP) Health Evidence Review Commission (HERC) Prioritized List of Health Services (see Additional Information section for full guideline note)?
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 3a, GLN 127])
18. Is the member's age less than 11 years for females and 12 years for males?
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 8a])

V. RENEWAL CRITERIA:

1. Is the drug prescribed for a diagnosis of cancer?
    a. Yes (go to #6)
    b. No (go to #2)
2. Is the drug prescribed for a diagnosis of endometriosis?
    a. Yes (go to #7)
    b. No (go to #3)
3. Is the drug prescribed for a diagnosis of leiomyoma?
    a. Yes (forward to pharmacist for review [deny 8a, max treatment duration is three months])
    b. No (go to #4)
4. Is the drug prescribed for a diagnosis of gender dysphoria?
    a. Yes (go to #8)
    b. No (go to #5)
5. Is the drug prescribed for a diagnosis of precocious puberty)?
    a. Yes (go to #9)
    b. No (forward to pharmacist for review [deny 8a])
6. Has there been evidence of disease responsiveness to therapy?
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 5a])
7. Has the length of therapy been less than one year?
    a. Yes (approve for six months)
    b. No (forward to pharmacist for review [deny 8a])
8. Is the member's age less than 18 years?
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 5a])
9. Is the member's age less than 11 years for females and 12 years for males?
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 8a])

VI. ADDITIONAL INFORMATION:

- Guideline Note 127: To qualify for cross-sex hormone therapy, the patient must:
    - Have persistent, well-documented gender dysphoria;
    - Have the capacity to make a fully informed decision and to give consent for treatment;

- Have any significant medical or mental health concerns reasonably well controlled; and
- Have a comprehensive mental health evaluation provided in accordance with Version 7 of the World Professional Association for Transgender Health (WPATH) Standards of Care (www.wpath.org).

VII. REVISION HISTORY:

- **P&T Review Date:** 12/2019
- **Implementation Date:** 12/11/2019

Desmopressin

Policy Number: Rx029

I. MEDICATION NAME(S):

- desmopressin acetate tablets
- desmopressin acetate nasal spray

II. LENGTH OF AUTHORIZATION:

- Initial: length of benefit (LOB)

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug used for a diagnosis of enuresis (bedwetting)?
    a. Yes (forward to pharmacist for review [deny 3a, bedwetting])
    b. No (go to #2)
2. Is the drug used for a diagnosis of diabetes insipidus?
    a. Yes (approve tablets for LOB)
    b. No (go to #3)
3. Is the drug used for a diagnosis of hemophilia A with factor VIII level greater than 5% or von Willebrand disease type 1 with factor VIII levels greater than 5%?
    a. Yes (approve nasal spray for LOB)
    b. No (forward to pharmacist for review [deny 8a])

V. RENEWAL CRITERIA:

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 6/2019
- **Implementation Date:** 6/12/2019

Growth Hormones

Policy Number: Rx030

I. MEDICATION NAME(S):

- **Norditropin (somatropin) (*preferred)***
- Genotropin (somatropin)
- Humatrope (somatropin) cartridge
- Omnitrope (somatropin)
- Multiple non-formulary drugs

II. LENGTH OF AUTHORIZATION:

- Initial and renewal: one year

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug used for an FDA-approved indication or a medically appropriate off-label use with strong evidence supporting safety and efficacy (see chart under Additional Information section)?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])
2. Is the drug prescribed for a condition funded by the Oregon Health Plan (OHP) in a manner consistent with the Health Evidence Review Commission (HERC) Prioritized List of Health Services, OR is there a comorbid condition for which coverage would be allowed?
    a. Yes (go to #3)
    b. No (forward to pharmacist for review [deny 3a])
3. Is the drug used for a member who is less than 18 years of age OR a member with bone age that is less than or equal to 14 years for females or 16 years for males?
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 5a, 3a GLN 74])
4. Does the member have documented biochemical Growth Hormone Deficiency (GHD) by one of the following tests: (1) Two growth hormone (GH) stimulations tests < 10 ng/mL (microgram/L); OR (2) One GH stimulation test < 15 ng/mL and IGF – 1 below normal for bone age and sex?
    a. Yes (go to #5)
    b. No (forward to pharmacist for review [deny 5a, 3a GLN 74])
5. Is the member over 12 years of age?
    a. Yes (go to #6)
    b. No (go to #7)
6. Is there evidence of non-closure of epiphyses confirmed by X-ray?

a. Yes (go to #7)
b. No (forward to pharmacist for review [deny 5a, 3a GLN 74])

7. Is the medication prescribed by or in consultation with a pediatric endocrinologist or a pediatric nephrologist?
    a. Yes (go to #8)
    b. No (forward to pharmacist for review [deny 5a])
8. Has the member had an adequate trial and failure of, contraindication to, or intolerance to Norditropin, OR is Norditropin not appropriate for the diagnosis (see chart under Additional Information section)? (Adequate trial is defined as adherent to therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 7a])

V. RENEWAL CRITERIA:

1. Is there evidence of growth velocity (GV) greater than 2.5 cm/year?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 5a])
2. Is the member over 12 years of age?
    a. Yes (go to #3)
    b. No (go to #4)
3. Is there evidence of non-closure of epiphyses confirmed by X-ray?
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 5a, 3a GLN 74])
4. Has the member's bone age not reached height potential defined as bone age not exceeding 16 years for males (required annually when chronological age reaches 15) and bone age not exceeding 14 years for females (required annually when chronological age reaches 13)?
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 5a, 3a GLN 74)

VI. ADDITIONAL INFORMATION:

- **Pediatric and Adult FDA Approved Indications for Growth Hormone**

	Genotropin®	Humatrope®	Norditropin®	Nutropin AQ®	Omnitrope®	Saizen®	Serostim®	Zomacton®	Zorbtive®
Pediatric Indications									
GHD	x	x	x	x	x	x		x	
Prader-Willi Syndrome	x		x		x				
Noonan Syndrome			x						
Turner Syndrome	x	x	x	x	x			x	
Idiopathic Short Stature	x	x	x	x	x			x	
SHOX Deficiency		x						x	

CKD with Growth Failure				x					
Small for Gestational Age	x	x	x		x			x	
HIV Associated Cachexia							x		
Adult Indications (not funded)									
GHD	x	x	x	x	x	x		x	
HIV Associated Cachexia							x		
Short Bowel Syndrome									x

Abbreviations: CKD = chronic kidney disease; FDA = Food and Drug Administration; GHD = growth hormone deficiency; HIV = human immunodeficiency virus; SHOX = Short stature homeobox-containing gene

VII. REVISION HISTORY:

- **P&T Review Date:** 12/2019
- **Implementation Date:** 12/11/2019

UMPQUA HEALTH
ALLIANCE
500 SE CASS AVENUE, SUITE 200
ROSEBURG, OR 97470

Pancreatic Enzymes

Policy Number: Rx031

I. MEDICATION NAME(S):

- Creon (lipase/protease/amylase)
- Pancreaze (lipase/protease/amylase)
- Zenpep (lipase/protease/amylase)
- Multiple non-formulary drugs (Pertzye, Viokace)

II. LENGTH OF AUTHORIZATION:

- Initial: length of benefit (LOB)

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug being used for a diagnosis of cystic fibrosis?
    a. Yes (go to #6)
    b. No (go to #2)
2. Has the member had a pancreatectomy?
    a. Yes (go to #6)
    b. No (go to #3)
3. Is the drug being used for a diagnosis of exocrine pancreatic cancer?
    a. Yes (go to #6)
    b. No (go to #4)
4. Is the drug being used for a diagnosis of chronic pancreatitis confirmed by imaging?
    a. Yes (go to #6)
    b. No (go to #5)
5. Does the member have exocrine pancreatic insufficiency confirmed with one of the following methods: (1) Confirmed steatorrhea with fecal fat determination; (2) Measurement of fecal elastase; OR (3) Secretin or CCK pancreatic function testing?
    a. Yes (go to #6)
    b. No (forward to pharmacist for review [deny 5a, 8a])
6. Is the request for a drug that is on the UHA formulary (Creon, Pancreaze, or Zenpep)?
    a. Yes (approve for LOB)
    b. No (go to #7)
7. Is the request for Viokace?
    a. Yes (go to #8)
    b. No (go to #9)

8. Is the member taking a proton pump inhibitor like omeprazole or pantoprazole? (Note: Viokace must be administered with a proton pump inhibitor (PPI) since it is not enteric coated.)
    a. Yes (go to #9)
    b. No (forward to pharmacist for review [deny 5a])
9. Has the member had an adequate trial and failure of, contraindication to, or intolerance to all formulary drugs (Creon, Pancreaze, and Zenpep)? (Adequate trial is defined as adherent to therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 7a])

V. RENEWAL CRITERIA:

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 12/2019
- **Implementation Date:** 12/11/2019

Aprepitant

Policy Number: Rx032

I. MEDICATION NAME(S):

- aprepitant capsules

II. LENGTH OF AUTHORIZATION:

- Initial and renewal: six months

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the member currently receiving moderate to highly emetogenic chemotherapy (refer to NCCN antiemesis guidelines)?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 5a, 7a])
2. Is the member receiving concurrent treatment with IV or oral ondansetron, granisetron, or palonosetron, AND dexamethasone?
    a. Yes (approve for three months)
    b. No (deny 5a)

V. RENEWAL CRITERIA:

See Initial Criteria

VI. ADDITIONAL INFORMATION:

EMETOGENIC POTENTIAL OF INTRAVENOUS ANTICANCER AGENTS[a]

LEVEL	AGENT		
High emetic risk (>90% frequency of emesis)[b,c]	• AC combination defined as any chemotherapy regimen that contains an anthracycline and cyclophosphamide • Carboplatin AUC ≥4	• Carmustine >250 mg/m² • Cisplatin • Cyclophosphamide >1,500 mg/m² • Dacarbazine • Doxorubicin ≥60 mg/m²	• Epirubicin >90 mg/m² • Ifosfamide ≥2 g/m² per dose • Mechlorethamine • Streptozocin
Moderate emetic risk (>30%–90% frequency of emesis)[b,c]	• Aldesleukin >12–15 million IU/m² • Amifostine >300 mg/m² • Arsenic trioxide • Azacitidine • Bendamustine • Busulfan • Carboplatin AUC <4[d] • Carmustine[d] ≤250 mg/m² • Clofarabine • Cyclophosphamide ≤1500 mg/m² • Cytarabine >200 mg/m²	• Dactinomycin[d] • Daunorubicin[d] • Dual-drug liposomal encapsulation of cytarabine and daunorubicin • Dinutuximab • Doxorubicin[d] <60 mg/m² • Epirubicin[d] ≤90 mg/m² • Idarubicin • Ifosfamide[d] <2 g/m² per dose • Interferon alfa ≥10 million IU/m² • Irinotecan[d]	• Melphalan • Methotrexate[d] ≥250 mg/m² • Oxaliplatin[d] • Temozolomide • Trabectedin[d]

LEVEL	AGENT		
Low emetic risk (10%–30% frequency of emesis)[b]	• Ado-trastuzumab emtansine • Aldesleukin ≤12 million IU/m² • Amifostine ≤300 mg/m² • Atezolizumab • Belinostat • Blinatumomab • Brentuximab vedotin • Cabazitaxel • Carfilzomib • Cytarabine (low dose) 100–200 mg/m² • Docetaxel • Doxorubicin (liposomal) • Eribulin	• Etoposide • 5-Fluorouracil (5-FU) • Floxuridine • Gemcitabine • Interferon alfa >5 - <10 million international units/m² • Irinotecan (liposomal) • Ixabepilone • Methotrexate >50 mg/m² - <250 mg/m² • Mitomycin • Mitoxantrone • Necitumumab • Olaratumab	• Omacetaxine • Paclitaxel • Paclitaxel-albumin • Pemetrexed • Pentostatin • Pralatrexate • Romidepsin • Talimogene laherparepvec • Thiotepa • Topotecan • Ziv-aflibercept
Minimal emetic risk (<10% frequency of emesis)[b]	• Alemtuzumab • Avelumab • Asparaginase • Bevacizumab • Bleomycin • Bortezomib • Cetuximab • Cladribine • Cytarabine <100 mg/m² • Daratumumab • Decitabine • Denileukin diftitox • Dexrazoxane • Durvalumab	• Elotuzumab • Fludarabine • Interferon alpha ≤5 million IU/m² • Ipilimumab • Methotrexate ≤50 mg/m² • Nelarabine • Nivolumab • Obinutuzumab • Ofatumumab • Panitumumab • Pegaspargase • Peginterferon • Pembrolizumab • Pertuzumab	• Ramucirumab • Rituximab • Rituximab and hyaluronidase human injection for SQ use • Siltuximab • Temsirolimus • Trastuzumab • Valrubicin • Vinblastine • Vincristine • Vincristine (liposomal) • Vinorelbine

VII. REVISION HISTORY:

- **P&T Review Date:** 12/2019
- **Implementation Date:** 12/11/2019

Temazepam

Policy Number: Rx033

I. MEDICATION NAME(S):

- temazepam capsules

II. LENGTH OF AUTHORIZATION:

- Initial: one to six months
- Renewal: up to six months

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug used for insomnia?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])
2. Is there a comorbid condition for which coverage would be allowed (for example, mental health conditions that would be impacted by untreated insomnia)?
    a. Yes (go to #3)
    b. No (forward to pharmacist for review [deny 3a])
3. Is the member taking a concurrent sedative, hypnotic or opioid?
    a. Yes (forward to pharmacist review [deny 5a]
    b. No (go to #4)
4. Is this a new start request for short-term use (less than 4 weeks)?
    a. Yes (approve for one month)
    b. No (go to #5)
5. Is there appropriate rationale to support long-term benzodiazepine use?
    a. Yes (approve for six months)
    b. No (forward to pharmacist review [deny 5a])

V. RENEWAL CRITERIA:

1. Is the member taking a concurrent sedative, hypnotic or opioid?
    a. Yes (forward to pharmacist review [deny 5a]
    b. No (go to #2)
2. Is there appropriate rationale to support long-term benzodiazepine use? (Exceptions may be made to allow time to taper off of medication.)
    a. Yes (approve for up to six months)
    b. No (forward to pharmacist review [deny 5a])

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 12/2019
- **Implementation Date:** 12/11/2019

Pulmonary Antihypertensive Phosphodiesterase Inhibitors

Policy Number: Rx034

I. MEDICATION NAME(S):

- sildenafil citrate (generic Revatio)
- Alyq (tadalafil)
- tadalafil (generic Adcirca)

II. LENGTH OF AUTHORIZATION:

- Initial: length of benefit (LOB)

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug used for a diagnosis of pulmonary arterial hypertension WHO Group I diagnosed by right heart catheterization? (Note: Sexual dysfunction is not a condition funded by the Oregon Health Plan (OHP) according to the Health Evidence Review Commission (HERC) Prioritized List of Health Services.)
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 3a])
2. Is the drug prescribed by or in consultation with a pulmonologist or cardiologist?
    a. Yes (go to #3)
    b. No (forward to pharmacist for review [deny 5a])
3. Is the request for sildenafil (generic Revatio)?
    a. Yes (approve for LOB)
    b. No (go to #4)
4. Has the member had an adequate trial and failure of, contraindication to, or intolerance to sildenafil? (Adequate trial is defined as adherent to therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (approve for LOB)
    b. No (forward to pharmacist for review [deny 7a])

V. RENEWAL CRITERIA:

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 12/2019
- **Implementation Date:** 12/11/2019

Omalizumab

Policy Number: Rx035

I. MEDICATION NAME(S):

- Xolair (omalizumab)

II. LENGTH OF AUTHORIZATION:

- Initial: four months
- Renewal: six months

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug being used for a diagnosis of moderate to severe persistent asthma?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])
2. Is the member six years of age or older?
    a. Yes (go to #3)
    b. No (forward to pharmacist for review [deny 8a])
3. Is the drug prescribed by or in consultation with a pulmonologist or immunologist?
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 5a])
4. Is the member a current smoker?
    a. Yes (forward to pharmacist for review [deny 5a])
    b. No (go to #5)
5. Does the member have a positive skin test or RAST to a perennial aeroallergen?
    a. Yes (go to #6)
    b. No (forward to pharmacist for review [deny 5a])
6. Is the member's baseline IgE serum level between 30 to 1,300 IU/mL for members age 6 to 11, OR between 30 to 700 IU/mL for members age 12 and older?
    a. Yes (go to #7)
    b. No (forward to pharmacist for review [deny 5a])
7. Have the provider and member taken all steps to reduce and maximally manage environmental allergens and other triggers (e.g., tobacco smoke, dust mites, pets, molds, occupational exposures, GERD)?
    a. Yes (go to #8)
    b. No (forward to pharmacist for review [deny 5a])
8. Has the member had an adequate trial and failure of, contraindication to, or intolerance to all of the following agents used as combination therapy: (1) High-dose inhaled

corticosteroid with a long acting beta agonist (such as fluticasone-salmeterol [generic Advair] or Symbicort); (2) Long-acting muscarinic antagonist (such as Incruse Ellipta, Tudorza, or Spiriva); AND (3) Leukotriene inhibitor (such as montelukast)? (Adequate trial is defined as adherent to therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (go to #9)
    b. No (forward to pharmacist for review [deny 7a])
9. Has the member tried and failed or have contraindications to allergen immunotherapy?
    a. Yes (go to #10)
    b. No (forward to pharmacist for review [deny 7a])
10. Does the member have a history of compliance with all asthma medications?
    a. Yes (go to #11)
    b. No (forward to pharmacist for review [deny 5u])
11. In the past year has the member had frequent asthma exacerbations resulting in repeated use of health care services, such as urgent care or ED visits or hospitalization?
    a. Yes (go to #12)
    b. No (forward to pharmacist for review [deny 5a])
12. Will this drug be professionally administered and billed under the medical benefit?
    a. Yes (approve for four months)
    b. No (forward to pharmacist for review [deny 5k, 5a])

V. RENEWAL CRITERIA:

1. Has the member had a reduction in asthma exacerbations necessitating frequent office visits, ED or urgent care visits, hospitalizations, oral steroids and demonstrated sustained clinical improvement from baseline while on omalizumab?
    a. Yes (go to #12)
    b. No (forward to pharmacist for review [deny 5a])
2. Will this drug be professionally administered and billed under the medical benefit?
    a. Yes (approve for four months)
    b. No (forward to pharmacist for review [deny 5k, 5a])

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 12/2019
- **Implementation Date:** 12/11/2019

Topical Immunosuppressants

Policy Number: Rx036

I. MEDICATION NAME(S):

- tacrolimus oint.

II. LENGTH OF AUTHORIZATION:

- Initial: length of benefit (LOB)

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug prescribed for chronic, severe atopic dermatitis with functional impairment and one or more of the following: (1) at least 10% body surface area involved; or (2) hand, foot or mucous membrane involvement?
    a. Yes (go to #3)
    b. No (go to #2)
2. Is there a comorbid condition for which coverage would be allowed?
    a. Yes (go to #3)
    b. No (forward to pharmacist for review [deny 3a/5a GLN 21])
3. Has the member had an adequate trial and failure of, contraindication to, or intolerance to both of the following: (1) high-potency topical corticosteroids – betamethasone dipropionate, clobetasol, fluocinonide (all require prior authorization); and (2) UVB phototherapy? (Adequate trial is defined as compliant with therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (approve for LOB)
    b. No (forward to pharmacist for review [deny 7a])

V. RENEWAL CRITERIA:

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 9/2019
- **Implementation Date:** 9/25/2019

Topical Antipsoriatic Agents

Policy Number: Rx037

I. MEDICATION NAME(S):

- calcipotriene cream
- calcipotriene oint.
- calcipotriene solution
- tazarotene cream

II. LENGTH OF AUTHORIZATION:

- Initial: length of benefit (LOB)

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug prescribed for chronic, moderate to severe plaque psoriasis with functional impairment and one or more of the following: (1) at least 10% body surface area involved; or (2) hand, foot or mucous membrane involvement?
    a. Yes (go to #3)
    b. No (go to #2)
2. Is there a comorbid condition for which coverage would be allowed?
    a. Yes (go to #3)
    b. No (forward to pharmacist for review [deny 3a/5a GLN 21])
3. Has the member had an adequate trial and failure of, contraindication to, or intolerance to high-potency topical corticosteroids – betamethasone dipropionate, clobetasol, fluocinonide (all require prior authorization)? (Adequate trial is defined as compliant with therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (approve for LOB)
    b. No (forward to pharmacist for review [deny 7a])

V. RENEWAL CRITERIA:

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 9/2019
- **Implementation Date:** 9/25/2019

Acitretin

Policy Number: Rx038

I. MEDICATION NAME(S):

- acitretin capsule

II. LENGTH OF AUTHORIZATION:

- Initial: six months
- Renewal: one year

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug prescribed for chronic, moderate to severe plaque psoriasis with functional impairment and one or more of the following: (1) at least 10% body surface area involved; or (2) hand, foot or mucous membrane involvement?
    a. Yes (go to #3)
    b. No (go to #2)
2. Is there a comorbid condition for which coverage would be allowed?
    a. Yes (go to #3)
    b. No (forward to pharmacist for review [deny 3a/5a GLN 21])
3. Is the medication prescribed by or in consultation with a dermatologist?
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 5a (prescriber)])
4. Has the member had an adequate trial and failure of, contraindication to, or intolerance to **all** of the following: (1) high-potency topical corticosteroids – betamethasone dipropionate, clobetasol, fluocinonide (all require prior authorization); (2) at least one other topical – calcipotriene, tazarotene, anthralin (all require prior authorization); (3) PUVA or UVB phototherapy; (4) methotrexate; and (5) at least one other second line systemic agent such as cyclosporine? (Adequate trial is defined as compliant with therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (approve for six months)
    b. No (forward to pharmacist for review [deny 7a])

V. RENEWAL CRITERIA:

1. Has the prescriber submitted documentation of at least a 50% reduction in plaques and/or is there evidence of functional improvement?
    a. Yes (approve for one year)

b. No (forward to pharmacist for review [deny 5a (renewal)])

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 9/2019
- **Implementation Date:** 9/25/2019

Tolterodine

Policy Number: Rx039

I. MEDICATION NAME(S):

- tolterodine tartrate tablets
- tolterodine tartrate ER capsules

II. LENGTH OF AUTHORIZATION:

- Length of benefit (LOB)

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug prescribed for overactive bladder that is a condition funded by the Oregon Health Plan (OHP) in a manner consistent with the Health Evidence Review Commission (HERC) Prioritized List of Health Services?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review)
2. Has the member had an adequate trial and failure of, contraindication to, or intolerance to both oxybutynin IR or ER, and trospium IR? (Adequate trial is defined as compliant with therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (approve for LOB)
    b. No (forward to pharmacist review [deny 7a, oxybutynin IR/ER and trospium IR])

V. RENEWAL CRITERIA:

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 12/2019
- **Implementation Date:** 12/11/2019

Biologics for Inflammatory Disease

Policy Number: Rx040

I. MEDICATION NAME(S):

- Humira (adalimumab)
- Siliq (brodalumab)
- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Simponi (golimumab)
- Simponi Aria (golimumab)
- Tremfya (guselkumab)
- Remicade (infliximab)
- Renflexis (infliximab-abda)
- Inflectra (infliximab-dyyb)
- Taltz (ixekizumab)
- Skyrizi (risankizumab-rzaa)
- Cosentyx (secukinumab)
- Ilumya (tildrakizumab-asmn)
- Stelara (ustekinumab)
- Entyvio (vedolizumab)

II. LENGTH OF AUTHORIZATION:

- Initial: three months for HS, six months for all others
- Renewal: one year

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug used for an FDA-approved indication or a medically appropriate off-label use with strong evidence supporting safety and efficacy (see indications chart under the 'Additional Information' section)?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])
2. Is the request for maintenance of remission in a patient who already achieved remission with the requested product or has already initiated therapy?
    a. Yes (go to 'Renewal Criteria')
    b. No (go to #3)
3. Is the medication prescribed by or in consultation with an appropriate health care provider with expertise in treating this condition (rheumatologist, gastroenterologist, or dermatologist)?
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 5a])
4. Has the risk of infection been assessed including: (1) Initial testing for latent TB and treatment (if necessary); (2) No current active infection; (3) Risks and benefits documented in cases of chronic or recurrent infection?
    a. Yes (go to #5)
    b. No (forward to pharmacist for review [deny 5a])

5. Is the requested drug to be used in combination with another biologic or Otezla?
    a. Yes (forward to pharmacist for review [deny 5a])
    b. No (go to #6)
6. Is the request for Inflectra or Renflexis (infliximab biosimilars)?
    a. Yes (go to #10)
    b. No (go to #7)
7. Has the member had an adequate trial and failure of, contraindication to, or intolerance to infliximab (Inflectra or Renflexis), if appropriate to treat the member's condition (see indications chart under the 'Additional Information' section)? (Adequate trial is defined as adherent to therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (go to #8)
    b. No (forward to pharmacist for review [deny 7a])
8. Is the request for Enbrel (etanercept) or Humira (adalimumab)?
    a. Yes (go to #10)
    b. No (go to #9)
9. Has the member had an adequate trial and failure of, contraindication to, or intolerance to Enbrel (etanercept) AND Humira (adalimumab) if appropriate for the condition (see indications chart under the 'Additional Information' section)? (Adequate trial is defined as adherent to therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (go to #10)
    b. No (forward to pharmacist for review [deny 7a])
10. Is the diagnosis ankylosing spondylitis (AS) or axial spondyloarthritis (axSpA)?
    a. Yes (go to #19)
    b. No (go to #11)
11. Is the diagnosis Crohn's disease (CD)?
    a. Yes (go to #23)
    b. No (go to #12)
12. Is the diagnosis hidradenitis suppurativa (HS)?
    a. Yes (go to #32)
    b. No (go to #13)
13. Is the diagnosis juvenile idiopathic arthritis (JIA)?
    a. Yes (go to #34)
    b. No (go to #14)
14. Is the diagnosis plaque psoriasis (Ps)?
    a. Yes (go to #40)
    b. No (go to #15)
15. Is the diagnosis psoriatic arthritis (PsA)?
    a. Yes (go to #44)
    b. No (go to #16)
16. Is the diagnosis rheumatoid arthritis (RA)?
    a. Yes (go to #48)
    b. No (go to #17)
17. Is the diagnosis ulcerative colitis (UC)?
    a. Yes (go to #53)

b. No (go to #18)

18. Is the diagnosis non-infectious uveitis?
    a. Yes (go to #61)
    b. No (forward to pharmacist for review [deny 8a])
19. Does the member have a definitive diagnosis ankylosing spondylitis or axial spondyloarthritis (radiographic or non-radiographic)? Diagnosis is definitive if the following are met: (1) Back pain and stiffness for more than 3 months; AND (2) Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive.
    a. Yes (go to #20)
    b. No (forward to pharmacist for review [deny 5a])
20. Does the member have moderate to severe active disease at baseline, evidenced by a Bath AS Disease Activity Index (BASDAI) score of at least 4?
    a. Yes (go to #21)
    b. No (forward to pharmacist for review [deny 5a])
21. Is the member transitioning to the requested drug from a different biologic product?
    a. Yes (approve for six months)
    b. No (go to #22)
22. Has the member tried and failed conventional therapy with both of the following: (1) At least two NSAIDs for three months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated; AND (2) Physical therapy/exercise program?
    a. Yes (approve for six months)
    b. No (forward to pharmacist for review [deny 7a])
23. Does the member have a diagnosis of severe fistulizing Crohn's disease?
    a. Yes (go to #30)
    b. No (go to #24)
24. Does the member have moderate to severe Crohn's disease?
    a. Yes (go to #25)
    b. No (forward to pharmacist for review [deny 5a])
25. Is the member transitioning to the requested treatment from a different biologic product?
    a. Yes (go to #30)
    b. No (go to #26)
26. Is the request for induction of remission?
    a. Yes (go to #27)
    b. No (go to #28)
27. Has the member failed to achieve remission with a systemic corticosteroid?
    a. Yes (go to #30)
    b. No (forward to pharmacist for review [deny 7a])
28. Is the member currently stable on steroids and considered steroid-dependent?
    a. Yes (go to #29)
    b. No (forward to pharmacist for review [deny 5a])
29. Has the member tried and failed azathioprine, 6-mercaptopurine, or methotrexate for maintenance?
    a. Yes (go to #30)
    b. No (forward to pharmacist for review [deny 7a])
30. Is the request for Stelara (ustekinumab)?

a. Yes (go to #31)
b. No (approve for six months)

31. Has the member tried and failed ALL of the following biologics: (1) Cimzia (certolizumab); AND (2) An anti-integrin alpha-4 (i.e., Entyvio [vedolizumab] or Tysabri [natalizumab])? Note: as asked above, member must have also tried and failed infliximab (Remicade, Inflectra or Renflexis) and adalimumab (Humira).
    a. Yes (approve for six months)
    b. No (forward to pharmacist for review [deny 7a])
32. Does the member have a diagnosis of moderate to severe hidradenitis suppurativa (Hurley II/Hurley III stage), characterized by recurrent, painful, and suppurating lesions recurring at least twice in 6 months?
    a. Yes (go to #33)
    b. No (forward to pharmacist for review [deny 5a GLN 198])
33. Has the member tried and failed a three-month treatment course of ALL of the following: (1) Oral antibiotics, such as clindamycin and rifampin, dapsone, or doxycycline; (2) Intralesional corticosteroid injections; (3) Antiandrogenic hormonal treatments for women (OCP or spironolactone); AND (4) Acitretin if not of child-bearing potential?
    a. Yes (approve for three months)
    b. No (forward to pharmacist for review [deny 5a GLN 198, 7a])
34. Is the member transitioning to the requested treatment from a different biologic product?
    a. Yes (approve for six months)
    b. No (go to #35)
35. Does the member have juvenile idiopathic arthritis with active systemic features of juvenile idiopathic arthritis, with a physician global assessment of 5 or higher (or any systemic activity in the absence of active joint involvement)?
    a. Yes (go to #38)
    b. No (go to #36)
36. Does the member have juvenile idiopathic arthritis without active systemic features of juvenile idiopathic arthritis?
    a. Yes (go to #37)
    b. No (forward to pharmacist for review [deny 5a])
37. Has the member tried and failed either: (1) Intra-articular glucocorticoid injections (if fewer than 4 joints affected); OR (2) NSAIDS for at least one month?
    a. Yes (go to #39)
    b. No (forward to pharmacist for review [deny 7a])
38. Has the member had an adequate trial and failure of, contraindication to, or intolerance to systemic corticosteroids? (Adequate trial is defined as adherent to therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (go to #39)
    b. No (forward to pharmacist for review [deny 7a])
39. Has the member had an adequate trial and failure of methotrexate or leflunomide, or a contraindication to both? (Adequate trial is defined as adherent to therapy for at least

three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (approve for six months)
    b. No (forward to pharmacist for review [deny 7a])
40. Does the member have chronic, moderate to severe plaque psoriasis at baseline with functional impairment and one or more of the following: (1) At least 10% body surface area involved; OR (2) Hand, foot or mucous membrane involvement?
    a. Yes (go to #41)
    b. No (forward to pharmacist for review [deny 3a, GLN 21])
41. Is the member transitioning to the requested treatment from a different biologic product?
    a. Yes (go to #43)
    b. No (go to #42)
42. Has the member tried and failed or have contraindications to ALL of the following: (1) High-potency topical corticosteroids, such as augmented betamethasone cream 0.05%, desoximetasone 0.25% cream, or clobetasol; (2) At least one other topical agent, such as calcipotriene, tazarotene, anthralin, or tar; (3) PUVA or UVB Phototherapy; (4) Methotrexate; AND (5) At least one other second line systemic agent, such as cyclosporine or acitretin?
    a. Yes (go to #43)
    b. No (forward to pharmacist for review [deny 7a])
43. Has the member tried and failed other less costly biologics, if indicated (see indications chart under the 'Additional Information' section)?
    a. Yes (approve for six months)
    b. No (forward to pharmacist for review [deny 7a])
44. Does the member have psoriatic arthritis based on presence of at least 3 out of 5 of the following: (1) Psoriasis (1 point for personal or family history, 2 points for current); (2) Psoriatic nail dystrophy; (3) Negative test result for rheumatoid factor; (4) Dactylitis (current or history); or (5) Radiological evidence of juxta-articular new bone formation?
    a. Yes (go to #45)
    b. No (forward to pharmacist for review [deny 5a])
45. Is the member transitioning to the requested treatment from a different biologic product?
    a. Yes (go to #47)
    b. No (go to #46)
46. Has the member had an adequate trial and failure of, contraindication to, or intolerance to conventional therapy with ALL of the following: (1) NSAIDs; AND (2) Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine? (Adequate trial is defined as adherent to therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (go to #47)
    b. No (forward to pharmacist for review [deny 7a])
47. Has the member tried and failed other less costly biologics, if indicated (see indications chart under the 'Additional Information' section)?
    a. Yes (approve for six months)
    b. No (forward to pharmacist for review [deny 7a])

48. Does the member have a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI)?
    a. Yes (go to #49)
    b. No (forward to pharmacist for review [deny 5a])
49. Is the member transitioning to the requested treatment from a different biologic product?
    a. Yes (go to #52)
    b. No (go to #50)
50. Has the member had an adequate trial and failure of, contraindication to, or intolerance to methotrexate dosed at least 20 mg per week? (Adequate trial is defined as adherent to therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (go to #51)
    b. No (forward to pharmacist for review [deny 7a])
51. Has the member had an adequate trial and failure of, contraindication to, or intolerance to leflunomide, hydroxychloroquine, or sulfasalazine? (Adequate trial is defined as adherent to therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (go to #52)
    b. No (forward to pharmacist for review [deny 7a])
52. Is the requested product being prescribed along with at least one of the following DMARDs (unless contraindicated): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine?
    a. Yes (approve for six months)
    b. No (forward to pharmacist for review [deny 5a])
53. Does the member have a diagnosis of moderate to severe ulcerative colitis defined by the following criteria: (1) for moderate, greater than or equal to four stools daily; OR (2) for severe, greater than or equal to six bloody stools daily and evidence of toxicity such as fever, anemia, elevated ESR, or tachycardia?
    a. Yes (go to #54)
    b. No (forward to pharmacist for review [deny 5a])
54. Is the member transitioning to the requested treatment from a different biologic product?
    a. Yes (go to #59)
    b. No (go to #55)
55. Is the request for induction of remission?
    a. Yes (go to #56)
    b. No (go to #57)
56. Has the member failed to achieve remission with a systemic corticosteroid?
    a. Yes (go to #59)
    b. No (forward to pharmacist for review [deny 5a, 7a])
57. Is the member currently stable on steroids and considered steroid-dependent?
    a. Yes (go to #58)
    b. No (forward to pharmacist for review [deny 5a])

58. Has the member had an adequate trial and failure of, contraindication to, or intolerance to azathioprine, 6-mercaptopurine, or a 5-ASA for maintenance? (Adequate trial is defined as adherent to therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (go to #59)
    b. No (forward to pharmacist for review [deny 7a])
59. Is the request for Stelara?
    a. Yes (go to #60)
    b. No (approve for six months)
60. Has the member had an adequate trial and failure of, contraindication to, or intolerance to Entyvio (vedolizumab) AND Simponi (golimumab) (in addition to infliximab, Humira and Enbrel as mentioned above)? (Adequate trial is defined as adherent to therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (approve for six months)
    b. No (forward to pharmacist for review [deny 7a])
61. Does the member have a diagnosis of non-infectious, intermediate, posterior or panuveitis?
    a. Yes (go to #62)
    b. No (forward to pharmacist for review [deny 5a])
62. Is the member transitioning to the requested treatment from a different biologic product?
    a. Yes (approve for six months)
    b. No (go to #63)
63. Has the member had an adequate trial and failure of, contraindication to, or intolerance to ALL of the following: (1) Topical glucocorticoids for at least one month, or periocular steroid injections; (2) Oral corticosteroids; AND (3) one immunomodulatory – mycophenolate, tacrolimus, cyclosporine, azathioprine, or methotrexate?
    a. Yes (approve for six months)
    b. No (forward to pharmacist for review [deny 7a])

V. RENEWAL CRITERIA:

1. Is the diagnosis ankylosing spondylitis (AS) or axial spondyloarthritis (axSpA)?
    a. Yes (go to #10)
    b. No (go to #2)
2. Is the diagnosis Crohn's disease (CD)?
    a. Yes (go to #11)
    b. No (go to #3)
3. Is the diagnosis hidradenitis suppurativa (HS)?
    a. Yes (go to #12)
    b. No (go to #4)
4. Is the diagnosis juvenile idiopathic arthritis (JIA)?
    a. Yes (go to #14)
    b. No (go to #5)
5. Is the diagnosis plaque psoriasis (Ps)?
    a. Yes (go to #15)

    b. No (go to #6)
6. Is the diagnosis psoriatic arthritis (PsA)?
    a. Yes (go to #16)
    b. No (go to #7)
7. Is the diagnosis rheumatoid arthritis (RA)?
    a. Yes (go to #17)
    b. No (go to #8)
8. Is the diagnosis ulcerative colitis (UC)?
    a. Yes (go to #18)
    b. No (go to #9)
9. Is the diagnosis non-infectious uveitis?
    a. Yes (go to #19)
    b. No (forward to pharmacist for review [deny 8a])
10. Does the member have significant improvement in signs and symptoms of AS/axSpA and/or functioning, such as 50% relative change or 2-point improvement in BASDAI?
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 5a])
11. Has the member experienced a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission?
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 5a])
12. Is there a valid, medical reason surgical intervention is not being pursued?
    a. Yes (go to #13)
    b. No (forward to pharmacist for review [deny 5a])
13. Has there been a significant treatment response as defined as ALL of the following: (1) A reduction of 25% or more in the total abscess and inflammatory nodule count; AND (2) No increase in abscesses and draining fistulas?
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 5a GLN 198])
14. Has the member experienced 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability?
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 5a])
15. Has the member experienced a clinically significant response, such as PASI-75 (75% improvement) or is there evidence of functional improvement?
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 5a])
16. Has the member experienced 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability?
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 5a])
17. Has the member experienced 20% or greater improvement in tender joint count and swollen joint count or has there been and improvement in functional ability?
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 5a])

18. Has the member demonstrated a significant response including the following: (1) Decrease in bloody stools per day; OR (2) Elimination of signs of toxicity?
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 5a])
19. Is there documentation that disease activity has been controlled, such as a lack of inflammation, no new inflammatory vascular lesions, no vitreous haze or decreases in visual acuity?
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 5a])

VI. ADDITIONAL INFORMATION:

- Indications:

Drug	AS	axSpA	CD	HS	JIA	Ps	PsA	RA	UC	Uveitis
Humira (adalimumab)	x		x	x	x	x	x	x	x	x
Siliq (brodalumab)						x				
Cimzia (certolizumab pegol)	x	x	x			x	x	x		
Enbrel (etanercept)	x				x	x	x	x		
Simponi, Simponi Aria (golimumab)	x	x*					x	x	x	
Tremfya (guselkumab)						x				
Remicade, Renflexis, Inflectra (infliximab)	x		x	x*		x	x	x	x	
Taltz (ixekizumab)	x					x	x			
Skyrizi (risankizumab)						x				
Cosentyx (secukinumab)	x					x	x			
Ilumya (tildrakizumab)						x				
Stelara (ustekinumab)			x			x	x		x	
Entyvio (vedolizumab)			x						x	

**Off-label*

Abbrebreviations:

AS = Ankylosing Spondylitis
axSpA = Axial Spondyloarthritis
CD = Crohn's Disease
HS = Hidradenitis Suppurativa
JIA = Juvenile Idiopathic Arthritis
Ps = Plaque Psoriasis
PsA = Psoriatic Arthritis
RA = Rheumatoid Arthritis
UC = Ulcerative Colitis

VII. REVISION HISTORY:

- **P&T Review Date:** 12/2019
- **Implementation Date:** 12/11/2019

Fluticasone/Umeclidinium/Vilanterol

Policy Number: Rx041

I. MEDICATION NAME(S):

- Trelegy Ellipta (fluticasone/umeclidinium/vilanterol)

II. LENGTH OF AUTHORIZATION:

- Initial and renewal: one year

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug used for a diagnosis of COPD?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])
2. Has the member had an adequate trial and failure of a combined LAMA/LABA (Bevespi Aerosphere, Utibron Neohaler, Stiolto Respimat, or Anoro Ellipta) or LABA/ICS (fluticasone/salmeterol, Dulera or Symbicort) inhaler? (Adequate trial is defined as adherent to therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days AND documentation of persistent symptoms or exacerbations.)
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 7a])

V. RENEWAL CRITERIA:

1. Is the member adherent to therapy? (Adherence defined as a MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (go to #2)
    b. No (forward to pharmacist for review)
2. Has documentation been submitted stating this medication has been effective for reducing COPD symptoms or exacerbations?
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review)

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 12/2019

- **Implementation Date:** 12/11/2019

Erythropoiesis-Stimulating Agents (ESA)

Policy Number: Rx042

I. MEDICATION NAME(S):

- Aranesp (darbepoetin alfa)
- Epogen (epoetin alfa)
- Procrit (epoetin alfa)
- **Retacrit (epoetin alfa-epbx)** ***preferred***

II. LENGTH OF AUTHORIZATION:

- Initial: three months
- Renewal: six months

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug being used for a diagnosis of chronic renal failure (CRF) OR anemia due to myelosuppressive chemotherapy?
    a. Yes (go to #2)
    b. No (go to #3)
2. Does the member meet all of the following criteria: (1) hemoglobin (HGB) less than 10 g/dL or hematocrit (HCT) less than 30%; (2) transferrin saturation greater than 20%; AND (3) ferritin greater than 100 ng/mL?
    a. Yes (go to #7)
    b. No (forward to pharmacist for review [deny 5a])
3. Is the drug being used for a diagnosis of anemia associated with HIV/AIDS zidovudine therapy?
    a. Yes (go to #4)
    b. No (go to #5)
4. Does the member meet all of the following criteria: (1) HGB less than 10 g/dL or HCT less than 30%; (2) transferrin saturation greater than 20%; (3) ferritin greater than 100 ng/mL; (4) endogenous erythropoietin levels of 500IU/L or less; AND (5) zidovudine dose of 4200 mg per week or less?
    a. Yes (go to #7)
    b. No (forward to pharmacist for review [deny 5a])
5. Is the drug being used for pre-operative treatment to raise hemoglobin and hematocrit prior to scheduled surgical procedures AND the member has religious beliefs that preclude blood product transfusions?
    a. Yes (go to #6)
    b. No (forward to pharmacist for review [deny 8a])

6. Is the member currently anemic with a hemoglobin less than 13 g/dL for men or less than 12 g/dL for women?
    a. Yes (go to #7)
    b. No (forward to pharmacist for review [deny 5a])
7. Is the medication prescribed by or in consultation with an appropriate health care provider with expertise in treating this condition (e.g. hematologist/oncologist, nephrologist, surgeon etc.)?
    a. Yes (go to #8)
    b. No (forward to pharmacist for review [deny 5a])
8. Is the request for Retacrit?
    a. Yes (approve for three months)
    b. No (go to #9)
9. Has the member had an adequate trial and failure of, contraindication to, or intolerance to Retacrit (epoetin alfa biosimilar)? (Adequate trial is defined as adherent to therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (approve for three months)
    b. No (forward to pharmacist for review [deny 7a])

V. RENEWAL CRITERIA:

1. Has the member maintained adequate iron stores (transferrin saturation greater than 20%)?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 5a])
2. Has the member continued to see a response to treatment demonstrated by an increase from baseline HGB/HCT or at HGB/HCT target?
    a. Yes (approve for six months)
    b. No (forward to pharmacist for review [deny 5a])

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 12/2019
- **Implementation Date:** 12/11/2019

Colony-Stimulating Factors

Policy Number: Rx043

I. MEDICATION NAME(S):

- Neupogen (filgrastim)
- **Nivestym (filgrastim-aafi)** ***preferred***
- **Zarxio (filgrastim-sndz)** ***preferred***
- **Granix (tbo-filgrastim)** ***preferred***
- Neulasta (pegfilgrastim)
- Udenyca (pegfilgrastim-cbqv)
- Fulphila (pegfilgrastim-jmdb)
- Leukine (sargramostim)

II. LENGTH OF AUTHORIZATION:

- Initial and renewal: four months

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the request for pegfilgrastim?
    a. Yes (go to #2)
    b. No (go to #3)
2. Has the provider submitted medically appropriate rationale explaining why filgrastim cannot be used (i.e., dexterity issues)?
    a. Yes (go to #13)
    b. No (forward to pharmacist for review [deny 7a])
3. Is the request for Neupogen?
    a. Yes (go to #4)
    b. No (go to #5)
4. Has the provider submitted medically appropriate rationale explaining why a filgrastim biosimilar cannot be used (Nivestym, Zarxio, or Granix)?
    a. Yes (go to #5)
    b. No (forward to pharmacist for review [deny 7a])
5. Is the drug being used to treat chemotherapy-induced neutropenia?
    a. Yes (go to #6)
    b. No (go to #8)
6. Has the member been on prophylactic therapy with a colony-stimulating factor?
    a. Yes (approve for four months)
    b. No (go to #7)
7. Does the member have one or more of the following risk factors for developing infection-related complications: Sepsis Syndrome; age over 65 or older; absolute neutrophil count [ANC] <100/mcL; duration of neutropenia expected to be greater than

10 days; pneumonia or other clinically documented infections; invasive fungal infection; hospitalization at the time of fever; prior episode of febrile neutropenia?
    a. Yes (approve for four months)
    b. No (forward to pharmacist for review [deny 5a])
8. Is the drug being used for Myelodysplastic Syndromes (MDS)?
    a. Yes (go to #9)
    b. No (go to #13)
9. Does the member have an endogenous serum erythropoietin level of 500 mU/mL or less?
    a. Yes (go to #10)
    b. No (forward to pharmacist for review [deny 5a])
10. Does the member have lower risk disease (i.e., defined as IPSS-R [Very Low, Low, Intermediate], IPSS [Low/Intermediate-1], WPSS [Very Low, Low, Intermediate])?
    a. Yes (go to #11)
    b. No (forward to pharmacist for review [deny 5a])
11. Is the drug being used for treatment of symptomatic anemia in members without del(5q)?
    a. Yes (go to #12)
    b. No (forward to pharmacist for review [deny 5a])
12. Is the member receiving concurrent therapy with an Erythropoiesis Stimulating Agent (ESA) and have one of the following: (1) Ring sideroblasts less than 15% and will use in combination with lenalidomide following no response (despite adequate iron stores) or loss of response to an ESA alone; OR (2) Ring sideroblasts greater than or equal to 15%?
    a. Yes (approve for four months)
    b. No (forward to pharmacist for review [deny 5a])
13. Is the drug being used prophylactically in a member with a non-myeloid malignancy?
    a. Yes (go to #14)
    b. No (go to #16)
14. Is the member undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 20% or greater? (See NCCN Guidelines for Management of Neutropenia https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf.)
    a. Yes (approve for four months)
    b. No (go to #15)
15. Is the member undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 10% or greater AND has one or more of the following comorbidities: age 65 or older receiving full dose intensity chemotherapy; history of recurrent febrile neutropenia from chemotherapy; extensive prior exposure to chemotherapy; previous exposure of pelvis, or other areas of large amounts of bone marrow, to radiation; pre-existing neutropenia (ANC ≤ 1000/mm3) or bone marrow involvement with tumor; patient has a condition that can potentially increase the risk of serious infection (i.e. HIV/AIDS); infection/open wounds; recent surgery; poor performance status; poor renal function (creatinine clearance <50); liver dysfunction (elevated bilirubin >2.0); chronic immunosuppression in the post-transplant setting including organ transplant? (See NCCN Guidelines for Management of Neutropenia https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf.)
    a. Yes (approve for four months)

b. No (forward to pharmacist for review [deny 5a])

16. Is the drug being used for a member who experienced a neutropenic complication from a prior cycle of the same chemotherapy?
    a. Yes (approve for four months)
    b. No (go to #17)
17. Is the drug being used for Bone Marrow Transplantation (BMT) failure or Engraftment Delay?
    a. Yes (approve for four months)
    b. No (go to #18)
18. Is the drug being used for Peripheral Blood Stem Cell (PBSC) mobilization and transplant?
    a. Yes (approve for four months)
    b. No (go to #19)
19. Is the drug being used for members acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome)?
    a. Yes (approve for four months)
    b. No (forward to pharmacist for review [deny 8a])

V. RENEWAL CRITERIA:

See Initial Criteria

VI. ADDITIONAL INFORMATION:

- Febrile neutropenia is defined as:
    - A single temperature ≥38.3 °C orally or ≥38.0 °C over 1 hour; AND
    - Neutropenia <500 neutrophils/mcL or <1,000 neutrophils/mcL and a predicted decline to ≤500 neutrophils/mcL over the next 48 hours.

VII. REVISION HISTORY:

- **P&T Review Date:** 12/2019
- **Implementation Date:** 12/11/2019

UMPQUA HEALTH ALLIANCE
500 SE CASS AVENUE, SUITE 200
ROSEBURG, OR 97470

Nicotine Replacement Preparations

Policy Number: Rx044

I. MEDICATION NAME(S):

- nicotine gum (QL)
- Nicorelief gum (QL)
- Quit 2 gum (QL)
- Quit 4 gum (QL)
- nicotine lozenge (QL)
- Nicorette lozenge (QL)
- Quit 2 lozenge (QL)
- Quit 4 lozenge (QL)
- Stop Smoking Aid lozenge (QL)
- nicotine patch (QL)
- Nicotrol inhaler (PA, non-preferred)
- Nicotrol NS nasal spray (PA, non-preferred)

II. LENGTH OF AUTHORIZATION:

- Initial and renewal: up to 12 weeks

III. QUANTITY LIMITS:

- All products are limited to two quit attempts per year
- Patches: 30 patches per 30 days; 180 patches per year
- Gum and lozenges: 120 units per 5 days; 4,320 units per year

IV. INITIAL CRITERIA:

1. Is the request for a quantity exception for nicotine gum, lozenge or patches?
    a. Yes (go to #2)
    b. No (go to #5)
2. Has the member completed two quit attempts in the past year?
    a. Yes (forward to pharmacist for review [deny 5q])
    b. No (go to #3)
3. Has the provider submitted documentation that the member has stopped using tobacco?
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 5a])
4. Is the member enrolled in a tobacco cessation support program, such as Quit 4 Life?
    a. Yes (approve up to 12 weeks [QL: patches 30/30; gum and lozenges 120/5])
    b. No (forward to pharmacist for review [deny 5a])
5. Has the member had a documented medical reason why they cannot use ALL of the following: nicotine gum, nicotine lozenge, AND nicotine patch?
    a. Yes (approve for 12 weeks)
    b. No (forward to pharmacist for review [deny 7a])

V. RENEWAL CRITERIA:

See Initial Criteria

VI. ADDITIONAL INFORMATION:

- For tobacco cessation support, UHA recommends using Quit 4 Life. Quit 4 Life has a team of trained experts to help members develop a quit plan and provides tools for tobacco cessation. Expert support and assistance is available from coaches who specialize in tobacco cessation. For additonal details or for enrollment, call 1-866-QUIT-4-LIFE (1-866-784-8454), or visit www.quitnow.net.

VII. REVISION HISTORY:

- **P&T Review Date:** 12/2019
- **Implementation Date:** 12/11/2019

Testosterone Cypionate

Policy Number: Rx045

I. MEDICATION NAME(S):

- testosterone cypionate vials
- all other products, see Additional Information section

II. LENGTH OF AUTHORIZATION:

- Initial and renewal: one year

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug used for a diagnosis of gender dysphoria, female-to-male transsexualism?
    a. Yes (go to #2)
    b. No (go to #3)
2. Does the request meet Guideline Note 127 of the Oregon Health Plan (OHP) Health Evidence Review Commission (HERC) Prioritized List of Health Services (see Additional Information section for full guideline note)?
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 3a, GLN 127])
3. Is the drug used for a diagnosis of primary or secondary hypogonadism?
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 8a])
4. Is the member a male age 12 years or older?
    a. Yes (go to #5)
    b. No (forward to pharmacist for review [deny 8a])
5. Does the member have a total testosterone level < 300ng/dL or a free testosterone level < 50ng/dL? For obese members with a BMI greater than 30, use free testosterone levels only. (For renewals or new members previously taking testosterone, proceed to renewal criteria.)
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 5a, initial labs])

V. RENEWAL CRITERIA:

1. Has testosterone levels been drawn after the member initiated therapy and/or after any dose changes?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 5a])

2. Are total testosterone levels within therapeutic range (320 to 1000 ng/dL for gender dysphoria and 450 to 600 ng/dL for primary or secondary hypogonadism)?
    a. Yes (approve for one year)
    b. No (forward to pharmacist for review [deny 5a, renewal labs])

VI. ADDITIONAL INFORMATION:

- All other testosterone products are not on the UHA formulary. These products must meet this criteria as well as the General Utilization Management criteria. Specifically, trial and failure of formulary alternatives (testosterone cypionate vials) and all less-costly non-formulary alternatives.
- Guideline Note 127: To qualify for cross-sex hormone therapy, the patient must:
    - Have persistent, well-documented gender dysphoria;
    - Have the capacity to make a fully informed decision and to give consent for treatment;
    - Have any significant medical or mental health concerns reasonably well controlled; and
    - Have a comprehensive mental health evaluation provided in accordance with Version 7 of the World Professional Association for Transgender Health (WPATH) Standards of Care (www.wpath.org).

VII. REVISION HISTORY:

- **P&T Review Date:**
- **Implementation Date:**

Oral Antifungals

Policy Number: Rx046

I. MEDICATION NAME(S):

- itraconazole capsule
- ketoconazole tablet
- Lamisil (terbinafine HCl) gran pack
- terbinafine HCl tablet

II. LENGTH OF AUTHORIZATION:

- Initial: up to six months
- Renewal: six months

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug used for an FDA-approved indication or a medically appropriate off-label use with strong evidence supporting safety and efficacy?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])
2. Is the drug prescribed for a condition funded by the Oregon Health Plan (OHP) in a manner consistent with the Health Evidence Review Commission (HERC) Prioritized List of Health Services? (Fungal infections of the skin, scalp, groin and nails are not funded for most members. Some conditions are covered if the member is immunocompromised, like those with AIDS or cancer.)
    a. Yes (go to #4)
    b. No (go to #3)
3. Is there a comorbid condition for which coverage would be allowed? For example, type 2 diabetes or other conditions that may increase the risk of serious secondary skin infections.
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 3a/3c])
4. Is the request for itraconazole?
    a. Yes (go to #5)
    b. No (approve for up to six months)
5. Has the member tried and failed terbinafine and ketoconazole, if indicated?
    a. Yes (approve for up to six months)
    b. No (forward to pharmacist review [deny 5k])

V. RENEWAL CRITERIA:

1. Is the drug used for an FDA-approved indication or a medically appropriate off-label use with strong evidence supporting safety and efficacy?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])
2. Is the drug prescribed for a condition funded by the Oregon Health Plan (OHP) in a manner consistent with the Health Evidence Review Commission (HERC) Prioritized List of Health Services? (Fungal infections of the skin, scalp, groin and nails are not funded for most members. Some conditions are covered if the member is immunocompromised, like those with AIDS or cancer.)
    a. Yes (approve for six months)
    b. No (go to #3)
3. Is there a comorbid condition for which coverage would be allowed? For example, type 2 diabetes or other conditions that may increase the risk of serious secondary skin infections.
    a. Yes (go to #4)
    b. No (forward to pharmacist for review [deny 3a/3c])
4. Has documentation been submitted to support the continued use of this medication in accordance with clinical guidelines? (Refer to UpToDate or product labeling for appropriate treatment duration.)
    a. Yes (approve for six months)
    b. No (forward to pharmacist for review [deny 5a])

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 9/2019
- **Implementation Date:** 9/25/2019

Rifaximin

Policy Number: Rx047

I. MEDICATION NAME(S):

- Xifaxan (rifaximin)

II. LENGTH OF AUTHORIZATION:

- Length of benefit (LOB)

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug used for hepatic encephalopathy associated with chronic liver disease? Note: Irritable bowel syndrome (IBS) and travelers' diarrhea are not funded conditions according to the Oregon Health Plan Prioritized List of Health Services.
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 3a or 8a])
2. Has the member had an adequate trial and failure of, contraindication to, or intolerance to lactulose? (Adequate trial is defined as compliant with therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (approve for LOB)
    b. No (forward to pharmacist for review [deny 7a, lactulose])

V. RENEWAL CRITERIA:

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 12/2019
- **Implementation Date:** 12/11/2019

UMPQUA HEALTH ALLIANCE
500 SE CASS AVENUE, SUITE 200
ROSEBURG, OR 97470

Palivizumab

Policy Number: Rx048

I. MEDICATION NAME(S):

- Synagis (palivizumab)

II. LENGTH OF AUTHORIZATION:

- Typically, approval is given from November 1st through March 31st of the following year for a maximum of five doses during each season. Authorizations may be allowed outside of this window depending on the start and end of Respiratory Syncytial Virus (RSV) season according to the OHA RSV surveillance data for Southern Oregon (report link: https://www.oregon.gov/oha/PH/DiseasesConditions/CommunicableDisease/DiseaseSurveillanceData/Pages/RespiratorySyncytialVirusSurveillanceData.aspx). As defined by the CDC:
    - RSV season onset is the first of two consecutive weeks during which the mean percent-age of specimens testing positive for RSV antigen is ≥10% or the mean percentage of specimens testing positive for RSV by PCR is ≥3%, whichever occurs first.
    - RSV season offset is the last of two consecutive weeks during which the mean percentage of positive specimens by antigen is <10%, or the mean percentage of positive specimens by PCR is <3%, whichever occurs last.
- Qualifying infants born during RSV season may require fewer doses. If any infant or young child receiving monthly palivizumab prophylaxis experiences a breakthrough RSV hospitalization, monthly prophylaxis should be discontinued.

III. QUANTITY LIMITS:

- A maximum of five doses per season.
- A maximum of two seasons may be allowed for some members; until the member's age is 24 months or less at the start of RSV season.

IV. INITIAL CRITERIA:

1. Is the request for palivizumab (Synagis) to be initiated prior to November 1st?
    a. Yes (go to #2)
    b. No (go to #3)
2. Based on the OHA's weekly RSV Surveillance Report for Southern Oregon (see link under 'Length of Authorization' section), has there been at least two consecutive weeks during which the mean percent-age of specimens testing positive for RSV antigen is ≥10% **or** the mean percentage of specimens testing positive for RSV by PCR is ≥3%?
    a. Yes (go to #3)
    b. No (forward to pharmacist for review [deny 5a, start of season])

3. Is the request for palivizumab (Synagis) to be administered after March 31st?
    a. Yes (go to #4)
    b. No (go to #5)
4. Based on the OHA's weekly RSV Surveillance Report for Southern Oregon (see link under 'Length of Authorization' section), has there been two consecutive weeks during which the mean percentage of positive specimens by antigen is <10%, or the mean percentage of positive specimens by PCR is <3%, whichever occurs last.
    a. Yes (forward to pharmacist for review [deny 5a, end of season])
    b. No (go to #5)
5. Does the member meet **any** of the following:
        i. *Age < 12 months at the start of RSV season, and gestational age <29 weeks, 0 days;* ***or***
        ii. *Preterm infants who develop chronic lung disease (CLD) of prematurity defined as birth at gestational age of <32 weeks, 0 days' gestation and a requirement for >21% oxygen for at least 28 days after birth, and one of the following:*
            1. *Age <12 months at the start of RSV season;* ***or***
            2. *Age 12-24 months at the start of RSV season, and continued medical need for supplemental oxygen, chronic corticosteroids, or diuretic therapy during the 6-month period prior to the start of RSV season;* ***or***
        iii. *Age < 12 months at the start of RSV season, with hemodynamically significant congenital heart disease (CHD), and at least one of the following:*
            1. *Acyanotic heart disease who are receiving medication to control CHF and will require cardiac surgical procedures;* ***or***
            2. *Moderate to severe pulmonary hypertension;* ***or***
        iv. *Age < 12 months at the start of RSV season, with congenital abnormalities of the airway or neuromuscular disease that impairs the ability to clear secretions from the upper airways;* ***or***
        v. *Age < 24 months at the start of RSV season, who will be profoundly immunocompromised during RSV season (such as chemotherapy, or post solid organ or stem cell transplant)?*
    a. Yes (go to #6)
    b. No (forward to pharmacist for review [deny 5a, conditions])
6. Is the request for more than 5 doses within the same RSV season or for dosing <28 days apart?
    a. Yes (forward to pharmacist for review [deny 5q, limit to 5 doses])
    b. No (go to #7)
7. Is the requested amount dosed at 15 mg/kg using a weight taken within the past month?
    a. Yes (approve for up to five fills through March 31st or according to the 'Length of Authorization' section [fills after March 31st should only be approved one at a time])
    b. No (forward to pharmacist for review [deny 5a, weight])

V. RENEWAL CRITERIA:

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 12/2019
- **Implementation Date:** 12/11/2019

UMPQUA HEALTH
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ROSEBURG, OR 97470

Lacosamide

Policy Number: Rx049

I. MEDICATION NAME(S):

- Vimpat (lacosamide) tablets

II. LENGTH OF AUTHORIZATION:

- Length of benefit (LOB)

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug used for partial-onset seizures?
    a. Yes (go to #2)
    b. No (forward to pharmacist for review [deny 8a])
2. Is the member at least four years of age?
    a. Yes (go to #3)
    b. No (forward to pharmacist for review [deny 8a])
3. Has the member failed to achieve successful control of their seizures with at least two other antiepileptic drugs, such as carbamazepine, oxcarbazepine, phenytoin, topiramate, or valproic acid? (Note: members who are currently taking lacosamide should not be required to try and fail alternative agents.)
    a. Yes (approve for LOB)
    b. No (forward to pharmacist for review [deny 7a])

V. RENEWAL CRITERIA:

VI. ADDITIONAL INFORMATION:

VII. REVISION HISTORY:

- **P&T Review Date:** 12/2019
- **Implementation Date:** 12/11/2019

UMPQUA HEALTH ALLIANCE
500 SE CASS AVENUE, SUITE 200
ROSEBURG, OR 97470

Mesalamine

Policy Number: Rx050

I. MEDICATION NAME(S):

- mesalamine DR 800 mg tab (generic Asacol HD)
- Apriso (mesalamine) 0.375 g cap ER 24h
- mesalamine DR 400 mg cap (generic Delzicol)
- mesalamine DR 1.2 g tab (generic Lialda)
- mesalamine 1000 mg rectal suppository
- *Pentasa (mesalamine) 250 mg cap ER (non-formulary)*
- *Pentasa (mesalamine) 500 mg cap ER (non-formulary)*

II. LENGTH OF AUTHORIZATION:

- Initial: length of benefit (LOB)

III. QUANTITY LIMITS:

- N/A

IV. INITIAL CRITERIA:

1. Is the drug prescribed for Crohn's disease?
    a. Yes (go to #4)
    b. No (go to #2)
2. Is the drug prescribed for ulcerative colitis?
    a. Yes (go to #3)
    b. No (forward to pharmacist for review)
3. Is the disease described as active in the small bowel (proximal to the colon)?
    a. Yes (go to #5)
    b. No (go to #4)
4. Has the member had an adequate trial and failure of, contraindication to, or intolerance to one of the following: sulfasalazine or balsalazide? (Adequate trial is defined as compliant with therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (approve for LOB)
    b. No (forward to pharmacist for review [deny 7a])
5. Is the request for Pentasa?
    a. Yes (go to #6)
    b. No (go to #7)
6. Does the member have full GI tract involvement that requires the Pentasa release mechanism?

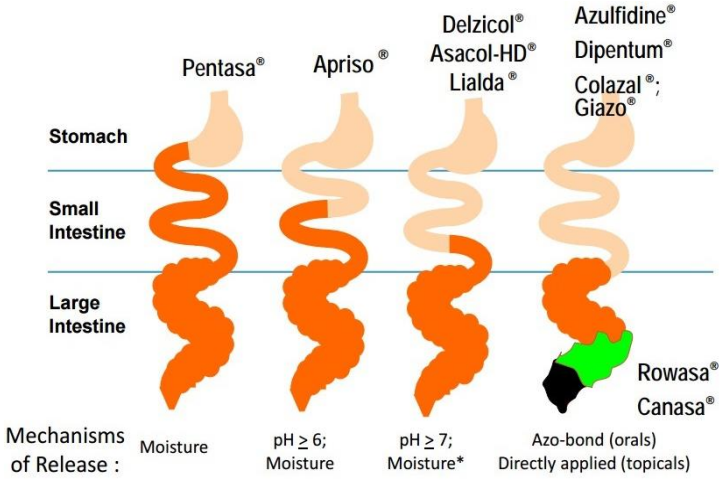
a. Yes (approve for LOB)
b. No (go to #7)

7. Has the member had an adequate trial and failure of, contraindication to, or intolerance to at least one generic oral mesalamine product (generic Lialda, Asacol, Delzicol) or Apriso? (Adequate trial is defined as compliant with therapy for at least three consecutive months, MPR greater than or equal to 80% or no gaps between fills that exceed 5 days.)
    a. Yes (approve for LOB)
    b. No (forward to pharmacist for review [deny 7a])

V. RENEWAL CRITERIA:

VI. ADDITIONAL INFORMATION:

- 5-ASA Release Sites:



- Medications:

Drug Name	Strength	Site of Delivery	Qt/DS	Price	Ulcerative Colitis		Crohn's Colitis		Crohn's Ileitis	
					Active	Maint	Active	Maint	Active	Maint
Pentasa (mesalamine CR) oral cap	500 mg	Jejunum, ileum, colon	240/30	$1,404	4	2-4	4*	2-4*	4*	2-4*
Pentasa (mesalamine CR) oral cap	250 mg	Jejunum, ileum, colon	480/30	$1,404	4	2-4	4*	2-4*	4*	2-4*
Apriso (mesalamine ER) oral cap	0.375 g	Terminal ileum, colon	120/30	$489	1.5-3*	1.5	2.4-4.8*	2.4-4.8*	2.4-4.8*	2.4-4.8*
mesalamine DR (generic Asacol HD) oral tab	800 mg	Distal ileum, colon	180/30	$1,107	2.4-4.8	2.4-4.8	2.4-4.8*	2.4-4.8*	2.4-4.8*	2.4-4.8*
mesalamine DR (generic Delzicol) oral cap	400 mg	Distal ileum, colon	180/30	$395	2.4-4.8	2.4-4.8	2.4-4.8*	2.4-4.8*	2.4-4.8*	2.4-4.8*
mesalamine DR (generic Lialda) oral tab	1.2 g	Distal ileum, colon	120/30	$443	2.4-4.8	2.4	2.4-4.8*	2.4-4.8*	2.4-4.8*	2.4-4.8*
sulfasalazine (generic Azulfidine) oral tab	500 mg	Colon	120/30	$21	2-4	2-4	2-4*	NR	NR	ID
sulfasalazine DR (generic Azulfidine EC) oral tab	500 mg	Colon	120/30	$37	2-4	2-4	2-4*	NR	NR	ID
Dipentum (olsalazine sodium) oral cap	250 mg	Colon	120/30	$1,567	2-3*	1	2-3*	1*	NR	NR

balsalazide disodium (generic Colazal) oral cap	750 mg	Colon	270/30	$104	6.75	3-6*	ID	ID	NR	NR
mesalamine (generic SFRowasa) rectal enema	4 G/60 mL	Sigmoid colon, rectum	1680/28	$353	4	2-4*	4*	ID	NR	NR
mesalamine (generic Rowasa) rectal enema kit	4 G/60 mL	Sigmoid colon, rectum	4/28	$479	4	2-4*	4*	ID	NR	NR
mesalamine (generic Canasa) rectal supp	1000 mg	Rectum	30/30	$750	1	1*	ID	ID	NR	NR

**Off-label indication*

Maint: maintenance; ID: insufficient data; NR: not recommended.

Doses shown are total grams per day and must be divided in 3 or 4 equally divided doses for certain formulations. For details, see Lexi-Comp drug information included with UpToDate and the official prescribing information.

VII. REVISION HISTORY:

- **P&T Review Date:** 9/2019
- **Implementation Date:** 9/25/2019