PROVIDENCE Health Plan

Healthcare Services Medical & Pharmacy Policy Alerts

Number 237

July 1, 2019

This is the July 1, 2019 issue of the Providence Health Plans, Providence Health Assurance and Providence Plan Partners, Medical and Pharmacy Policy Alert to our providers. The focus of this update is to communicate to providers' new or revised Medical or Pharmacy policy changes. The Health Plan has a standard process to review all Medical & Pharmacy Policies annually. Policies will be available for review on ProvLink and via the PHP website at: https://healthplans.providence.org/providers/provider-support/medical-policy-and-provider-information/

The Provider Alert, Prior Authorization Requirements, and Medical policies are all available on ProvLink and through the link above.

As of 9/1/2019, the Botulinum Toxin Types A and B medical policy will be archived and the Pharmacy and Therapeutics Committee (PMT) will maintain a Botulinum Toxin policy. Prior authorizations and claims will still be through Health Care Services. Please see below for a list of major criteria changes from the current medical policy.

PROVIDENCE Health Plan

Here's what's new from the following policy committees:

MEDICAL POLICY COMMITTEE

Archive

Effective September 1, 2019

Drug.Botulinum Toxin Types A and B MED209	• Effective 9/1/19, the medical policy addressing botulinum toxin therapy will be archived.
	• Pharmacy and Therapeutics Committee (PMT) will maintain two new botulinum therapies policies—one for commercial and one for Medicare
	• Prior authorizations and claims will still go through Health Care Services
	• Major changes from the current medical policy are as follows:
	  ○ Separate Medicare only policy based on Local Coverage Determination (LCD) criteria – LCD35172
	  ○ Onabotulinumtoxin A (Botox®)
	  ▪ For *chronic* migraine only, may be covered when additional criteria are met
	  ▪ New medically necessary indications, include: lower limb spasticity, severe axillary hyperhidrosis, and excessive salivation due to advanced Parkinson's disease
	  ○ AbobotulinumtoxinA (Dysprot®)
	  ▪ New medically necessary indications, include: spasticity and blepharospasm
	  ○ IncobotulinumtoxinA (Xeomin®)
	  ▪ New medically necessary indications, include: chronic sialorrhea and upper limb spasticity
	  ○ The following indications are no longer covered:
	  ▪ Achalasia
	  ▪ Adductor spasmodic dysphonia
	  ▪ Anal fissure and anismus
	  ▪ Detrusor instability
	  ▪ Spasmotic torticollis
	  ▪ Spastic hemiplegia
	  ▪ Sphincter of Oddi dysfunction
	  ▪ Writer's cramp

New Policies or Major Changes

Effective September 1, 2019

Back: Artificial Intervertebral Discs SUR138	**Annual Update** The following changes have been made to the policy criteria: Cervical Disc Replacement

	1. Clarified the language in criterion I. to indicate that cervical disc replacement may be medically necessary when the patient is diagnosed with either degenerative disc disease OR herniated disc(s). Revised the general language in I. as well as specific language in I.E. (I.E. was based on the FDA language for 2-level devices). 2. Changed FDA contraindication in criterion I.G.4. from "Cervical degenerative disc disease at more than two levels" to "More than two cervical levels requiring surgical intervention". 3. Added investigational criterion II.B. which indicates the replacement of a cervical artificial disc is not covered. (Note: Prior surgery at operative level is an FDA contraindication). Lumbar Disc Replacement 1. Investigational criterion V. has been expanded to indicate that both disc replacement at more than one lumbar level and replacement of a lumbar artificial disc are non-covered. 2. Based on new Medicare non-coverage guidance for patients ≤60 years, the medical necessity criteria for lumbar disc replacement now only applies to all lines of business except Medicare. Therefore, the following changes have been made: a. Former coverage criterion IV.B. for Medicare patients ≤60 years old has been removed. b. Criterion VII. has been created to outline our non-coverage stance for Medicare members regardless of age. Device Table: Added one FDA-approved device (Table 1). The M6-C™ Artificial Cervical Disc (Spinal Kinetics) was recently approved for single cervical level replacement only. **Codes:** All Lines of Business: 0164T for the removal of a lumbar artificial disc will change from not covered to PA required. Medicare only: CPT codes for lumbar disc replacement (22857, 22862, and 0098T) will change from PA required to not covered (not medically necessary).
Breast Reconstruction SUR162	**Interim Update** A cosmetic criterion has been added to the policy. This criterion aligns with the non-coverage criteria identified in the Medicare NCD and LCD that address reconstructive breast surgery. This criterion (III.) reads as follows: "Breast surgery is considered cosmetic when used strictly to reshape the breasts to improve appearance in the absence of a medically necessary indication. Therefore, breast surgery is considered **cosmetic and not covered** if the patient does not meet any of the criteria I.A. – C. above." Also added several policies to the Cross References section.
Rhinoplasty SUR337 *Previously: Rhinoplasty Functional (Non-cosmetic)*	**Interim Update** The following changes to the policy have been made: • Due to differences in coverage criteria for rhinoplasty for Medicare members, we are separating out criteria by line of business. ○ Have added criterion III. for Medicare members. This criterion differs from our commercial criteria in that Medicare does not outline specific documentation requirements and does not specify that if rhinoplasty is required due to trauma that the trauma be recent (less than six months). • Have also added a cosmetic criterion IV., which applies to all lines of business. This criterion had been removed from the Cosmetic and Reconstructive Procedures policy. • Added a billing guideline section specifically for Medicare members, which includes a list of 26 ICD-10 diagnosis codes that Medicare considers to be the only codes that support medical necessity. These ICD codes will be paired with the six CPT codes listed in the LCD to allow for Medicare only. • Added a Cross References section, which includes the two cosmetic medical policies. **Codes:** All lines of Business Except Medicare: No coding changes. Medicare Only: Removing the PA from six CPT codes for listed in the Medicare LCD. These six CPT codes will be paired with the 26 ICD codes in the LCD for coverage. All other ICD codes will deny as cosmetic.
Surgical Treatment for Skin Redundancy	**Interim Update** The following changes to the policy have been made:

SUR145	• Due to differences in coverage criteria for panniculectomy and abdominoplasty for Medicare members, we are separating out criteria by line of business. ○ Have added coverage criteria IV. (abdominal lipectomy/panniculectomy) and V. (abdominoplasty, including lipectomy) for Medicare members. The panniculectomy coverage criteria is much more general for Medicare than our commercial criteria (I. and II.). Also, Medicare allows for coverage of abdominoplasty when specific criteria are met. Our commercial criterion (III.) considers abdominoplasty cosmetic under all circumstances. • Added a billing guideline section specifically for Medicare members, which provides a link to the Noridian LCD that includes a list of 63 ICD-10 diagnosis codes that Medicare considers to be the only codes that support medical necessity for panniculectomy. • Updated the definitions of cosmetic and reconstruction to be in-line with those we are adding to the commercial Cosmetic policy. • Added a Cross References section, which includes the two cosmetic medical policies.
Inflammatory Bowel Disease: Serologic Testing and Therapeutic Monitoring LAB312	**Annual Update** The following criteria changes have been made: • Fecal calprotectin testing may now be considered medically necessary to help distinguish between irritable bowel syndrome and inflammatory bowel disease. This is based on recommendations from three evidence-based clinical practice guidelines (American College of Gastroenterology, National Institute for Health and Care Excellence, and World Gastroenterology Organization). • NUDT15 genetic testing has been added to the policy and is considered investigational. **Codes:** Three codes have been added to the policy per coding plan survey. • 0034U- TPMT and NUDT15 • 81306- NUDT15 • 83993- fecal calprotectin 83993 will only pay when billed with IBD/IBS diagnosis codes. See policy Billing Guidelines for complete list of diagnosis codes.

Archive

Effective July 1, 2019

Massage Therapy: PEBB and Providence Health and Services (PH&S) MED278	This policy has been archived as of 7/1/19. The massage therapy codes do not require review. **Member benefits still apply.**

PHARMACY & THERAPEUTICS COMMITTEE

Oregon Region P&T Committee Meeting June 14, 2019

Go-Live Date: Thursday, August 01, 2019, unless otherwise noted

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New Drugs and Combinations:

Siponimod (Mayzent®) Tablet
• **Indication:** Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. • **Formulary Alternatives**: Aubagio®, Tecfidera®, Rebif®, Avonex®, Gilenya®
• **Commercial**: Formulary, Preferred Specialty • **Medicaid**: Formulary, Specialty • **Medicare Part D:** Formulary, Specialty

Cladribine (Mavenclad®) Tablet
• **Indication:** For the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, use of cladribine tablet is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternate drug indicated for the treatment of MS. • **Formulary Alternatives**: Aubagio®, Tecfidera®, Rebif®, Avonex®, Gilenya
• **Commercial**: Formulary, Non Preferred Specialty, Prior authorization • **Medicaid**: Medicaid: Formulary, Specialty, Prior authorization • **Medicare Part D:** Formulary, Specialty, Prior authorization **Prior Authorization Criteria:** Documented trial and failure, intolerance, or contraindication to two (2) conventional therapies for multiple sclerosis

Esketamine HCL (Spravato®) Spray
• **Indication:** Treatment of treatment-resistant depression (TRD), in conjunction with an oral antidepressant. • **Formulary Alternatives**: generic antidepressants
• **Commercial**: Medical Benefit, Prior Authorization • **Medicaid**: Covered by DMAP • **Medicare Part D:** Formulary, Specialty, Prior Authorization

- **Medicare Part B:** Medical Benefit, Prior Authorization

Prior Authorization Criteria for Commercial/Medicare Part B:
For initial authorization all of the following criteria must be met:
1. Individual has been diagnosed with major depressive disorder
2. Individual has had an inadequate response to the maximum tolerated dose of two antidepressant therapies for at least 6 weeks of treatment
3. Documentation of the patient's baseline depression status using an appropriate rating scale (e.g. PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, HAM-D)
4. Documentation that esketamine (Spravato®) will be used in combination with oral antidepressant therapy
5. Dosing is in accordance with the United States Food and Drug Administration approved labeling.

For reauthorization, all of the following criteria must be met:
1. Documentation of clinical improvement in depression symptoms as measured by an appropriate rating scale (compared to previous measurements)
2. Documentation that esketamine (Spravato®) will continue to be used in combination with oral antidepressant therapy

Prior Authorization Criteria for Medicare Part D:
For initial authorization **all** of the following criteria must be met:
1. Individual has been diagnosed with major depressive disorder
2. Individual has had an inadequate response to the maximum tolerated dose of two antidepressant therapies for at least 6 weeks of treatment
3. Documentation that esketamine (Spravato®) will be used in combination with oral antidepressant therapy
4. Dosing is in accordance with the United States Food and Drug Administration approved labeling.

Onasemnogene abeparvovec-xioi (Zolgensma) Kit

Indication: An adeno-associated virus vector-based gene therapy indicated for the treatment of pediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene.

- Limitation of Use:
  - The safety and effectiveness of repeat administration have not been evaluated.
  - The use in patients with advanced SMA (e.g., complete paralysis of limbs, permanent ventilator dependence) has not been evaluated
- **Formulary Alternatives:** Spinraza® (nusinersen)

- **Commercial**: Medical, Prior Authorization
- **Medicaid**: Medical, Prior Authorization
- **Medicare Part D**: Non-formulary
- **Medicare Part B**: Prior Authorization

Prior Authorization Criteria:

1) Confirmed genetic diagnosis of SMA with documentation of bi-allelic mutations in the survival motor neuron 1 (SMN1) gene and less than or equal to 3 copies of SMN2
   a) For patients with 3 copies of SMN2, documentation of clinical symptoms of disease is required
2) Documentation that premedication will be started 24 hours prior to infusion with prednisolone at 1 mg/kg/day
3) Documentation of baseline anti-AAV9 antibody titers of ≤ 1:50
4) Documentation of baseline tests for liver function, platelet count, and troponin-I

Tagraxofusp-erzs (Elzonris) Vial

- **Indication:** Treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and in pediatric patients 2 years and older.

- **Commercial**: Medical Benefit, Prior Authorization
- **Medicaid**: Medical Benefit, Prior Authorization
- **Medicare Part D**: Non-Formulary
- **Medicare Part B**: Medical Benefit, Prior Authorization

Prior Authorization Criteria:

For initial authorization all of the following criteria must be met:

1. Diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN)
2. Documentation that patient has a current Eastern Cooperative Oncology Group (ECOG) status of 0-1
3. Documentation that patient has a baseline serum albumin level of at least 3.2 g/dL
4. Documentation that patient has adequate cardiac function, defined as LVEF of at least 50% none of the following:
   a. Uncontrolled or any NYHA Class 3 or 4 congestive heart failure
   b. Uncontrolled angina
   c. History of myocardial infarction or stroke within 6 months of initiating therapy
   d. Uncontrolled hypertension
   e. Clinically significant arrhythmias not controlled by medication

- Reauthorization requires documentation of positive response to therapy, such as a lack of disease progression

Dolutegravir sodium Lamivudine (Dovato®) Tablet
• **Indication:** A complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults with no antiretroviral treatment history and with no known substitutions associated with resistance to the individual components of Dovato®. • **Formulary Alternatives:** generic lamivudine and brand Tivicay® (dolutegravir)
• **Commercial:** Non-Formulary • **Medicaid:** Non-Formulary • **Medicare Part D:** Formulary, Specialty

New Strengths and Formulations:

Caplacizumab-yhdp (Cablivi®) Kit
• **Indication:** Treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy.
• **Commercial:** Formulary, Non-preferred Specialty, Prior Authorization, Quantity Limit (1 vial per day) • **Medicaid:** Formulary, Specialty, Prior Authorization, Quantity Limit (1 vial per day) • **Medicare Part D:** Formulary, Specialty, Prior Authorization, Quantity Limit (1 vial per day) **Prior Authorization Criteria:** Initial Criteria: 1. Diagnosis of acquired thrombotic thrombocytopenic purpura 2. Documentation that therapy will be given in combination with plasma exchange therapy 3. Documentation that therapy will be given in combination with immunosuppressive therapy (i.e., glucocorticoids, rituximab) Reauthorization criteria: If the request is for a new treatment cycle:

1. Documentation of previous positive response to therapy (such as an improvement in platelet counts, reduction in neurological symptoms, or improvements in organ-damage markers)
2. Documentation that therapy will be given in combination with plasma exchange therapy and immunosuppressive therapy (i.e., glucocorticoids, rituximab)
3. Documentation that length of therapy post plasma exchange will not exceed 58 days
4. Documentation that patient has not had more than two recurrences of acquired thrombotic thrombocytopenic purpura while on therapy with caplacizumab. Recurrence is defined as initial platelet normalization followed by a reduction in platelet count that necessitates re-initiation of plasma exchange.

If request is for treatment extension:

1. Documentation of positive response to therapy (such as an improvement in platelet counts, reduction in neurological symptoms, or improvements in organ-damage markers)
2. Documentation that patient has signs of persistent underlying disease such as persistent severe ADAMTS13 deficiency
3. Documentation that length of therapy post plasma exchange will not exceed 58 days

Prucalopride succinate (Motegrity®) Tablet

- **Indication:** Treatment of chronic idiopathic constipation (CIC) in adults
- **Formulary Alternatives:** linaclotide (Linzess®), lubiprostone (Amitiza®), and plecanatide (Trulance®)

- **Commercial:** Formulary, Non-Preferred Brand, Prior Authorization
- **Medicaid:** Non-Formulary, Prior Authorization
- **Medicare Part D:** Non-Formulary

Prior Authorization Criteria:

1) **For all requests**, the patient must have an FDA labeled indication for the requested agent.
2) For patients *already established* on the requested product (starting on samples will not be considered as established on therapy):
   a) Documentation of response to therapy (e.g., less straining, less pain on defecation, improved stool consistency, increased number of stools per week or reduction in the number of days between stools)
3) For patients *not established* on the requested product must meet ALL of the following indication-specific criteria:
   a) For **chronic idiopathic constipation (CIC):**
      i) Documentation of weekly constipation (less than 3 spontaneous bowel movements) for at last 3 months

ii) Screen for constipation-inducing medications and medical rationale provided for continuing these medications, if applicable
iii) Inadequate response or contraindication to a reasonable trial (at least two weeks treatment) of **ALL** of the following:
(1) Regular use of dietary fiber supplementation (e.g. cereal, citrus, fruits or legumes) or use of bulking agents (e.g., psyllium or methylcellulose taken with adequate fluids),
(2) A combination of a stool softener plus a stimulant laxative (e.g. docusate plus senna, docusate sodium plus bisacodyl)
(3) Routine laxative therapy, with a different mechanism of action than the laxative above (e.g., lactulose, Miralax®)

Sarecycline HCL (Seysara®) Tablet

- **Indication:** Treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older.
- **Formulary Alternatives:** minocycline, doxycyline

- **Commercial:** Non-Formulary, Prior Authorization
- **Medicaid:** Non-Formulary, Prior Authorization
- **Medicare Part D:** Non-Formulary,

Prior Authorization Criteria:
Add to "New Medications and Formulations Without Established Benefit" policy

Eravacycline Di-Hydrochloride (Xerava®) Vial

- **Indication:** Complicated Intra-abdominal Infection caused by susceptible organisms

- **Commercial:** Medical Benefit
- **Medicaid:** Medical Benefit
- **Medicare Part D**: Non-Formulary
- **Medicare Part B:** Medical Benefit

New Strengths and Formulations: See Other Formulary Changes

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New Indications:

Amphetamine (Dyanavel® XR) Susp
Expanded FDA-approved or New Indication: • The treatment of attention deficit hyperactivity disorder (ADHD) in patients 6 years and older
Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Pembrolizumbab (Keytruda®) Vial
Expanded FDA-approved or New Indication: • For the adjuvant treatment of patients with melanoma with involvement of lymph node(s) following complete resection.
Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN) so no updates to the policy are warranted.

Ribociclib Succinate/Letrozole (Kisqali Femara® Co-Pack) Tablet
Expanded FDA-approved or New Indication: • as initial endocrine-based therapy for the treatment of pre/perimenopausal or postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer
Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN) so no updates to the policy are warranted.

Tipiracil/Trifluridine hcl (Lonsurf®) Tablet
Expanded FDA-approved or New Indication: • Metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy

Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN) so no updates to the policy are warranted.

Insulin Degludec/Liraglutide (Xultophy®) Pen

Expanded FDA-approved or New Indication:

- Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus

Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Insulin Glargine/Lixisenatide (Soliqua®) Pen

Expanded FDA-approved or New Indication:

- Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus

Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Atezolizumab (Tecentriq®) Vial

Expanded FDA-approved or New Indication:

Triple-Negative Breast Cancer (TNBC)

- In combination with paclitaxel protein-bound for the treatment of adult patients with unresectable locally advanced or metastatic TNBC whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] of any intensity covering ≥ 1% of the tumor area), as determined by an FDA approved test[1]

Small Cell Lung Cancer (SCLC)

- In combination with carboplatin and etoposide, for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC)

[1]This indication is approved under accelerated approval based on progression free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN) so no updates to the policy are warranted.

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Dupilumab (Dupixent®) Syringe
Expanded FDA-approved or New Indication: • Treatment of patients aged 12 years and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable
Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert and clinical prior authorization policy was updated during annual policy review April 2019 P&T; no further update needed.

Fulvestrant (Faslodex®) Syringe
Expanded FDA-approved or New Indication: • HR-positive, HER2-negative advanced or metastatic breast cancer in postmenopausal women in combination with ribociclib, as initial endocrine based therapy or following disease progression on endocrine therapy
Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN) so no updates to the policy are warranted.

Ceftazidime/Avibactam (Avycaz®) Vial
Expanded FDA-approved or New Indication: • Complicated intra-abdominal infectins (cIAI), used in combination with metronidazole, in adult and pediatric patients 3 months and older • Complicated urinary tract infections (cUTI), including pyelonephritis, in adult and pediatric patients 3 months and older • Hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) in patients 18 years and older
Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert and update clinical prior authorization clinical policy.

Certolizumab (Cimzia®)
Expanded FDA-approved or New Indication: • Treatment of adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation

Decision: Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert and update clinical prior authorization clinical policy with new indication for June P&T.

Drug Safety Monitoring:

Uloric (febuxostat): Boxed Warning Added - Due to Increased Risk of Death with Gout Medicine intended for: Health Professional, Patient, Pharmacy

ISSUE:

FDA has concluded there is an increased risk of death with Uloric (febuxostat) compared to another gout medicine, allopurinol. This conclusion is based on our in-depth review of results from a safety clinical trial that found an increased risk of heart-related death and death from all causes with Uloric.

RECOMMENDATION:

Patients should:

- Tell your health care professional if you have a history of heart problems or stroke and discuss the benefits and risks of using Uloric to treat your gout. Do not stop taking Uloric without first talking to your health care professional, as doing so can worsen your gout. Seek emergency medical attention right away if you experience the following symptoms while taking Uloric:
    - Chest pain
    - Shortness of breath
    - Rapid or irregular heartbeat
    - Numbness or weakness on one side of your body
    - Dizziness
    - Trouble talking
    - Sudden severe headache

Health care professionals should:

- Reserve Uloric for use only in patients who have failed or do not tolerate allopurinol. Counsel patients about the cardiovascular risk with Uloric and advise them to seek medical attention immediately if they experience the symptoms listed above.
- Health care professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:
    - Complete and submit the report Online: www.fda.gov/MedWatch/report

Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

Xeljanz, Xeljanz XR (tofacitinib): Drug Safety Communication - Safety Trial Finds Increased Risk of Blood Clots in the Lungs and Death with Higher Dose in Rheumatoid Arthritis Patients intended for: Patient, Health Professional, Pharmacy, Rheumatology.

ISSUE:

FDA is alerting the public that a safety clinical trial found an increased risk of blood clots in the lungs and death when a 10 mg twice daily dose of tofacitinib (Xeljanz, Xeljanz XR) was used in patients with rheumatoid arthritis (RA). FDA has not approved this 10 mg twice daily dose for RA; this dose is only approved in the dosing regimen for patients with ulcerative colitis.

RECOMMENDATION:

Patients should:

- Not stop or change your dose of tofacitinib without first talking to your health care professional, as doing so may worsen your condition. Patients taking tofacitinib should seek medical attention immediately if you experience symptoms of a blood clot in your lungs or other unusual symptoms such as:
    - Sudden shortness of breath or difficulty breathing
    - Chest pain or pain in your back
    - Coughing up blood
    - Excessive sweating
    - Clammy or bluish colored skin

Health care professionals should:

- Should follow the recommendations in the tofacitinib prescribing information for the specific condition they are treating. Monitor patients for the signs and symptoms of pulmonary embolism, and advise them to seek medical attention immediately if they experience them.
- Health care professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:
    - Complete and submit the report Online: www.fda.gov/MedWatch/report

Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert.

FDA not objecting to losartan with NMBA below 9.82 ppm remaining on the market

ISSUE:

To ensure patient access to losartan, FDA will not object to certain manufacturers temporarily distributing losartan containing N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) above the interim acceptable intake limit of 0.96 parts per million (ppm) and below 9.82 ppm until the impurity can be eliminated. The agency expects many companies will be able to manufacture losartan without nitrosamine impurities and replenish the U.S. supply in approximately six months.

Agency scientists evaluated the risk of exposure to NMBA at levels up to 9.82 ppm and determined that it presents no meaningful difference in cancer risk over a six-month time period when compared to a lifetime of exposure to NMBA at 0.96 ppm. Distributing losartan containing NMBA up to 9.82 ppm, will help maintain adequate losartan supply while companies obtain approval for manufacturing processes that produce nitrosamine-free losartan for patients.

RECOMMENDATION:

Patients should:

- FDA reminds patients taking recalled losartan to continue taking their current medicine until their pharmacist provides a replacement or their doctor prescribes a different medication that treats the same condition. Untreated hypertension (high blood pressure) leads to an increase in the risk of heart attacks and stroke. Untreated heart failure increases the risk of hospitalization and death. Untreated diabetic nephropathy (kidney disease) leads to worsening renal (kidney) disease.

FDA continues to work with companies and international regulators to ensure products entering the U.S. market do not contain nitrosamine impurities. **FDA updated list of valsartan products under recall:** https://www.fda.gov/downloads/Drugs/DrugSafety/UCM615703.pdf **FDA updated list of vasartan prodcuts not under recall:** https://www.fda.gov/downloads/Drugs/DrugSafety/UCM615704.pdf **FDA updated list of irbesartan products under recall:** https://www.fda.gov/downloads/Drugs/DrugSafety/UCM629626.pdf **FDA updated list of losartan products under recall:** https://www.fda.gov/downloads/Drugs/DrugSafety/UCM628993.pdf **Learn more about the Recall: Questions and Answers About the Recalls:** https://www.fda.gov/Drugs/DrugSafety/ucm626122.htm
Inform prescribers via Healthcare Services Medical & Pharmacy Policy Alert and to visit the websites listed above for the most recent recall information.

Other Formulary Changes:

Drug/Policy Name	Recommendation
Buprenorphine hcl 2 mg tablets and buprenorphine/naloxone 2mg-0.5 mg tablets	Change Quantity Limit from 3 tablets per day to 4 tablets per day for all lines of business
Buprenorphine hcl/naloxone hcl (Suboxone®) Film and tablet	Quantity Limit change for Commercial and Medicaid. • 4 mg-1 mg, 2 mg-0.5: 4 films per day • 2 mg-0.5 mg: 4 films per day
Chlorpheniramine maleate/codeine phosphate (Tuxarin® ER) Tab ER 12H	New combination. • Commercial/Medicaid: Non-Formulary, Prior Authorization ○ Add to New Formulations and Medications without established benefit policy • Medicare Part D: Non-Formulary

Chlorzoxazone Tablet	New generic. • Commercial/Medicaid: Non Formulary, Prior Authorization Added to New Medications and Formulations without established benefit policy
Elapegademase-lvlr (Revcovi®)	Add to formulary. • Commercial: Formulary, Non-Preferred Specialty, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Specialty, Prior Authorization
Estradiol (Vagifem®) Tablet	• Commercial: Change from Formulary, Non-Preferred Brand to Formulary, Non-Preferred Generic • Medicare Part D: Add generic to Formulary, Non-Preferred Generic tier
Fexofenadine hcl (Children's Allegra Allergy) Tab Rapdis	Remove from Medicaid formulary, keep prior authorization
Fluticasone furoate (Flonase® Sensimist) Spray Sus	Remove from Medicaid formulary, keep prior authorization
Interferon Beta-1A (Avonex®) Syringekit/kit	Add Quantity Limit (4 injections per 28 days) to align with other multiple sclerosis drugs for Commercial and Medicaid
Ipratropium bromide (Atrovent®) Spray	Remove from Medicaid formulary, keep prior authorization
Ivermectin (Soolantra®) Cream	Change Quantity Limit to 45 grams per 30 days for Commercial and Medicaid
Loteprednol etabonate (Lotemax® SM) Drops Gel	New strength. • Commercial: Formulary, Non-Preferred Brand • Medicaid: Formulary • Medicare Part D: Formulary, Preferred Brand
Meloxicam (Qmiiz ODT®) tab rapdis	New dosage form • Commercial/Medicaid: Non-Formulary, Prior Authorization ○ Add to New Formulations and Medications without established benefit policy • Medicare Part D: Non-Formulary
Naloxone hcl (Narcan®) Spray	Change Quantity Limit from 2 doses per year to 2 doses per 30 days for Commercial and Medicaid
Netarsudil mesylate/latanoprost (0.02-0.005) (Rocklatan®) drops	New Combination: Non-Formulary for all lines of business
Oxycodone myristate (Xtampza® ER) Capsule	Add to Formulary. Commercial: Formulary, Non-Preferred Brand, Prior Authorization, Quantity Limit (2 capsules per day)

	Add to long-acting opioid policy
prenatal vitamins no.147/ferrous gluconate/folic acid (Azesco®) Tablet	Non-Formulary for all lines of business
Sumatriptan succinate (Sumavel Dosepro®) NDL FR INJ	Add Quantity Limit of 4 ml per 30 days for Commercial and Medicaid
Tacrolimus (Prograf®) Gran Pack	New Dosage Form and Strength ([0.2 mg/gran pack]; [1 mg/gran pack]). • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Formulary, Specialty, Prior Authorization (new starts) Criteria: 1. Documentation that medically necessary dose of tacrolimus cannot be achieved through use of generic tacrolimus capsules (which are available in 0.5, 1, and 5 mg strengths) OR 2. Documentation that the patient has difficulty swallowing generic tacrolimus capsules
Tildrakizumab-asmn (Ilumya®) Syringe	Move from Therapeutic Immunomodulators policy to Medically Infused Therapeutic Immunomodulators (Tims) policy • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization
Trastuzumab-hyaluronidase-oysk (Herceptin Hylect®) Vial	New combination. • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization Added to Injectable ANTI-Cancer Medications policy

The formulary status for the following drugs was line extended in accordance with Providence Health Plan Pharmacy Operational Policy ORPTCOPS062

INFORMATIONAL ONLY

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS	

Erenumab-aooe (Aimovig® Autoinjector) Auto Injct	New strength (140 mg/5ml). Line extend with Aimovig 70ml/ml autoinjector. • Commercial/Medicaid: Non-Formulary, Prior Authorization ○ Added to Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists Policy • Medicare Part D—NF
Dexamethasone (Dxevo®) Tab DS PK	New Package Size Line extend with DexPak. • Non-Formulary for all lines of business
Atezolizumab (Tecentriq®) Vial	New Package Size (840 mg/14 ml). Line extend with Tecentriq 1200mg/20ml. • Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization Added to Injectable Anti-Cancer Medications Policy

Health Plan Clinical Policy Changes:

Policy Name	Change Summary
Abstral, Fentora, Lazanda, Subsys	Added that documentation of breakthrough cancer pain must be supported by chart notes. Added prescriber restrictions (must be prescribed by or in consultation with an oncologist or pain specialist) and reauthorization criteria.
Aranesp, Epogen, Procrit, Retacrit	The coverage duration was updated to one year for both initial and reauthorization. A review of claims data shows very little inappropriate utilization after initial approval (all submitted lab values were within range); therefore, these claims will no longer be pended for review.
CFTR Modulators	Criteria preferring Symdeko over Kalydeco was removed as these are similar cost and choice of therapy should be left to the prescriber.
Daliresp	The policy criteria was updated to match the current FDA-approved indication. In addition, specific confirmatory diagnostic criteria was removed to improve operational burden of this prior authorization.

Fentanyl Citrate	Added that documentation of breakthrough cancer pain must be supported by chart notes. Added prescriber restrictions (must be prescribed by or in consultation with an oncologist or pain specialist) and reauthorization criteria.
Gonadotropin Releasing Hormone Agonists	Vantas (histrelin implant) was added to this policy to align with other agents in this class. Effective: 09/01/2019
Krystexxa	Removed criteria that required trial of lesinurad (Zurampic®), as this drug has been withdrawn from the market.
Long Acting Opioids	Criteria was updated for some of the drugs on this policy as follows: created separate criteria for Butrans and Belbuca and added tramadol ER as another trial and failure option. Added requirement that approval of Belbuca will also require trial of Butrans. Removed separate criteria for Xtampza and added to the criteria for Avinza, Exalgo,
Maximum Allowable Opioid Dose	Removed criteria for Medicaid on conditions of the back and spine as requirement is changing per Oregon Health Authority (OHA).
Medicaid Intranasal Medications	The policy was updated to align with the OHA preferred drug list and prior authorization criteria. The acceptable comorbidities were narrowed to asthma (without inhaled steroid therapy), acute/chronic sinusitis, and sleep apnea. In addition, the requirement for oral antihistamine use was removed and the preferred intranasal therapy was limited to fluticasone propionate (Flonase®).
Nucynta	Increase initial approval length to 1 year. Changed covered uses to "Relief of moderate to severe pain"
Oxymorphone (Opana)	Removed criteria for Medicaid on conditions of the back and spine as requirement is changing per OHA.
Revcovi	Revcovi® may be approved as a “bridge” therapy before undergoing HSCT or a HSC-Gene Therapy clinical trial if a donor/ clinical trial has been identified (subject to policy coverage durations). A recent consensus approach statement for the management of ADA-SCID recommends enzyme replacement therapy at time of diagnosis followed by definitive treatment with HSCT or HCSC-Gene Therapy.
Second and Third generation antihistamines – Medicaid	The policy was reviewed for alignment with the OHA preferred drug list and Prior Authorization criteria. "Routine use of oxygen therapy” was removed as an acceptable comorbidity, as this is not included in the OHA criteria.

Therapeutic Immunomodulators – Comm and Medicaid	Updating clinical policy with Cimzia's new indication for use in adult patients with non-radiographix axial spondyloarthritis (nr-axSpA) with objective signs of inflammation; no clinical criteria required as it is the only medication FDA approved for non-radiographic axial spondyloarthritis.
Triptan QL	Removing neurologist provider restriction. Increasing quantity limits for sumatriptan injectable (Medicaid and commercial lines of business) to four (4) doses per 30 days (including Sumatriptan Dosepro)
Xolair	For asthma, modifying number of months' patient needs to be adherent inhalers (from 6 months to 3 months) to be in-line with IL-5 and Dupixent® policies. Modifying reauthorization criteria for asthma to "Reauthorization documentation of response to therapy, such as attainment and maintenance of remission or decrease.
The following policies were retired effective 8/1/2019. • Duzallo, Zurampic • Trelegy Ellipta – MAPD – Effective: 06/01/2019 (chair vote) • Ocrevus	

New Policies:

Botulinum Toxin-Commercial	New policy. Replaces Medical Policy 209 - Drug: Botulinum Toxin Types A and B.
Botulinum Toxin – Medicare Part B	New policy. Replaces Medical Policy 209 - Drug: Botulinum Toxin Types A and B.

New Generic Medications

First time generics to market
• **Norethindrone acetate-ethinyl estradiol/ferrous fumarate (Aurovela® 24 FE) Tablet -** Line extend as generic Loestrin 24 FE. ○ Commercial: Formulary, ACA Preventive ○ Medicaid: Formulary ○ Medicare Part D: Formulary, Non-Preferred Generic
• **Levorphanol tartrate 3 mg -** Non-formulary for all lines of business

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- **Deferasirox Tab Disper -** First generic (Exjade). Line extend as generic.
  - Commercial: Formulary, Non-Preferred Specialty
  - Medicaid: Formulary
  - Medicare Part D: Formulary, Specialty
- **Praziquantel Tablet -** First Generic (Biltricide). Line extend as generic.
  - Commercial: Formulary, Non-Preferred Generic, Quantity Limit (12 tablets per 30 days)
  - Medicaid: Non-Formulary, Quantity Limit (12 tablets per 30 days)
  - Medicare Part D: Non-Formulary
- **Pyridostigmine Bromide -** First generic (Mestinon). Line extend as generic.
  - Commercial/Medicare Part D: Formulary, Non-Preferred Generic
  - Medicaid: Formulary
- **Norethindrone acetate-ethinyl estradiol/ferrous fumarate (Tarina® 24 FE) Tablet -** Line extend as generic Loestrin 24 FE.
  - Commercial: Formulary, ACA Preventive
  - Medicaid: Formulary
  - Medicare Part D: Formulary, Non-Preferred Generic
- **Aliskiren Hemifumarate (Aliskiren) Tablet -** First generic (Tekturna). Line extend as generic.
  - Commercial: Formulary, Non-Preferred Generic
  - Medicaid: Non-Formulary
  - Medicare Part D: Non-Formulary
- **Ranolazine ER (Ranolazine) Table ER 12H -** First generic (Ranexa). Line extend as generic.
  - Commercial: Formulary, Non-Preferred Generic, Step Therapy, Quantity Limit (2 tablets per day)
  - Medicaid: Non-Formulary, Step Therapy, Quantity Limit (2 tablets per day)
  - Medicare Part D: Formulary, Non-Preferred Generic
- **Diclofenac epolamin Patch -** First generic (Flector). Line extend as generic.
  - Commercial: Formulary, Non-Preferred Generic, Step Therapy
  - Medicaid: Non-Formulary, Step Therapy
  - Medicare Part D: Non-Formulary
- **Treprostinil sodium (Treprostinil) Vial -** First generic (Remodulin). Line extend as generic.
  - Commercial/Medicaid: Medical Benefit, Prior Authorization
    - Add to Pulmonary Arterial Hypertension Policy
  - Medicare Part D: Non-Formulary
  - Medicare Part B: Medical Benefit, Prior Authorization
    - Pulmonary Arterial Hypertension Policy - Medicare Part B
- **Ambrisentan Tablet -** First generic (Letairis). Line extend as generic.
  - Commercial: Formulary, Specialty, Prior Authorization
  - Medicaid: Formulary, Prior Authorization

▪ Add to Pulmonary Arterial Hypertension Policy ○ Medicare Part D: Formulary, Specialty	
• **Solifenacin succinate Tablet -** First generic (Vesicare). Line extend as generic. ○ Commercial: Formulary, Non-Preferred Generic, Step Therapy ○ Medicaid: Non-Formulary, Step Therapy ○ Medicare Part D: Formulary, Non-Preferred Generic	
• **Valrubicin Vial -** First generic. Line extend as generic Valstar. ○ Commercial/Medicaid: Medical Benefit ○ Medicare Part D: Non-Formulary ○ Medicare Part B: Medical Benefit	