PROVIDENCE Health Plan

PROVIDENCE Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 253

November 1, 2020

This is the November 1, 2020 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-pharmacy-policy-and-provider-information/

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

FDA Recalls:

BDA Alaris™ System Infusion Pump.
FDA recall information is linked here:
https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bd-provides-update-previously-disclosed-recall-bd-alaris-system-hardware

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

MEDICAL POLICY COMMITTEE

Effective 1/1/2021, Providence Health Plan and Providence Health Assurance will be integrating behavioral health services into our network. Therefore, the following medical policies (new and existing) have been created and/or annually updated for the 1/1 implementation. *Note: these policies and associated coding configuration will not apply to OHP or the PSJH lines of business.*

Effective January 1, 2021

Cranial Electrical Stimulation BH001	**New Policy** Cranial electrical stimulation will deny not medically necessary and not covered for the treatment of any indication, including but not limited to depression or anxiety disorders. **Codes/PA:** One unlisted code
Ultra-Rapid Detoxification **BH002**	**New Policy** Ultra-rapid detoxification is considered not medically necessary and not covered for the treatment of any indication, including but not limited to, withdrawal from opioid dependence. • Note added to criteria: "This policy does not apply to detoxification or emergency detoxification, which may be considered medically necessary." **Codes/PA:** One unlisted code
Applied Behavior Analysis **BH003**	**New Policy** Applied Behavior Analysis (ABA) will be considered medically necessary and covered when criteria are met, in accordance with the Oregon and Washington state mandates. This includes the ABA assessment, initiation of treatment, and continuation of treatment. **Codes/PA:** ABA will require PA. This includes the ABA assessment, initiation of ABA treatment, and continuation review of ABA treatment every 12 months.
Extended Outpatient Psychotherapy (All Lines of Business Except Medicare) **BH004**	**New Policy** • Implement new BH medical policy for *extended* outpatient psychotherapy that will be used for outlier management and fraud/waste/abuse audits. No PA required, no claim edits. • Policy outlines multiple indications for medically necessary extended psychotherapy (e.g., acute crisis, prolonged exposure therapies, EDMR, etc). All indications based on well-established clinical practice guidelines. **Codes/PA:** No PA or claim edits will be configured. The following codes have been added to the policy and may be used to identify "extended" outpatient psychotherapy. Claims for psychotherapy in excess of 90+ minutes may require medical necessity review. 90837 — Psychotherapy, 60 minutes with patient 90838 — Psychotherapy, 60 minutes with patient when performed with an evaluation and

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<tr><td>Extended Outpatient Psychotherapy (Medicare Only)

BH007</td><td>
New Policy
Recommendation:
• Local Coverage Determination (LCD): Psychiatry and Psychology Services (L34616)
• Local Coverage Article: Billing and Coding: Psychiatry and Psychology Services (A57480)
According to the LCA, “for psychotherapy sessions lasting longer than 90 minutes, reimbursement will only be made if the report is supported by the medical record documenting the face-to-face time spent with the patient and the medical necessity for the extended time.”
Codes/PA: No PA or claim edits will be configured. The following codes have been added to the policy and may be used to identify “extended” outpatient psychotherapy. Claims for psychotherapy in excess of 90+ minutes may require medical necessity review.
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<tr><td>Transcranial Magnetic Stimulation (All Lines of Business Except Medicare)

BH005</td><td>
New Policy
Initial and subsequent use of transcranial magnetic stimulation (TMS) may be considered medically necessary and covered for the treatment of major depressive disorder when criteria are met. Use of TMS maintenance therapy, or use of TMS for the treatment of behavioral disorders other than clinical depression (e.g. obsessive-compulsive disorder (OCD) and migraine with aura) are considered not medically necessary.
Codes/PA: TMS will require PA
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<tr><td>Transcranial Magnetic</td><td>New Policy</td></tr>
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Stimulation (Medicare Only) **BH006**	• Local Coverage Determination (LCD): Repetitive Transcranial Magnetic Stimulation (rTMS) in Adults with Treatment Resistant Major Depressive Disorder (L37008) • Local Coverage Article: Billing and Coding: Repetitive Transcranial Magnetic Stimulation (rTMS) in Adults with Treatment Resistant Major Depressive Disorder (A57693) **Codes/PA:** TMS will require PA
Psychological and Neuropsychological Testing (All Lines of Business Except Medicare) **BH008**	**New Policy** Implement expanded medical policy with medically necessary criteria for psychological and neuropsychological testing when criteria are met. Psychological testing inventories are based on InterQual® Behavioral Health Procedures Psychological Testing policies. Neuropsychological testing criteria, with two new indications included by InterQual®, have been added to the policy from our current "Neuropsychological Testing (All Lines of Business Except Medicare)" policy, which will now be archived. Psychological testing inventories include: • Millon® Adolescent Clinical Inventory (MACI®) • Minnesota Multiphasic Personality Inventory-2® • Minnesota Multiphasic Personality Inventory-Adolescent® (MMPI-A®) • Personality Assessment Inventory™ (PAI®) • Unspecified Symptom Validity Test (SVT) • Unspecified Tests Billing guideline added to policy that psych/neuropsych testing will be limited to 8 hours of testing and only once per calendar year. Anything beyond this may be subject to medical necessity review. **Codes/PA:** As of 1/1, no PA will be required for psych or neuropsych testing. CPT codes will be paired to pay with diagnosis codes for the medically necessary indications for psych and neruopsych testing outlined by the InterQual policies.
Psychological and Neuropsychological Testing (Medicare Only) **BH009**	**New Policy** Psychological and neuropsychological testing is considered medically necessary when Medicare criteria from the documents below are met. • Local Coverage Determination (LCD): Psychological and Neuropsychological Testing (L34646) • Local Coverage Article: Billing and Coding: Psychological and Neuropsychological Testing (A57481) • CMS Publication 100-02; Medicare Benefit Policy Manual, Chapter 15- Covered Medical and Other Health Services: §80.2 Psychological and Neuropsychological Tests Our current "Neuropsychological Testing (Medicare Only)" policy will be archived and now addressed in this policy. **Codes/PA:** As of 1/1, no PA will be required for psych or neuropsych testing.

Biofeedback and Neurofeedback
 	
MED438
	New Policy
	Implement new policy for biofeedback and neurofeedback with the following criteria:
	• Medically necessary criteria for biofeedback includes urinary incontinence, migraine headaches, chronic cancer pain, and chronic constipation
	• Not medically necessary criteria for biofeedback with EEG monitoring/neurofeedback for the following indications:
	  ○ Anxiety
	  ○ Attention deficit hyperactivity disorder
	  ○ Autism spectrum disorder
	  ○ Depression
	  ○ Obsessive-compulsive disorder
	  ○ Post-traumatic stress disorder
	  ○ Substance use disorder
	  ○ Asthma
	  ○ Epilepsy

	○ Fibromyalgia ○ Primary headaches ○ Traumatic brain injury **Codes/PA:** Add 4 new codes: 90875, 90876, 90901, and E0746 • 90875, 90876, and 90901 would be configured to deny NMN with diagnosis codes for the non-covered indications above.
Drug Testing for Therapeutic or Substance Use Monitoring (All Lines of Business Except Medicare) **LAB361**	**Annual Update** • Title change to reflect the addition of hair and oral fluid drug testing. These testing methodologies will be considered not medically necessary. • Definitive UDT in excess of 7 drug classes (G0481) will now deny not medically necessary. • All other existing UDT limits will stay in effect. These are as follows: ○ Covered presumptive UDT is limited to CPT codes 80305, 80306, and 80307 (PHP Payment Policy 28.0) when medical policy criteria are met. ○ Covered definitive UDT is limited to CPT code G0480 (PHP Payment Policy 28.0) when an unexpected presumptive test warrants further, specific definitive testing (i.e., presumptive testing must precede definitive testing). ○ Definitive testing may only be performed by an independent laboratory or outpatient hospital (PHP Payment Policy 28.0). ○ Covered definitive UDT is limited to 14 tests in a 12-month period (PHP Payment Policy 28.0). **Codes/PA:** ○ 0227U (presumptive testing of 30 or more analytes) adding to policy to deny NMN; new code for 1/1. ○ G0481 (definitive testing for 8-14 drug classes) will now deny NMN ○ Two codes are being added that are specific to drug testing using "oral fluid". These are proprietary lab codes and can only be billed for the lab tests they are specific to. ▪ 0011U: Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, using oral fluid, reported as a comparison to an estimated steady-state range, per date of service including all drug compounds and metabolites ▪ 0116U: Prescription drug monitoring, enzyme immunoassay of 35 or more drugs confirmed with LC-MS/MS, oral fluid, algorithm results reported as a patient-compliance measurement with risk of drug to drug interactions for prescribed medications ○ Both 0011U and 0116U will be configured to deny NMN. 0116U is already denying per the Investigational Medical Technologies policy. The code will be removed from the IMT policy and will now deny per the drug testing policy.
Drug Testing for Therapeutic or Substance Use Monitoring (Medicare Only) **LAB414**	**Annual Update** No change to relevant Medicare guidelines. Policy updated to new Medicare format. • Local Coverage Determination (LCD): Lab: Controlled Substance Monitoring and Drugs of Abuse Testing (L36707) • Local Coverage Article: Billing and Coding: Lab: Controlled Substance Monitoring and Drugs of Abuse Testing (A55030) Medicare does not address drug testing using oral fluid or hair samples; therefore, commercial criteria should be followed. ○ 0227U (presumptive testing of 30 or more analytes) adding to policy to deny NMN; new code for 1/1. ○ G0481 (definitive testing for 8-14 drug classes) will now deny NMN ○ Two codes are being added that are specific to drug testing using "oral fluid". These are proprietary lab codes and can only be billed for the lab tests they are specific to. ▪ 0011U: Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, using oral fluid, reported as a comparison to an estimated steady-state range, per date of service including all drug compounds and metabolites ▪ 0116U: Prescription drug monitoring, enzyme immunoassay of 35 or more drugs confirmed with LC-MS/MS, oral fluid, algorithm results reported as a patient-compliance measurement with risk of drug to drug interactions for prescribed medications ○ Both 0011U and 0116U will be configured to deny NMN. 0116U is already denying per the Investigational Medical Technologies policy. The code will be removed from the IMT policy and will now deny per the drug testing policy.
Vagus Nerve Stimulation	**Annual Update**

(All Lines of Business Except Medicare) **SUR363**	Liberalization of criterion I. to remove the specificity of partial onset (focal) seizures, and broaden to "treatment of seizures" when criteria are met. Vagus nerve stimulation remains investigational and not covered for the following indications: • Refractory depression • Alzheimer's disease • Obesity • Migraine headaches • Essential tremor **Codes/PA:** No change to coding/PA.
Vagus Nerve Stimulation (Medicare Only) **SUR446**	**Annual Update** No recommended changes to criteria. • Continue to apply Centers for Medicare & Medicaid Service (CMS) National Coverage Determination 160.18. ○ Per the NCD, as of February 15, 2019, CMS provides coverage for FDA-approved VNS devices for treatment resistant depression when criteria are met. This was in draft at the last annual review of this policy, and was implemented by CMS on 07/22/2020. See the NCD for details.
Deep Brain and Responsive Cortical Stimulation (All Lines of Business Except Medicare) **SUR195**	**Annual Update** No recommended changes to criteria. Deep brain stimulation remains investigational and not covered for the following indications: • Chronic Pain • Multiple Sclerosis • Epilepsy • Depression • Obsessive Compulsive Disorder • Tourette's Syndrome **Codes/PA:** No changes to coding or PA
Deep Brain and Responsive Cortical Stimulation (Medicare Only) **SUR395**	**Annual Update** No recommended changes to criteria. • Continue to apply the following Centers for Medicare & Medicaid Service (CMS) National Coverage Determinations: ○ Deep Brain Stimulation for Essential Tremor and Parkinson's Disease (160.24) ○ Electrical Nerve Stimulators (160.7) ○ Treatment of Motor Function Disorders with Electric Nerve Stimulation (160.2) **Codes/PA:** No changes to coding or PA
Complementary and Alternative Medicine **MED437**	**New Policy** • Adopting a new policy with an investigational statement for complementary and alternative medicine therapies. • Medicare guidance exists for some codes in this policy given the broad nature of the codes listed (unlisted codes, and infusion and injection codes). No specific guidance was identified for the specific services listed, however a National Coverage Determination or Local Coverage Determination/Article may still be applicable. A note to this effect was included in the Medicare section of the policy with a link to the Medicare website for searching the applicable document.

	Codes/PA: No PA or coding configuration will be implemented for this policy.

Effective 1/1/2021
Back Pain and Procedures Medical Policies

Back: Fusion and Decompression Procedures **SUR120**	**Annual Update** • ***Documentation requirements***: we have added the following documentation requirements: ○ Clinical notes documenting that the individual has been evaluated at least once by the requesting surgeon before submitting a request for surgery. ○ Medical records must document that a physical examination has been performed or reviewed by the operating surgeon within 3 months prior to surgery. ○ Clinical documentation of ***extent and response to*** conservative care (see Policy Guidelines), as applicable to the policy criteria, ***including outcomes of any procedural interventions, medication use and physical therapy notes*** ○ Imaging reports ○ Evaluation and documentation of ***the extent and specifics of one or more*** of the functional impairments or disabilities ○ Evaluation and appropriate management of associated cognitive, behavioral or addiction issues if and when present ○ Copy of radiologist's report(s) for diagnostic imaging (MRIs, CTs, etc.) completed within the past 12 months or at the time of onset of symptoms ▪ Imaging must be performed and read by an independent radiologist ▪ If discrepancies should arise in the interpretation of the imaging, the radiologist report will supersede • ***More restrictive pain and disability requirements***: We have added the following language to criterion I. (cervical laminectomy), criterion III. (thoracic/lumbar laminectomy) and criterion IV.D and IV.F(thoracic/lumbar fusion)((e.g. Criterion I.A.1a.-b): ○ Persistent, debilitating, neck or cervicobrachial radicular pain, secondary to spinal cord or nerve root compression; **and** ○ Documentation that age-appropriate activities of daily living have been moderately or severely impacted (see Policy Guidelines); **or** ○ Moderate to severe disability as measured by the Neck Disability Index (i.e. 15 points or higher on Neck Disability Index) (see Policy Guidelines for complete definition) • ***Smoking abstinence before cervical fusion****:* Per evidence review, we are requiring smoking abstinence for at least 4 weeks prior to cervical fusion. One non-evidence based clinical practice guideline (North American Spine Society (2013) does not required abstinence prior to cervical fusion. We already require abstinence prior to lumbar fusion. • ***II. Cervical laminectomy/fusion:*** Expanded list of eligible indications

	• ***IV.D***.: Deleted requirement that scoliosis must cause "functional impairment" prior to thoracic or lumbar fusion; "functional impairment" language now captured in prior criterion IV.D.1-2. ("spinal instability with disabling pain that in*terferes with age-appropriate activities of daily living "; or 2. severe disability as measured by the Oswestry Disability Index* (this is defined in the "policy guidelines" section) • ***Conservative treatment:*** ○ Conservative treatment lengthened from 6 weeks to 3 months prior to thoracic or lumbar laminectomy ○ Specific indications for which conservative treatment may be waived now listed in the "policy guidelines" ○ Requirement of at least 3 physical therapy visits ○ Added language specifying that patients' "symptoms must have failed to improve" and that conservative care is intended "as part of pre-operative surgery planning." ○ Other requirements in policy guideline ▪ Participation in a physical therapy program must last for the duration of conservative management (i.e. 3 months before surgery depending on the indication for surgery), including at least 3 physical therapy visits ▪ Oral analgesics (including anti-inflammatory medications, if not contraindicated) or participation in an interdisciplinary pain management program ▪ Oral corticosteroids (if not contraindicated) • ***Annulus repair devices (e.g. Barricaid):*** Added to list of investigational procedures per evidence review and plan survey. 4 of 4 payers deny annular closure devices as investigational. One large (manufacturer-funded) RCT showing good results, but with no long-term follow-up. • ***Repeat surgery*****:** Added to "policy guidelines": Repeat fusion may only be covered in the event that new symptoms have returned following resolution from prior surgery. Residual deficits from prior surgery will not be considered. ○ No payers address in criteria; one NASS clinical practice guideline (not evidence-based) approved for cervical fusion. • ***New Policy Guidelines:*** ○ Activities of daily living ○ Conservative treatments ▪ Indications which may be exempt from conservative care requirements ○ Low back pain ○ Myelopathy ○ Radiculopathy added from 2020 North American Spine Society guideline, per input from LS. ○ Persistent, debilitating pain (measured by VAS) ○ Neck Disability Index: Definition and scoring guide added to aid in interpretation of new "moderate to severe disability" requirement. ○ Oswestry Disability Index: Definition and scoring guide added to aid in interpretation of new "severe disability" requirement. ○ Repeat fusion **Codes/PA:**

	• 2 codes (0274T and 62380) which currently deny "not medically necessary" and "not a covered benefit" for CMS lines of business, will be configured to deny investigational. • Removing PA from posterior cervical fusion codes (22590, 22595 and 22600) and removing codes from the policy. We would never deny these due to patients' severe spinal instability. We will be removing PA for these codes and let them pay. In 2019, we received only 88 PA's, only 6 of which denied (5 for OHP).
Back: Artificial Intervertebral Discs (All Lines of Business Except Medicare) **SUR138**	**Interim Update** Interim update to criteria to make consistent with changes in "Back: Fusion and Decompression Procedures" and "Back: Epidural Steroid Injections" policies. **We have liberalized and will consider cervical hybrid fusion procedures medically necessary when criteria are met for both an artificial disc and fusion.** **Documentation requirements***:* WE have added the following documentation requirements (based on "Back: Fusion and Decompression Procedures"): ○ Indication for the requested surgery ○ Clinical notes documenting that the individual has been evaluated at least twice by the requesting surgeon before submitting a request for injection. ○ Medical records must document that a detailed neurological examination has been performed by, or reviewed by the provider performing the injection, within 3 months prior to procedure. ○ Clinical documentation of extent and response to conservative care (see Policy Guidelines for all requirements), as applicable to the policy criteria, including outcomes of any procedural interventions, medication use and physical therapy notes ○ Evaluation and documentation of the extent and specifics of one or more of the functional impairments or disabilities ○ Evaluation and appropriate management of associated cognitive, behavioral or addiction issues if and when present ○ Copy of radiologist's report(s) for diagnostic imaging (MRIs, CTs, etc.) completed within the past 12 months or at the time of onset of symptoms ▪ Imaging must be performed and read by an independent radiologist ▪ If discrepancies should arise in the interpretation of the imaging, the radiologist report will supersede • **More restrictive pain and disability requirements**: we have replaced several criteria addressing conservative care and symptomology with criteria taken from "Back: Fusion and Decompression Procedures" • **Hybrid procedures:** We will cover cervical hybrid procedures (cervical fusion with cervical artificial intervertebral disc implantation) when criteria for artificial disc replacement are met. This recommendation is made on the basis of comparable safety and efficacy to fusion at 2-year follow-up. ○ III. "Cervical hybrid procedures (cervical fusion with cervical artificial intervertebral disc implantation) may be considered **medically necessary and covered** when both of the following criteria are met (A.-B.): A. For the artificial disc component of the hybrid procedure, criterion I. above is met; **and** B. For the cervical fusion component of the hybrid procedure when criteria in the policy "Back: Fusion and Decompression Procedures" are met.

- The following criteria have been copied over from relevant Fusion/Decompression criteria sections. See below:

Cervical Artificial Disc Replacement

- Physical and neurological abnormalities documented on physical exam suggestive of nerve root or spinal cord compression at the affected level (e.g., muscular weakness, sensory loss, hyperreflexia, reflex changes, myelopathy (see Policy Guidelines))
- At least one of the following criteria are met (1.-2.):
    - Imaging shows severe stenosis with cord signal changes;or
    - Exam shows major, progressive neurologic changes such as myelopathy or progressive weakness; o
    - Patient meets both of the following (a.-b.):
        - a. Persistent, debilitating, neck or cervicobrachial radicular pain (see Policy Guidelines), secondary to spinal cord or nerve root compression; and
        - b. Documentation that age-appropriate activities of daily living have been moderately or severely impacted (see Policy Guidelines); or Moderate to severe disability as measured by the Neck Disability Index (i.e. 15 points or higher on Neck Disability Index) (see Policy Guidelines for complete definition); or
    - Symptoms have failed to improve after 3 months **(up from 6 weeks**) conservative treatment (see Policy Guidelines for all requirements), as part of pre-operative surgery planning unless there is intolerable radicular pain (see Policy Guidelines), significant motor dysfunction, or progressive neurologic changes; and
- All other reasonable sources of radicular pain have been formally evaluated and ruled out; and

Lumbar Artificial Disc Replacement

- Persistent, debilitating, radicular pain (see Policy Guidelines) and at least one of the following criteria are met (1.-3.):
    - Documented moderate to severe interference of radicular pain with age-appropriate activities of daily living (see Policy Guidelines); or
    - Severe disability as measured by the Oswestry Disability Index (see Policy Guidelines) ; and
    - Neurological exam abnormalities and symptoms that correlate with spinal cord or nerve root compression that has been identified on neurological imaging studies; and
- Symptoms have failed to improve after 3 months (**down from 6 moths)** of conservative treatment (see Policy Guidelines for all requirements and exceptions), as part of pre-operative surgery planning, including but not limited to physical therapy (unless there is intolerable radicular pain (see Policy Guidelines)), significant motor dysfunction, or progressive neurologic changes); and
- Physical and neurological abnormalities documented on physical exam suggestive of nerve root or spinal cord compression at the affected level (e.g., muscular weakness, sensory loss, hyperreflexia, reflex changes, myelopathy (see Policy Guidelines); and
- Imaging studies (e.g., CT or MRI) indicate stenosis, or nerve root compression, or spinal cord compression at the level corresponding with above clinical findings; and

	• All other reasonable sources of radicular pain and/or neurological changes have been ruled out **New Policy Guidelines:** ○ Activities of daily living ○ Conservative treatments and list of example indications for which conservative care may be waived ○ Myelopathy ○ Radiculopathy ○ Persistent, debilitating pain (measured by VAS) ○ Neck Disability Index ○ Oswestry Disability Index
Back: Epidural Steroid Injections (All Lines of Business Except Medicare) **MED123**	**Annual Update** • **Documentation requirements***:* We have added the following documentation requirements (based on "Back: Fusion and Decompression Procedures"): ○ Indication for the requested procedure ○ Clinical notes documenting that the individual has been evaluated at least once by the requesting provider before submitting a request for injection (except in cases of malignancy, trauma, infection or rapidly progressive neurologic symptoms) ○ Medical records must document that a detailed neurological examination has been performed by, or reviewed by the provider performing the injection, within 3 months prior to procedure. ○ Clinical documentation of extent and response to conservative care (see Policy Guidelines for all requirements), as applicable to the policy criteria, including outcomes of any procedural interventions, medication use and physical therapy notes ○ Evaluation and documentation of the extent and specifics of one or more of the functional impairments or disabilities ○ Evaluation and appropriate management of associated cognitive, behavioral or addiction issues if and when present ○ Copy of radiologist's report(s) for diagnostic imaging (MRIs, CTs, etc.) completed within the past 12 months or at the time of onset of symptoms • Imaging must be performed and read by an independent radiologist • If discrepancies should arise in the interpretation of the imaging, the radiologist report will supersede. ***Initial Injections*** • **More restrictive pain and disability requirements**: We have added the following language to criterion I. B. "initial injections" (based on "Back: Fusion and Decompression Procedures"): B. Persistent, debilitating, radicular pain (see Policy Guidelines) and at least one of the following criteria are met (1.-3.):

1. Documented moderate to severe interference of radicular pain with age-appropriate activities of daily living (see Policy Guidelines); or
2. For thoracic/lumbar epidural steroid injections (ESIs), severe disability as measured by the Oswestry Disability Index (see Policy Guidelines); or
3. For cervical ESIs, moderate to severe disability as measured by the Neck Disability Index (i.e. 15 points or higher on Neck Disability Index) (see Policy Guidelines for complete definition).

- **Moved criteria:**
  - **I.D. is now I.F.** The injection is targeted to the documented impingement and/or contact point
- **Conservative treatment**: new requirements per North American Spine Society (NASS) guidelines

E. Symptoms have failed to respond to 6 weeks of conservative treatment (see Policy Guidelines for all requirements) within the last 6 months, including both of the following(1.-2.):

1. Physical therapy including either one the following (a.-b.)
   a. At least 3 physical therapy visits (including active muscle conditioning) over a course of 6 weeks or less; or
   b. Physical therapist's notes, or a physician's statement in the documentation explaining why physical therapy is contraindicated (e.g. progressively worsening pain and disability); and
2. Documented medication usage (e.g. narcotic analgesics, muscle relaxants, non-steroidal anti-inflammatory drugs) or participation in an interdisciplinary pain management program; and

- **Max number of nerve root levels per session:** New requirement per NASS guidelines.

I.G. No more than the maximum number of nerve root levels per session is performed (1.-2.)

1. Caudal and interlaminar: No more than 1 level per session may be performed and not in conjunction with an transforaminal injection.
2. Transforaminal: No more than 2 transforaminal ESIs may be performed at a single setting (e.g. single level bilaterally or two nerve root levels unilaterally)

- **New Policy Guidelines**:
  - Activities of daily living
  - Conservative treatments with list of example indications for which conservative care may be waived
  - Maximum number of nerve root levels per session
  - Repeat injections
  - Radiculopathy
  - Persistent, debilitating pain (measured by VAS)
  - Neck Disability Index
  - Oswestry Disability Index

	Repeat Injections
	
	• **III.A.:** Criteria for initial injections must now be met prior to offering a repeat injection (defined as an injection via same technique (e.g. interlaminar, caudal) at same location as past injection).
	• **III.B.** Language changes
	  ○ "Documentation of clinically relevant sustained pain reduction" now replaced with "documentation that initial injection resulted in greater than 50% radicular pain relief as measured by a standardized rating scale (e.g. ODI and NDI).
	  ○ "Improvement in patient's activities of daily living" replacing "improvement in the patient's functional abilities.
	Frequency Limitations
	• Per NASS guidelines (2020), no more than 4 ESIs may be performed in a 6-month period; no more than 6 ESIs should be performed per 12-month period, regardless of the number of levels involved.
	
	Non-Covered Indications
	• Interlaminar ESI's performed above C7 now called out as not medically necessary, per NASS guidelines
	• Changing denial from investigational to not medically necessary for ESIs with ultrasound guidance and various contraindications (expanded list per NASS).
	• Conscious sedation, Monitored Anesthesia Care (MAC), and intraoperative neuromonitoring (IONM) is considered **not medically necessary and not covered** when performed with an epidural steroid injection.
	Codes/PA:
	• **New billing guideline:** The following codes for monitored anesthesia and moderate sedation (CPT: 00300, 00600, 00620, 00630, 00640, 01992, 99152, 99153, 99156, 99157) will deny "not medically necessary" when billed with an epidural steroid injection(CPT: 62321, 64479, 64480, 62323, 64483, 64484).
	• 0228T-0231T: denials will change from "investigational" to "not medically necessary" per input from Dr. Soot.

Back: Epidural Steroid Injections (Medicare Only)
 	
MED391
	Annual Update
	• We changed the formatting to our new Medicare policy format
	• We continue to follow the following CMS guidance:
	  ○ **Cervical and Thoracic Injections**
	  ▪ Local Coverage Determination (LCD): Nerve Blockade for Treatment of Chronic Pain and Neuropathy (L35457)
	  ▪ Local Coverage Article: Billing and Coding: Nerve Blockade for Treatment of Chronic Pain and Neuropathy (A52725)
	  ○ **Lumbar Injections**
	  ▪ Local Coverage Determination (LCD): Lumbar Epidural Injections (L34980)
	  ▪ Local Coverage Article: Billing and Coding: Lumbar Epidural Injections (A57203)
	Codes/PA:

	• 2 codes added to policy, per inclusion on A57203 (CPT: 62326, 62327)

Back: Implantable Spinal Cord and Dorsal Ganglion Stimulation (All Lines of Business Except Medicare)
 	
SUR133
	Annual Update
	Criteria have been updated to match language of our other policies addressing pain (e.g. Back Fusion)
	• **Documentation requirements** section has been added to the policy, including medical records of indication, medical records of neurological exam performed within 3 months prior to implantation, clinical documentation of conservative care, documentation of extent and specifics of functional impairments or disabilities, documentation of cognitive and behavior health evaluation, and other appropriate medical records.
	• **Criterion I.A:** Language has been changed to require that patient experiences 'persistent debilitating' neuropathic pain. Definition added to Policy Guidelines.
	• **Criterion I.B:** "Documentation that age-appropriate activities of daily living have been moderately or severely impacted" has been added as a criterion. Definition of "activities of daily life" has been added to Policy Guidelines.
	• **Criterion I.C.1:** Added the presence of radicular pain to Failed Back Surgery Syndrome indication. Added definition of radicular pain to the Policy Guidelines.
	• **Criterion I.D:** Changed language to "conservative treatment" and added definition to the Policy Guidelines, rather than listing it in the criteria section.
	• **Conservative Treatment:** Removed narcotic drugs and spinal injections from the conservative treatment requirements. Neither have shown to be effective in this population. Included physical therapy visits, cognitive therapy, and therapy with NSAIDs, antidepressants, and anticonvulsants, which are commonly used to treat radicular nerve pain.
	• **Criterion I.D:** "Surgical intervention is not indicated and spinal cord stimulation treatment is used only as last resort" was added as a criterion.
	• **Criterion I.F:** Added that a psychological evaluation identifies no problematic emotional reactions, maladaptive thinking and behavior, and/or social problems that may contribute to pain and disability.* The psychological evaluation should include documentation of valid and reliable assessments of all of the following (1.-5.):
	  ○ subjective pain intensity; and
	  ○ mood and personality; and
	  ○ activity interference; and
	  ○ pain beliefs; and
	  ○ coping
	• **Criterion II:** Initial trial period length was changed from ≤ 2 days to 3-7 days, based on FDA and UpToDate recommendations.
	• **Criterion III:** "Chronic" was added to "non-specific back and leg pain" as an investigational condition
	• CARF-accredited management programs were removed from the requirements in the criteria and were removed from Policy Guidelines, due to the lack of access
	Codes/PA: No changes to codes or PA

Back: Implantable Spinal Cord and Dorsal Ganglion	**Annual Update** • We changed the formatting to our new Medicare policy format • We continue to follow the following CMS guidance: ○ National Coverage Determination (NCD) for Electric Nerve Stimulators (106.7)

Stimulation (Medicare Only) **SUR134**	○ Local Coverage Determination (LCD): Spinal Cord Stimulators for Chronic Pain (L36204) ○ Local Coverage Article: Spinal Cord Stimulators for Chronic Pain (A57792) **Codes/PA:** No changes to codes or PA

Effective 12/1/2020

Liver Tumor Treatment (All Lines of Business Except Medicare) **SUR273**	**Annual Update** No recommended criteria changes. Policy was split into all lines of business except Medicare and Medicare only due to differences between CMS guidance and policy criteria. **Codes/PA:** We recommend adding the unlisted code, 47379- Unlisted laparoscopic procedures on the liver.
Liver Tumor Treatment (Medicare Only) **SUR450**	**New Policy** • Due to more restrictive commercial criteria around yttrium 90 microspheres for colorectal metastases, we decided to split out policies to ensure compliance with CMS. • This policy follows CMS guidance: Local Coverage Article: Billing and Coding: Treatment with Yttrium-90 Microspheres (A52950) **Codes/PA:** • CPT codes C2616 and Q3001 (Y-90 treatment) to pay when configured with diagnosis codes provided in the LCA above. • We recommend adding the unlisted code, 47379- Unlisted laparoscopic procedures on the liver.

VENDOR UPDATES

EviCore

Effective 1/1/2021, alternative care providers will now need to utilize eviCore for PA requests when billing any codes found on the eviCore PA code list, as updated on 9/1/2020. For additional information on eviCore please follow this link Outpatient Rehabilitation.

Alternative Care Providers include:

- **Chiropractic**
- **Acupuncture**
- **Massage**
- **Naturopath**

Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting October 2, 2020
Go-Live Date: Friday, January 01, 2021, unless otherwise noted

Table of Contents:

New Drugs and Combinations:

1. **Inebilizumab-cdon (Uplizna®) Vial**
   a. **Indication**: For the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.
   b. **Decision:**

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-Formulary Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit			
Audit			
Formulary Alternatives: N/A			

   c. **Prior Authorization Criteria for Commercial/Medicaid/Medicare Part B**:

PA PROGRAM NAME	Uplizna
MEDICATION NAME	Inebilizumab injection
COVERED USES	All FDA-approved indications not otherwise excluded from the benefit.
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For Neuromyelitis Optica Spectrum Disorder (NMOSD), all of the following must be met: 1. Diagnosis of neuromyelitis optica spectrum disorder as defined as the following: a. Presence of at least one core clinical characteristic (optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, symptomatic cerebral syndrome with NMOSD-typical brain lesions) AND b. Anti-AQP4 antibody positive 2. Documentation that other alternative diagnoses have been excluded (i.e. Multiple Sclerosis) 3. Trial and failure, intolerance or contraindication to rituximab 4. Medication will not be used in combination with complement-inhibitor, anti-CD20-directed, anti-CD19 directed, or IL-6 inhibition pathway therapies 5. Dose and frequency is in accordance with FDA-approved labeling Reauthorization for Neuromyelitis Optica Spectrums Disorder (NMOSD): 1. Documentation of positive clinical response to therapy 2. Medication will not be used in combination with complement-inhibitor, anti-CD20-directed, anti-CD19 directed, or IL-6 inhibition pathway therapies 3. Dose and frequency is in accordance with FDA-approved labeling.
AGE RESTRICTIONS	Approved for ages 18 and older
PRESCRIBER RESTRICTIONS	Must be prescribed by a neurologist
COVERAGE DURATION	Initial authorization for up to 6 months and reauthorization will be approved for up to one year

2. Satralizumab (Enspryng®) Syringe

a. **Indication:** For the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

b. **Decision:**

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Formulary
Tier**	N/A	N/A	Specialty

Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit			
Audit			
Formulary Alternatives: Azathioprine			

c. Prior Authorization Criteria for Commercial/Medicaid:

PA PROGRAM NAME	Enspryng
MEDICATION NAME	Satralizumab injection
COVERED USES	All FDA-approved indications not otherwise excluded from the benefit.
EXCLUSION CRITERIA	N/A
AGE RESTRICTIONS	Approved for ages 18 and older
PRESCRIBER RESTRICTIONS	Must be prescribed by a neurologist
COVERAGE DURATION	Initial authorization for up to 6 months and reauthorization will be approved for up to one year
REQUIRED MEDICAL INFORMATION	For Neuromyelitis Optica Spectrum Disorder (NMOSD), all of the following must be met: 1. Diagnosis of neuromyelitis optica spectrum disorder as defined as the following: a. Presence of at least one core clinical characteristic (optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, symptomatic cerebral syndrome with NMOSD-typical brain lesions) AND b. Anti-AQP4 antibody positive 2. Documentation that other alternative diagnoses have been excluded (i.e. Multiple Sclerosis) 3. Trial and failure, intolerance or contraindication to rituximab 4. Medication will not be used in combination with complement-inhibitor, anti-CD20-directed, anti-CD19 directed, or IL-6 inhibition pathway therapies 5. Dose and frequency is in accordance with FDA-approved labeling Reauthorization for Neuromyelitis Optica Spectrums Disorder (NMOSD): 1. Documentation of positive clinical response to therapy 2. Medication will not be used in combination with complement-inhibitor, anti-CD20-directed, anti-CD19 directed, or IL-6 inhibition pathway therapies 3. Dose and frequency is in accordance with FDA-approved labeling

d. Prior Authorization Criteria for Medicare Part D:

PA PROGRAM NAME	Enspryng
MEDICATION NAME	Satralizumab injection
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
AGE RESTRICTIONS	Approved for ages 18 and older
PRESCRIBER RESTRICTIONS	Must be prescribed by a neurologist
COVERAGE DURATION	Initial authorization for up to 6 months and reauthorization will be approved for up to one year
REQUIRED MEDICAL INFORMATION	For Neuromyelitis Optica Spectrum Disorder (NMOSD), all of the following must be met: 1. Diagnosis of neuromyelitis optica spectrum disorder as defined as the following: a. Presence of at least one core clinical characteristic (optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, symptomatic cerebral syndrome with NMOSD-typical brain lesions) AND b. Anti-AQP4 antibody positive 2. Documentation that other alternative diagnoses have been excluded (i.e. Multiple Sclerosis) 3. Trial and failure, intolerance or contraindication to rituximab 4. Medication will not be used in combination with complement-inhibitor, anti-CD20-directed, anti-CD19 directed, or IL-6 inhibition pathway therapies 5. Dose and frequency is in accordance with FDA-approved labeling Reauthorization for Neuromyelitis Optica Spectrums Disorder (NMOSD): 1. Documentation of positive clinical response to therapy 2. Medication will not be used in combination with complement-inhibitor, anti-CD20-directed, anti-CD19 directed, or IL-6 inhibition pathway therapies 3. Dose and frequency is in accordance with FDA-approved labeling

3. Lurbinectedin (Zepzelca®) Vial

a. **Indication**: Treatment of adult patients with metastatic small cell lung cancer (SCLD) with disease progression on or after platinum-based chemotherapy

b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-Formulary Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit			
Formulary Alternatives: N/A			

c. **Prior Authorization Criteria**: Added to Injectable Anti-Cancer Medications Policy

4. **Pertuzumab-trastuzumab-hyaluronidase-zzxf (Phesgo) Vial**

a. **Indication**:

- Use in combination with chemotherapy as:
  - neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer
  - adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence
- Use in combination with docetaxel for treatment of patients with HER2 positive metastatic breast cancer (MBC) who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease

b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-Formulary Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A
Formulary Alternatives: trastuzumab, pertuzumab			

c. **Prior Authorization Criteria**: Added to Injectable Anti-Cancer Medications Policy

5. Fenfluramine hcl (Fintepla®) Solution

a. Indication: Indicated for the treatment of seizures associated with Dravet syndrome (DS) in patients 2 years of age and older

b. Decision:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Formulary
Tier**	Non-Preferred Specialty	Specialty	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A
Formulary Alternatives: valproic acid, clobazam, Diacomit, topiramate, Epidiolex®, levetiracetam			

c. Prior Authorization Criteria for Commercial/Medicaid:

PA PROGRAM NAME	Fintepla
MEDICATION NAME	Fenfluramine hcl (Fintepla) Solution
COVERED USES	All FDA-approved indications not otherwise excluded from the benefit.
EXCLUSION CRITERIA	Concomitant use of, or within 14 days of administration of monoamine oxidase inhibitors because of an increased risk of serotonin syndrome

REQUIRED MEDICAL INFORMATION	Initial Authorization: 1. Documentation that the patient has seizures associated with Dravet syndrome (DS) 2. Documented trial, failure, intolerance, or contraindication to two* of the following: (*Coverage for Medicaid requires only one of the following) a. Valproate/Valproic acid b. Clobazam c. Levetiracetam d. Topiramate e. Stiripentol f. Diazepam 3. Dose will not exceed 26 mg daily Reauthorization: 1. Documentation of positive response to therapy such as a decrease in seizure frequency or intensity since beginning therapy 2. Dose continues to not exceed 26 mg daily
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an epilepsy specialist or pediatric neurologist
COVERAGE DURATION	Initial authorization will be approved for 6 months and reauthorization will be approved for 1 year

d. Prior Authorization Criteria for Medicare Part D:

PA PROGRAM NAME	Fintepla
MEDICATION NAME	Fenfluramine hcl (Fintepla) Solution
PA INDICATION INDICATOR	3 – All Medically-Accepted Indications
EXCLUSION CRITERIA	Concomitant use of, or within 14 days of administration of monoamine oxidase inhibitors because of an increased risk of serotonin syndrome

REQUIRED MEDICAL INFORMATION	Initial authorization: 1. Documentation that patient has seizures associated with Dravet syndrome (DS) AND 2. Documented trial, failure, intolerance or contraindication to one of the following: valproate/valproic acid, clobazam, levetiracetam, topiramate, or diazepam AND 3. Dose will not exceed 26 mg daily
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an epilepsy specialist or pediatric neurologist
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan

6. **Fostemsavir tromethamine (Rukobia) Tab ER 12H**
   a. **Indication**: In combination with other antiretroviral (ARV) therapies, for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Formulary
Tier**	Non-Preferred Specialty	Specialty	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	60/30	60/30	N/A
Formulary Alternatives: Selzentry (maraviroc), Trogarzo (ibalizumab), Fuzeon (enfuvirtide)			

   c. **Prior Authorization Criteria for Commercial/Medicaid**: Added to Trogarzo policy

PA PROGRAM NAME	Trogarzo, Rukobia
MEDICATION NAME	Rukobia (fostemsavir)
COVERED USES	All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.
EXCLUSION CRITERIA	N/A

REQUIRED MEDICAL INFORMATION	Initial Authorization: 1. Inadequate response to six (6) months of treatment with anti-retroviral therapy (ART) and have failed therapy within the last 8 weeks a. Defined as persistent viremic failure b. Failure must not be due to non-adherence (adherence may be verified by pharmacy claims) 2. Documentation of multi-drug resistant human immunodeficiency virus (HIV)-1 infection with viral resistance to at least one antiretroviral medication from each of the three (3) following classes: a. Non-nucleoside reverse transcriptase inhibitor b. Nucleoside reverse transcriptase inhibitor c. Protease inhibitor 3. Documentation of baseline viral load 4. Confirmation that patient will take an optimized background regimen of anti-retroviral therapy (ART) along with Trogarzo™ or Rukobia™ therapy Re-authorization or continuation of therapy: 1. Patient has previously received treatment with Trogarzo™. 2. Documentation of a clinically significant decrease in viral load from baseline (prior to starting therapy) 3. Confirmation that patient will continue to take an optimized background regimen of anti-retroviral therapy (ART) with Trogarzo™ or Rukobia™ therapy
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an infectious disease specialist.
COVERAGE DURATION	Initial authorization will be approved for 6 months and reauthorization will be approved for 1 year

7. Sacituzumab govitecan-hziy (Trodelvy) Vial

a. Indication: Sacituzumab govitecan is FDA approved for the treatment of adult patients with metastatic TNBC who have received ≥2 prior therapies for metastatic disease.

- Sacituzumab govitecan was approved under an accelerated pathway and continued approval is contingent upon demonstration of clinical benefit in confirmatory trials.

b. Decision:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-Formulary; Part B: Medical
Tier**	N/A	N/A	N/A

Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit			
Formulary Alternatives: N/A			

c. **Prior Authorization Criteria**: Added to Injectable Anti-Cancer agents policy

8. **Ripretinib (Qinlock) Tablet**
   a. **Indication:** Treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib.
   b. **Decision:**

	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Formulary	Formulary	Formulary
Tier**	Non-Preferred Specialty	Non-Preferred Specialty	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	N/A	N/A
Formulary Alternatives: N/A			

   c. **Prior Authorization Criteria**: Added to Oral Anti-Cancer Medications policy

9. **Capmatinib hydrochloride (Tabrecta) Tablet**
   a. **Indication**: Treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.
   b. **Decision**:

	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Formulary	Formulary	Formulary
Tier**	Preferred Specialty	Specialty	Specialty
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit			

Formulary Alternatives: N/A

c. **Prior Authorization Criteria**: Added to Oral Anti-Cancer Medications policy

10. Selpercatinib (Retevmo) Capsule

a. Indication:

- Metastatic RET Fusion-Positive Non-Small Cell Lung Cancer (Adult)
- RET-Mutant Medullary Thyroid Cancer (12 years and older)
- RET Fusion-Positive Thyroid Cancer (12 years and older)

b. Decision:

	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Formulary	Formulary	Formulary
Tier**	Preferred Specialty	Specialty	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	N/A	60 capsules /30 days for 40mg strength to encourage dose optimization.	
Formulary Alternatives: N/A			

c. **Prior Authorization Criteria**: Added to Oral Anti-Cancer Medications policy

11. Brexucabtagene autoleucel (Tecartus) Plast. Bag

a. Indication: For the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).

b. Decision:

	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Medical	Medical	Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit			
Formulary Alternatives: N/A			

c. Prior Authorization Criteria for Commercial/Medicaid/Medicare Part B: Added to CAR-T policy

PA PROGRAM NAME	CAR-T
MEDICATION NAME	Brexucabtagene autoleucel
COVERED USES	All FDA-approved indications not otherwise excluded from the benefit.
EXCLUSION CRITERIA	• Previous treatment with chimeric antigen receptor therapy or other genetically modified T-cell therapy ○ Repeat administration of CAR-T therapy is considered experimental and investigational because the effectiveness of this approach has not been established • History of allogenic stem cell transplantation and primary central nervous system (CNS) lymphoma • Presence or history of CNS disorder such as seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, brain metastases, or any autoimmune disease with CNS involvement • Active infection or inflammatory disorder (including hepatitis B or C, human immunodeficiency virus [HIV], active graft vs. host disease)
REQUIRED MEDICAL INFORMATION	For all indications, the following criteria must be met: 1. Documentation of adequate bone marrow, cardiac, pulmonary and organ function (e.g., kidney) to minimize risks of serious adverse reactions (e.g., cytokine release syndrome) For relapsed or refractory mantle cell lymphoma (MCL), Tecartus® may be approved when all of the following criteria are met: 1. Histologically confirmed mantle-cell lymphoma [i.e. cyclin D1 overexpression or presence of the translocation t(11;14)] 2. Disease is considered relapsed or refractory 3. Previous use to the following therapy: anthracycline or bendamustine containing chemotherapy, an anti-CD20 monoclonal antibody, and BTK inhibitor therapy 4. Asymptomatic or minimally symptomatic with Eastern cooperative oncology group (ECOG) performance status 0-1
AGE RESTRICTIONS	Approved for 18 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by an oncologist
COVERAGE DURATION	2 months (limited to one treatment course per lifetime, with 4 doses of tocilizumab [Actemra®] at up to 800mg per dose).

12. Elagolix sodium-estradiol-norethindrone acetate (Oriahnn) Cap Seq

a. Indication: For the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.

b. Decision:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Formulary
Tier**	Non-preferred Brand	Brand	Non-preferred Drug
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit			
Formulary Alternatives: hormonal contraceptives			

c. Prior Authorization Criteria for Commercial/Medicaid: Added to GnRH Antagonists policy

PA PROGRAM NAME	GnRH Antagonists
MEDICATION NAME	Oriahnn
COVERED USES	All FDA-approved indications not otherwise excluded from the benefit.
EXCLUSION CRITERIA	Patient has osteoporosis or severe hepatic impairment Undiagnosed abnormal uterine bleeding

REQUIRED MEDICAL INFORMATION	For endometriosis (Orilissa® only): Initial Authorization 1. Documentation that patient has moderate to severe pain associated with endometriosis, AND 2. Documentation that patient has trial and failure of, intolerance to, or contraindication to hormonal contraceptives Reauthorization: 1. Request is for the 150 mg daily dose and total duration will not exceed 24 months, AND 2. Documentation of a positive response to therapy (e.g., reduction in pain) For management of heavy menstrual bleeding associated with uterine leiomyomas/fibroids (Oriahnn™ only): Initial Authorization 1. Documentation of confirmed diagnosis of uterine fibroids (e.g. ultrasound), AND 2. Documentation of heavy menstrual bleeding, AND 3. Documentation that patient has trial and failure of, intolerance to, or contraindication to hormonal contraceptives Reauthorization: 1. Total treatment duration will not exceed 24 months, AND 2. Documentation of a positive response to therapy (e.g., reduction in bleeding)
AGE RESTRICTIONS	May be covered for those patients at least 18 years old
PRESCRIBER RESTRICTIONS	Must be written by on in consultation with an obstetrician-gynecologist (OB-GYN)
COVERAGE DURATION	Orilissa® 150 mg once daily: Initial authorization for 6 months. Reauthorization for up to 18 months. No reauthorization beyond 24 months Orilissa® 200 mg twice daily: Initial authorization for 6 months. No reauthorization.

	Oriahnn™: Initial authorization for 6 months. Reauthorization for up to 18 months. No reauthorization beyond 24 months

d. Prior Authorization Criteria for Medicare Part D: Added to GnRH Antagonists policy

PA PROGRAM NAME	GNRH ANTAGONISTS
MEDICATION NAME	ORIAHNN
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Patient has osteoporosis or severe hepatic impairment. Undiagnosed abnormal uterine bleeding
REQUIRED MEDICAL INFORMATION	Initial authorization in endometriosis: 1. Documentation that patient has moderate to severe pain associated with endometriosis AND 2. Documentation that patient has trial and failure of, intolerance to, or contraindication to hormonal contraceptives. Reauthorization: 1. Request is for the 150 mg daily dose and total duration will not exceed 24 months AND 2. Documentation of a positive response to therapy (e.g., reduction in pain). Initial authorization in the management of heavy menstrual bleeding associated with uterine leiomyomas/fibroids (Oriahnn only): 1. Documentation of confirmed diagnosis of uterine fibroids (e.g. ultrasound), AND 2. Documentation of heavy menstrual bleeding, AND 3. Documentation that patient has trial and failure of, intolerance to, or contraindication to hormonal contraceptives. Reauthorization: 1. Total treatment duration will not exceed 24 months, AND 2. Documentation of a positive response to therapy (e.g., reduction in bleeding)
AGE RESTRICTIONS	Approved for patients 18 years of age and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, an obstetrician-gynecologist (OB-GYN)

COVERAGE DURATION	Initial: 6 mo. Reauth (Oriahnn, Orilissa 150 only): approved for a total treatment of 24 mo.
OTHER CRITERIA	N/A

13. Lactic acid-citric acid-potassium bitartrate (Phexxi) Gel PF App

a. **Indication**: Prevention of pregnancy

b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Non-formulary	Non-formulary
Tier**	ACA Preventive	N/A	N/A
Affordable Care Act Eligible	Yes	N/A	N/A
Utilization Management Edits	N/A	N/A	N/A
Quantity Limit			
Formulary Alternatives: oral hormonal contraception, condoms			

c. **Prior Authorization Criteria**: N/A

14. Triheptanoin (Dojolvi) Liquid

a. **Indication**: Indicated as a source of calories and fatty acids for the treatment of pediatric and adult patients with molecularly confirmed LC-FAOD.

b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Non-formulary
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit			
Formulary Alternatives: N/A			

c. **Prior Authorization Criteria**: Added to Medications For Rare Indications (Orphan Drugs) policy

New Strengths or Formulations:

1. **Bimatoprost (Durysta) Implant**
   a. **Indication**: For the reduction of intraocular pressure (IOP) in patients with open angle glaucoma (OAG) or ocular hypertension (OHT).
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-Formulary; Part B: Medical
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	N/A; Non-Formulary	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit			
Formulary Alternatives: N/A			

   c. **Prior Authorization Criteria**:

PA PROGRAM NAME	Durysta
MEDICATION NAME	Bimatoprost Implant
COVERED USES	All FDA-approved indications not otherwise excluded from the benefit.
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	The following criteria must be met: 1. The patient is not receiving re-treatment of eye(s) previously treated with Durysta 2. Trial and failure, intolerance or contraindication to at least two ophthalmic products (either as monotherapy or as concomitant therapy) from two different pharmacological classes, one of which is an ophthalmic prostaglandin
AGE RESTRICTIONS	May be covered for adults 18 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by an ophthalmologist
COVERAGE DURATION	Initial will be approved for 6 months. Approval will be for a one-time use in each treated eye (one implant per treated eye, a total of two implants per patient)

Other Formulary Changes:

Drug Name	Recommendation	Policy Name
Baclofen 5 mg Tablet	Add to formulary. • Commercial: Formulary, Tier 2 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 2	N/A
Emtricitabine/ tenofov alafenamide (Descovy) tablet	Remove from Commercial and Medicaid formularies	N/A
Azelastine HCl 205.5 mg spray	Retire Prior Authorization for Commercial/Medicaid • Commercial: Formulary, Tier 3 • Medicaid: Non-Formulary	Remove from New Medications and Formulations without Established Benefit
Amphetamine sulfate (Evekeo®) 5 and 10 mg tablets	Retire Prior Authorization for Commercial/Medicaid • Commercial/Medicaid: Non-Formulary	Remove from New Medications and Formulations without Established Benefit
Clobetasol 0.05% spray	Retire Prior Authorization for Commercial/Medicaid • Commercial/Medicaid: Non-Formulary	Remove from New Medications and Formulations without Established Benefit
Asenapine (Secuado) patch	Remove from New Medications and Formulations without Established Benefit policy and add to "Antipsychotic" step therapy policy • Commercial: Formulary, Tier 4, Step Therapy • Medicaid: Non-Formulary	Antipsychotics
Methylphenidate ER (Jornay PM®) capsules	Retire Prior Authorization for Commercial/Medicaid • Commercial/Medicaid: Non-Formulary	Remove from New Medications and Formulations without Established Benefit
Fluvoxamine SR capsules	Retire Prior Authorization for Commercial/Medicaid • Commercial: Formulary, Tier 4 • Medicaid: Non-Formulary	Remove from New Medications and Formulations without Established Benefit
Betamethasone valerate 0.12% foam	Retire Prior Authorization for Commercial/Medicaid • Commercial/Medicaid: Non-Formulary	Remove from New Medications and Formulations without Established Benefit
Paroxetine CR tablet (Paxil CR®)	Retire Prior Authorization for Commercial/Medicaid • Commercial: Formulary, Tier 3 • Medicaid: Non-Formulary	Remove from New Medications and Formulations without Established Benefit

Olmesartan/amlodipine/ hydrochlorothiazide tablets	Retire Prior Authorization for Commercial/Medicaid • Commercial (Standard): Formulary, Tier 2 • Commercial (Cost-Based): Formulary, Tier 3 • Medicaid: Non-Formulary	Remove from New Medications and Formulations without Established Benefit
Cyclopentolate 1% drops	Add to formulary for Commercial/Medicaid: • Commercial: Formulary, Tier 2 • Medicaid: Formulary	N/A
Cysteamine bitartrate (Cystagon) Capsule	Add to Medicaid formulary, Specialty	N/A
• **Flash glucose scanning reader (Freestyle Libre 2 Reader)** • **Flash glucose sensor (Freestyle Libre 2 Sensor)**	Medical Benefit, Prior Authorization • All Lines of Business	Continuous Glucose Monitors for Personal Use
Riluzole Tablet	Change tier for Commercial: • Commercial (Standard): Move from Tier 6 to Tier 2 • Commercial (Cost-Based): Move from Tier 6 to Tier 3 •	N/A
Clobazam (Sympazan) Film	Remove from Specialty for Commercial/Medicaid: • Commercial: Change from Tier 6 to Tier 4 • Medicaid: Remove Specialty	• Commercial/Medicaid: Sympazan
Levonorgestrel/ ethinyl estradiol (Twirla) Patch TDWK	New Dosage Form (Patch), Route (transdermal), and Strength (120-30/24H); • Commercial: Formulary, ACA • Medicaid: Non-Formulary • Medicare Part D: Non-Formulary	N/A
Memantine hcl IR Tablet	• Commercial/Medicaid: Remove Quantity Limit	N/A
Butalbital/acetaminophen/caffeine (Fioricet) Capsule	Retire Prior Authorization for Commercial/Medicaid • Commercial: Formulary, Tier 3 • Medicaid: Non-Formulary	New Medications and Formulations without Established Benefit

Alirocumab (Praluent Syringe) Syringe	• Commercial: Change from Tier 5 to Tier 6	PCSK9 Inhibitors - Commercial
Ustekinumab (Stelara) 45 mg/0.5mL Vial	• Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (0.5 mL per 84 days) • Medicaid: Formulary, Specialty, Prior Authorization, Quantity Limit (0.5 mL per 84 days)	• Commercial: Therapeutic Immunomodulators – Commercial • Medicaid: Therapeutic Immunomodulators – Medicaid
Colesevelam hcl Powd Pack	• Commercial: Remove from formulary	N/A
Colesevelam hcl Tablet	Add to Medicaid formulary	N/A
Simvastatin (Zocor) 80 mg Tablet	Add to Medicaid formulary	N/A
Azacitidine (Onureg®) tablet	New Route, Dosage Form, and Strength: • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid/Medicare: Formulary, Specialty, Prior Authorization	• Commercial/Medicaid: Add to Oral Anti-Cancer Agents • Medicare: Add to Anti-Cancer Agents
Dimethyl fumarate Capsule DR	First Generic (Tecfidera). • Commercial: Non-Formulary, Specialty, Quantity Limit (2 capsules per day) • Medicaid: Formulary, Quantity Limit (2 capsules per day) • Medicare Part D: Non-Formulary	N/A
Tacrolimus (Prograf) granule	Retire Prior Authorization for Medicare to align with Commercial/Medicaid	Prograf
Colesevelam tablet and powder pack	Retire Prior Authorization for Medicare to align with Commercial/Medicaid	Welchol

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

NEW DRUGS / COMBINATIONS / STRENGTHS / DOSAGE FORMS		
Drug Name	**Action Taken**	**Policy Name**
Romidepsin Vial	**Update from June 2020 P&T:** Add prior authorization to all lines of business.	Injectable Anti-Cancer Medications

Dupilumab (Dupixent Pen) Pen Injctr	New Dosage Form (Pen); Line extend with Dupixent; • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (4 mL per 28 days) • Medicaid: Non-Formulary, Specialty, Prior Authorization, Quantity Limit (4 mL per 28 days) • Medicare Part D: Tier 5, Prior Authorization	Dupixent
Bedaquiline fumarate (Sirturo) Tablet	New Strength (20mg). Line extend with Sirturo 100mg; • Commercial: Formulary, Tier 6 • Medicaid: Formulary, Specialty • Medicare Part D: Formulary, Tier 5	N/A
Etanercept (Enbrel) Vial	New Dosage Form (vial). Line extend with Enbrel 25mg/0.5 mL; • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (2 mL per 28 days) • Medicaid: Formulary, Specialty, Prior Authorization, Quantity Limit (2 mL per 28 days) • Medicare Part D: Formulary, Tier 5, Prior Authorization	• Commercial: Therapeutic Immunomodulators – Commercial • Medicaid: Therapeutic Immunomodulators – Medicaid • Medicare Part D: Therapeutic Immunomodulators
Dexamethasone (Zcort) Tab DS PK	New Dose Pack Size. Line extend with Taperdex, Hidex, Dxevo; • Non-Formulary for all lines of business.	N/A

New Generics:

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Metyrosine Capsule	First Generic (Demser). Line extend as generic; • Non-Formulary for all lines of business	N/A
Deferasirox Gran Pack	First Generic (Jadenu Capsule). Line extend as generic; • Commercial: Formulary, Tier 6 • Medicaid: Formulary, Specialty • Medicare Part D: Formulary, Tier 5	N/A

Ciprofloxacin-dexamethasone Drops Susp	First generic (Ciprodex). Line extend as generic;
	• Commercial:
	  ○ Standard: Generic – Formulary, Tier 2 (move Brand to Tier 4)
	  ○ Cost-Based: Formulary, Tier 3
	• Medicaid: Formulary
	• Medicare Part D: Formulary, Tier 3
		N/A

Pantoprazole sodium Granpkt DR	First generic (Protonix susp). Line extend as generic;
	• Commercial:
	  ○ Standard: Formulary, Tier 2
	  ○ Cost-Based: Formulary, Tier 4
	• Medicaid: Formulary
	• Medicare Part D: Formulary, Tier 4
		N/A

SBAR - Sedatives in Medicaid

a. Recommend the following as preferred sedatives: zolpidem immediate-release and eszopiclone
b. Recommend the following formulary changes for Medicaid:

Decision			
Drug	**Formulary Status**	**Utilization Management**	**Quantity Limits**
Zolpidem immediate-release	Formulary	Prior Authorization	5mg tablet: 0.5/1 10mg tablet: 0.5/1
Eszopiclone	Formulary	Prior Authorization	1mg tablet: 0.5/1 2mg tablet: 0.5/1 3 mg tablet: 0.5/1
Zolpidem extended-release	Non-formulary	Prior Authorization	6.25mg tablet: 0.5/1 12.5mg tablet: 0.5/1
Zaleplon	Non-formulary	Prior Authorization	5mg capsule: 0.5/1 10mg capsule: 0.5/1
Temazepam	Non-formulary	Prior Authorization	7.5mg capsule: 0.5/1 15mg capsule: 0.5/1 22.5mg capsule: 0.5/1 30mg capsule: 0.5/1
Triazolam	Non-formulary	Prior Authorization	0.125mg tablet: 0.5/1

			0.25mg tablet: 0.5/1
Flurazepam	Non-formulary	Prior Authorization	15mg capsule: 0.5/1 30mg capsule: 0.5/1
Belsomra	Non-formulary	Prior Authorization	5mg tablet: 0.5/1 10mg tablet: 0.5/1 15mg tablet: 0.5/1 20mg tablet: 0.5/1
Dayvigo	Non-formulary	Prior Authorization	5mg tablet: 0.5/1 10mg tablet: 0.5/1
Intermezzo	Non-formulary	Prior Authorization	1.75mg tablet: 0.5/1 3.5mg tablet: 0.5/1
Rozerem	Non-formulary	Prior Authorization	8mg tablet: 0.5/1
Silenor	Non-formulary	Prior Authorization	3mg tablet: 0.5/1 6mg tablet: 0.5/1

c. Prior Authorization Criteria:

PA PROGRAM NAME	Insomnia Agents - Medicaid
COVERED USES	Insomnia that is contributing to a covered co-morbid condition
EXCLUSION CRITERIA	N/A
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	**Drug Prior Authorization and Quantity Limit:** • Palliative care services: Initial and reauthorization will be approved up to 1 year. • Chronic benzodiazepine use: Initial and reauthorization will be approved up to 1 year. • Insomnia for other funded conditions: Initial authorization will be approved up to 2 months. Reauthorization will be approved up to 6 months.
REQUIRED MEDICAL INFORMATION	**New Start:** Patient has insomnia that is contributing to a covered comorbid condition. 1. Patient must meet one of the following: i. Patient is being treated under palliative care services with a life-threatening illness or severe advanced illness (i.e. cancer) ii. Patient is being treated for a funded condition that cannot be controlled with standard treatments and meets all of the following: i. The patient is being treated for one of the following: a) Obstructive sleep apnea and compliant with CPAP (Note: sedative/hypnotics are contraindicated in untreated OSA due to depressant effects)

	b) Depression, bipolar disorder, anxiety or panic disorder and there is documentation of adherence to current treatment (i.e. antidepressant, lithium, lamotrigine, antipsychotic, or other appropriate mental health drug) c) Other funded condition which is being exacerbated by insomnia, for which there is evidence of medical benefit of sedatives, and is not currently controlled by standard treatments ii. Patient has not been treated with another non-benzodiazepine sedative, benzodiazepine, or opioid within the past 30 days. If patient has been treated with a sedative in past 30 days, this criteria may be waived if this is a switch in sedative therapy due to intolerance, allergy, or ineffectiveness of prior sedative and notes clearly indicate that the other sedative has been discontinued iii. For non-preferred drugs: Trial and failure, contraindication, or intolerance to zolpidem AND eszopiclone iv. Dose does not exceed the FDA recommended daily dose **Established Patients:** 1. Patient has a need for continued treatment with a sedative, meeting one of the following: a. Patient is being treated under palliative care services with a life-threatening illness or severe advanced illness (i.e. cancer) b. The request is for continuation of a sedative therapy for a patient with a history of chronic sedative use where discontinuation would be difficult or unadvisable c. Patient is being treated for a funded condition that cannot be controlled with standard treatments and meets all of the following: i. The patient is being treated for one of the following: a) Obstructive sleep apnea and compliant with CPAP (Note: sedative/hypnotics are contraindicated in untreated OSA due to depressant effects) b) Depression, bipolar disorder, anxiety or panic disorder and there is documentation of adherence to current treatment (i.e. antidepressant, lithium, lamotrigine, antipsychotic, or other appropriate mental health drug) c) Other funded condition which is being exacerbated by insomnia, for which there is evidence of medical benefit of sedatives, and is not currently controlled by standard treatments ii. Patient has not been treated with another non-benzodiazepine sedative, benzodiazepine, or opioid within the past 30 days. If patient has been treated with a sedative in past 30 days, this criteria may be waived if this is a switch in sedative therapy due to intolerance, allergy, or ineffectiveness of prior sedative and notes clearly indicate that the other sedative has been discontinued iii. Dose does not exceed the FDA recommended daily dose 2. Patient has had a positive response to therapy without side effects and noted improvement in the funded condition

Clinical Policy Changes:

Syprine	Clarified the required prerequisite therapy is the tablet formulation of penicillamine (generic for Depen). The capsules (generic for Cuprimine) are significantly higher in cost.
Continuous Glucose Monitors for Personal Use (Non-professional) - Medicaid	Updated criteria to align with Oregon Health Authority coverage guidelines for patients with Type 1 diabetes.
Therapeutic Immunomodulators (TIMs) – Medicaid	Criteria was added for coverage Hidradenitis Suppurativa, as this is now considered a funded condition for severe disease. In addition, the requirement of trial of tofacitinib (Xeljanz®) for rheumatoid arthritis was removed, is considered more costly and less efficacious than adalimumab (Humira®) per 2017 ICER report, and does not align with Oregon Health Authority criteria. Coverage of ustekinumab (Stelara®) every 4 weeks (instead of every 8 weeks per FDA label) was noted to be considered experimental and investigational and will not be covered.
PCSK9s Inhibitors- Medicaid	The criteria for definition of ASCVD was updated to align with the Oregon Health Authority coverage criteria. In addition, a pre-treatment LDL >100 mg/dL requirement for familial hypercholesterolemia (FH) was added.
Long-Acting Stimulant Medications Quantity Limit	The Medicaid line of business was removed from this policy, as criteria for quantity exceptions are outlined in the Adult long-acting stimulant policy for Medicaid.
Adult Long-Acting Stimulant Medications - Medicaid	Criteria for more than once daily dosing was added to the policy.
Infusion Therapy Site of Care	The infliximab biosimilar, Avsola, was added to this policy.
Maximum Allowable Opioid Dose - Comm	Criteria related to quantity exceptions was removed from this policy. Quantity exceptions are reviewed in a standard way so these criteria were redundant and causing confusion.
Northera	Policy: Extended initial coverage duration to 3 months and reauthorization to 1 year.
Brisdelle	Removed quantity limit and added Medicaid to this policy, as the medication is not a “carve-out” for DMAP.

Sabril	Change coverage duration for infantile spasms to 12 months for safety. Medication has potential for vision loss and only indicated for up to 2 years of age for this indication.
Procysbi	Changed coverage duration to lifetime, granule packets added to policy.
Vistogard	Removed quantity limit.
Medical Nutrition – Medicaid	Combined standard and elemental formula criteria for oral use into 1 category and remove exclusion that milk protein intolerance is not covered as an in-born error of metabolism.
Oral Rinses	Split out trial and failure requirement for mucositis versus xerostomia. Extended coverage duration for chemotherapy related to 6 months and Sjogren's syndrome to 1 year initial with lifetime reauthorization.
Keveyis	Policy exclusion criteria updated to include contraindication of concomitant therapy with high-dose aspirin.
Vascepa	The criterion related to prerequisite therapy for severe hypertriglyceridemia was clarified to require either fenofibrate or gemfibrozil.
Antipsychotics Step Therapy	Removing Secuado patch from commercial "New Medications and Formulations Without Established Benefit" policy and adding to Antipsychotic Step Therapy Policy.
New Medications and Formulations without Established Benefit	Removed Astepro, Clobex, Fioricet, Jornay, Luvox CR, Luxiq Foam, Paxil CR, Tribenzor, Evekeo IR, Secuado from policy based on efficacy, utilization and cost reviews. Added Secuado to Antipsychotics policy.
Pulmonary Arterial Hypertension	Added a new formulation of Tracleer 32 mg Tab Susp to the policy.
Interleukin -1 inhibitors	Criteria were added for new indication.
Therapeutic Immunomodulators (TIMs) - Comm	Policy criteria were updated to better clarify prerequisite therapy requirements for preferred and non-preferred agents.

New Indications:

a. **RECARBRIO®**
CILASTATIN SODIUM/IMIPENEM/RELEBACTAM
New indication approved 06/04/2020:
patients 18 years of age and older for the treatment of the following infections caused by susceptible gram-negative microorganisms:

- **Hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP)**
- **Complicated urinary tract infections, including pyelonephritis (cUTI) in patients who have limited or no alternative treatment options.**
- **Complicated intra-abdominal infections (cIAI) in patients who have limited or no alternative treatment options.**

RECOMMENDATION: Inform prescribers via MD alert.

b. **INLYTA®**
AXITINIB
New indication approved 06/04/2020:
- **in combination with avelumab or pembrolizumab for the first-line treatment of patients with advanced renal cell carcinoma.**

RECOMMENDATION: Inform prescribers via MD 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.

c. **OPDIVO®**
NIVLUMAB
New indication approved 06/10/2020:
- **in combination with ipilimumab, first-line treatment of adult patients with metastatic or recurrent non-small cell lung cancer (NSCLC) whose tumors express PD-L1 (≥1%) as determined by an FDA-approved test with no EGFR or ALK genomic tumor aberrations**

RECOMMENDATION: Inform prescribers via MD 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.

d. **ERELZI®**
ETANERCEPT-SZZS
New indication approved 06/11/2020:
- **Plaque Psoriasis (PsO) in patients 4 years or older**

RECOMMENDATION: Inform prescribers via MD alert. This biosimilar has not yet gone to market. Will continue to monitor for the release date.

e. **TIVICAY®**
DOLUTEGRAVIR SODIUM
New indication approved 06/12/2020:
- **in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults (treatment-naïve or -experienced) and in pediatric patients (treatment-naïve or -experienced but INSTI- naïve) aged at least 4 weeks and weighing at least 3 kg.**

- **TIVICAY is indicated in combination with rilpivirine as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure or known substitutions associated with resistance to either antiretroviral agent**

RECOMMENDATION: Inform prescribers via MD alert.

f. ILARIS®
CANAKINUMAB
New indication approved 06/16/2020:

- **Active Still's disease, including Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older**

RECOMMENDATION: Inform prescribers via MD alert. This policy is being reviewed for and updated with the current October P&T cycle. Update the Commercial, Medicaid, and Medicare policy to include Adult-Onset Still's Disease as an approved diagnosis.

g. COSENTYX®
SECUKINUMAB
New indication approved 06/16/2020:

- **active non-radiographic axial spondyloarthritis (nr-axSpA) in adult patients with objective signs of inflammation.**

RECOMMENDATION: Inform prescribers via MD alert. This policy is being reviewed and updated with the current October P&T cycle and will be added to the policy as a non-preferred agent for this indication.

h. KEYTRUDA®
PEMBROLIZUMAB
New indication approved 06/16/2020 and 06/24/2020 and 6/29/2020:

- **treatment of adult and pediatric patients with unresectable or metastatic tumor mutational burden-high (TMB-H) [≥10 mutations/megabase (mut/Mb)] solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options.**
- **for an alternate dose/schedule of 400 mg every 6 weeks for adult patients with unresectable or metastatic TMB-H [≥10 mutations/megabase (mut/Mb)] solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options**
- **treatment of patients with recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation.**
- **an alternate dosage regimen of 400 mg every 6 weeks for adult patients with recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation**

- **first-line treatment of patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer**

RECOMMENDATION: Inform prescribers via MD 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.

i. **MYLOTARG®**
GEMTUZUMAB OZOGAMICIN
New indication approved 06/16/2020:
- **treatment of newly-diagnosed CD33-positive acute myeloid leukemia (AML) in adults and pediatric patients 1 month and older**

RECOMMENDATION: Inform prescribers via MD 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.

j. **CRYSVITA®**
BUROSUMAB-TWZA
New indication approved 06/18/2020:
- **treatment of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adult and pediatric patients 2 years of age and older**

RECOMMENDATION: Inform prescribers via MD alert. Update Commercial, Medicare Part B, and Medicaid policy as follows:

PA PROGRAM NAME	Crysvita
MEDICATION NAME	Crysvita® (burosumab-twza vial)
COVERED USES	All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	**Initial authorization:** 1. One of the following diagnoses: a. Diagnosis of X-linked hypophosphatemia (XLH) supported by ONE or more of the following: i. Confirmed PHEX mutation in the patient or a directly related family member with appropriate X-linked inheritance ii. Elevated Serum fibroblast growth factor 23 (FGF23) level greater than 30 pg/mL b. Clinical diagnosis of tumor-induced osteomalacia (TIO) and all of the following: i. Associated with tumors that cannot be identified or curatively resected

	ii. FGF23 level of at least 100 pg/mL; and 2. Documentation that serum phosphorus level is below the normal range for age; (use laboratory-specific reference ranges if available; otherwise, see appendix for ranges); and 3. One of the following: a. Patient's epiphyseal plate has NOT fused; or b. Patient meets all of the following: i. Patient's epiphyseal plate has fused; and ii. Patient is experiencing clinical signs and symptoms of disease (e.g., limited mobility, musculoskeletal pain, bone fractures); and 4. Failure of calcitriol with an oral phosphate agent, unless contraindicated or clinically significant adverse effects are experienced; and 5. Documentation of patient's current weight and that dosing is in accordance with the United States Food and Drug Administration approved labeling **For patients established on therapy with burosumab for X-linked hypophosphatemia all of the following criteria must be met:** 1. Documentation of recent serum phosphorus level and levels have normalized while on therapy; and 2. Documentation of at least one of the following responses to therapy: a. Improvement in skeletal deformities b. Healing of fracture or pseudofractures c. Reduction in number of fractures/pseudofractures d. Increase in growth velocity; and 3. Documentation of patient's current weight and that dosing continues to be in accordance with the United States Food and Drug Administration approved labeling **For patients established on therapy with burosumab for hypophosphatemia in tumor induced osteomalacia (TIO) all of the following criteria must be met:** 1. Documentation that tumor continues to be unidentifiable or unresectable; and 2. Documentation of recent serum phosphorus level and levels have normalized while on therapy; and 3. Documentation of at least one of the following responses to therapy: a. Improvement in skeletal deformities b. Healing of fracture or pseudofractures c. Reduction in number of fractures/pseudofractures

	d. Increase in growth velocity; and 4. Documentation of patient's current weight and that dosing continues to be in accordance with the United States Food and Drug Administration approved labeling
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Prescribed by, or in consultation with, an endocrinologist or specialist experienced in the treatment of metabolic bone disorders.
COVERAGE DURATION	Initial authorization will be approved for 6 months and reauthorization will be approved for 1 year.

k. TAZVERIK®
TAZEMETOSTAT HYDROBROMIDE
New indication approved 06/18/2020:
- **treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies.**
- **treatment of adult patients with R/R FL who have no satisfactory alternative treatment options.**

RECOMMENDATION: Inform prescribers via MD 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.

l. SIVEXTRO®
TEDIZOLID
New indication approved 06/19/2020:
- **adult and pediatric patients 12 years of age and older for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria.**

RECOMMENDATION: Inform prescribers via MD alert.

m. XPOVIO®
SELINEXOR
New indication approved 06/22/2020:
- **For the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy**

RECOMMENDATION: Inform prescribers via MD 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.

n. **LIALDA®**
MESALAMINE
New indication approved 06/26/2020:
- **Induction and maintenance of remission in adult patients with mildly to moderately active ulcerative colitis.**
- **treatment of mildly to moderately active ulcerative colitis in pediatric patients weighing at least 24 kg.**

RECOMMENDATION: Inform prescribers via MD alert.

o. **BAVENCIO®**
AVELUMAB
New indication approved 06/30/2020:
Urothelial Carcinoma (UC)
- **Maintenance treatment of patients with locally advanced or metastatic UC that has not progressed with first-line platinum-containing chemotherapy**

RECOMMENDATION: Inform prescribers via MD 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.

p. **TREMFYA®**
GUSELKUMAB
New indication approved 07/13/2020:
- **treatment of adult patients with active psoriatic arthritis**

RECOMMENDATION: Inform prescribers via MD alert. This policy is being reviewed and updated with the current October P&T cycle.

q. **VECTICAL®**
CALCITRIOL TOPICAL
New indication approved 07/17/2020:
- **the topical treatment of mild to moderate plaque psoriasis in adult and pediatric patients 2 years and older.**

Limitations of Use
The safety and effectiveness of VECTICAL Ointment in patients with known or suspected disorders of calcium metabolism have not been evaluated.

RECOMMENDATION: Inform prescribers via MD alert.

r. **QUTENZA®**
CAPSAICIN PATCH

New indication approved 07/17/2020:

- **treatment of neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet.**

RECOMMENDATION: Inform prescribers via MD alert.

s. STELERA®
USTEKINUMAB
New indication approved 07/29/2020:

Pediatric patients 6 years and older with:

- **moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy.**

RECOMMENDATION: Inform prescribers via MD alert. This policy is being reviewed and updated with the current October P&T cycle and the will be updated to reflect the changed indication.

t. TECENTRIQ®
ATEZOLIZUMAB
New indication approved 07/30/2020:

Melanoma

- **in combination with cobimetinib and vemurafenib for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.**

RECOMMENDATION: Inform prescribers via MD 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.

u. PREZCOBIX®
DARUNAVIR AND COBICISTAT
New indication approved 07/31/2020:

- **use in the pediatric population weighing at least 40 kg**

RECOMMENDATION: Inform prescribers via MD alert.

v. EVOTAZ®
ATAZANAVIR AND COBICISTAT
New indication approved 07/31/2020:

- **use in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg**

RECOMMENDATION: Inform prescribers via MD alert.

w. EPIDIOLEX®
CANNABIDIOL
New indication approved 07/31/2020:

- **treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex in patients 1 year of age and older**

RECOMMENDATION: Inform prescribers via MD alert. The Commercial and Medicaid policy will be updated as follows:

PA PROGRAM NAME	Epidiolex
MEDICATION NAME	Epidiolex (cannabidiol extract solutions)
COVERED USES	All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	Initial Authorization: 1. Documentation that patient has one of the following: a. Seizures associated with Lennox-Gastaut syndrome (LGS) b. Seizures associated with Dravet syndrome (DS) c. Tuberous sclerosis complex (TSC) 2. Documented trial, failure, intolerance or contraindication to two* of the following: (*Coverage for Medicaid requires only one of the following) a. Valproate / Valproic acid b. Lamotrigine c. Clobazam d. Levetiracetam e. Topiramate f. Felbamate g. Zonisamide h. Vigabatrin 3. Documentation that it will be used as adjunctive therapy with other antiepileptic drugs 4. Baseline liver function tests must be documented 5. Dose will not exceed: a. 20 mg/kg/day in Lennox-Gastaut syndrome or Dravet Syndrome b. 25mg/kg/day in TSC Reauthorization: 1. Documentation of recent liver function test 2. Documentation of positive response to therapy such as a decrease in seizure frequency or intensity since beginning therapy 3. Dose continues to not exceed 20 mg/kg/day in Lennox-Gastaut syndrome or Dravet Syndrome or 25mg/kg/day in tuberous sclerosis complex

AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescriber by or in consultation with an epilepsy specialist or pediatric neurologist
COVERAGE DURATION	Initial authorization will be approved for 6 months and reauthorization will be approved for 1 year

x. **SPRAVATO®**
ESKETAMINE
New indication approved 07/31/2020:
- **in conjunction with an oral antidepressant, for the treatment of:**
  - **Treatment-resistant depression (TRD) in adults.**
  - **Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior**

RECOMMENDATION: Inform prescribers via MD alert. The Commercial and Medicare Part B policy will be updated with the December 2020 ORPTC meeting

Drug Safety Monitoring:

a. **FDA alerts patients and health care professionals of Amneal and Impax Laboratories epinephrine auto-injector device malfunctions**
[Posted 6/1/2020]
ISSUE:
FDA is alerting patients, caregivers and health care professionals to immediately inspect certain lots of Amneal and Impax epinephrine auto-injector 0.3 mg to ensure the yellow "stop collar" in the device is present.
In letters to health care professionals and consumers, Impax Laboratories LLC, a subsidiary of Amneal Pharmaceuticals LLC, the manufacturer of the epinephrine auto-injector, detailed how certain lots of these devices might not contain the yellow "stop collar" component. If the auto-injector is missing the yellow "stop collar" component, the device has the potential safety risk of delivering a double dose of epinephrine to a patient. It is vital for lifesaving products to work as designed in an emergency situation.

FDA RECOMMENDATION:
Patients, pharmacists and health care professionals who have received Amneal or Impax's epinephrine auto-injector after December 20, 2018, should immediately visually inspect the auto-injector to confirm the presence of the yellow "stop collar" by:
- Removing the auto-injector from the carrying case.
- Placing the auto-injector on a flat surface.
- Locating the edge of the label that states, "Peel here for further instructions." Lift the label edge until you see the clear part of the auto-injector.

- Looking for the yellow “stop collar” inside the clear part of the auto-injector. If the yellow “stop collar” is not visible inside the clear part of the auto-injector, gently rotate the blue sheath remover, without pulling or removing the blue sheath remover, to observe if the yellow “stop collar” comes into view inside the clear part of the auto-injector.
- If yellow “stop collar” is present, then the product is safe to use, and no further action is necessary. Re-wrap the label to its original position and place the auto-injector into the carrying case.

Recommendation: Notify via MD alert.