PROVIDENCE Health Plan

PROVIDENCE Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 270

May 1, 2022

This is the May 1, 2022 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.

MEDICAL POLICY COMMITTEE

MEDICAL

Effective 6/1/2022

Psychological and Neuropsychological Testing (All Lines of Business Except Medicare) MP274	**Policy Updates:** For **Yamhill Coordinated Care Organization (YCCO)** only, the following CPT codes will require prior authorization: 96116, 96121, 96130, 96131, 96132, 96133, 96136, 96137, 96138, 96139.
Prostate: Protein Biomarkers and Genetic Testing (All Lines of Business Except Medicare) MP96	**Policy Updates:** Per NCCN recommendations, liberalize coverage to allow for the following tests/services when criteria are met: • Decipher Prostate • Oncotype DX Genomic Prostate Score Assay • Prolaris • Androgen receptor splice variant 7 (AR-V7) testing (e.g. Oncotype DX AR-V7 Nucleus Detect Test) **Codes/PA:** • Add PA to 3 codes (0047U, 81541, 81542) specific to the tests above, which currently deny as investigational. • Code 81539 currently incorrectly denying as not a covered benefit. Change denial to investigational.
Cosmetic and Reconstructive Procedures (All Lines of Business Except Medicare) MP98	**Policy Updates:** • No criteria changes. **Codes/PA:** • Move autologous fat transfer code (15769) to "no PA" section of coding table. PA is being removed per archiving of "Autologous Fat Transfer" policy.
Eye: Retinopathy Telescreening (All Lines of Business Except Medicare) MP185 *Previously: Eye: Retinopathy Telescreening*	**Policy Updates:** • No change to criteria used for Commercial but archive the use of this policy for Medicare. As of September 2021, a Noridian LCD is available with potential coverage for services (codes) we currently deny. Claim/PA data reports ran in 202**1** (last year) showed **no** Medicare utilization (no PA and no claims). After pulling data in 202**2**, there was only one (1) Medicare claim and no PA. Therefore, due to very low utilization for the Medicare population as well as coverage criteria that differs from our current Commercial criteria, recommendation for this interim update is to archive the use of this policy for Medicare use in order to not conflict with the LCD.

	This will require a change to the policy title to an "All Lines of Business Except Medicare" policy, remove Medicare information from the policy, and update coding table and configuration. Of note, this policy is up for annual review in July. At that time, Commercial can re-evaluate the policy to determine whether additional recommendations may be considered for other LOBs. **Codes/PA:** • Remove all configuration for Medicare. No change to code configuration for Commercial LOBs.
Gender Affirming Surgical Interventions **MP32**	**Policy Updates:** • No criteria changes. **Codes/PA:** • Move autologous fat transfer codes (15769, 15771, 15772) to "no PA" section of coding table. PA is being removed per archiving of "Autologous Fat Transfer" policy.
Vestibular Function Testing **MP82**	**Policy Updates:** • Add note that investigational services are considered "not medically necessary" for Medicare Plan members. **Codes/PA:** • Changing denial from "investigational" to "not medically necessary" for VEMP codes for Medicare
Ankle-Foot/Knee-Ankle-Foot Orthoses (Medicare Only) **MP294**	**Policy Updates:** Minor changes: • Rearranged services in the criteria table and added a "HCPCS" column. • Added "Policy Guidelines" section with basic information about Medicare's overall position on these devices. • Reformatted the "Billing Guidelines" section, removing duplicative information found in the LCA. • Rearranged "Cross References" and added updated MP numbers • Removed duplicate citations from the "References" section, added new citations. **Codes/PA:** Coding and configuration changes are as follows: • Add NMN denial to A9285 per LCD/LCA. Add NMN denial to HCPCS codes L2840 and L2850 per LCD/LCA
Cosmetic and Reconstructive Surgery (Medicare Only) **MP232**	**Policy Updates:** • No change to criteria. **Codes/PA:** • Remove PA from CPT code 15769 and move to "No PA Required" section of Coding table in the policy. No other changes.

Genetic Testing: Myeloproliferative Diseases (Medicare Only) MP71 *Formerly: Genetic Testing: JAK2, CALR, and MPL (Medicare Only)*	**Policy Updates:** Minor changes to criteria table; however, no change to overall coverage or intent. • Added additional LCDs based on service area of performing laboratories for proprietary tests and added rows for select tests. • While there are no edits or PA requirements for *BCR-ABL* testing codes, because the policy includes these codes with applicable Medicare references, the policy title was updated to reflect this broader scope. **Codes/PA:** • Remove PA from 0171U and add NMN denial. • No changes to configuration for any other code in this policy.
Orthotic Foot Devices and Orthopedic Shoes (Medicare Only) MP298	**Policy Updates:** Minor changes to policy: • Rearranged services in the criteria table and added a "HCPCS" column. • Moved local coverage articles (LCAs) to the "Billing Guidelines" section. • Added "Policy Guidelines" section with additional information about Medicare's overall position on these devices. • Reformatted the "Billing Guidelines" section. • Rearranged "Cross References" and added updated MP numbers • Removed duplicate citations from the "References" section, added new citations. **Codes/PA:** • Added HCPCS code A9270 to the policy, based on LCA A52501; however, no change to configuration. • HCPCS codes L3215, L3216, L3217, L3219, L3221, and L3222 were moved from the "No PA Required" section to the "Not Covered" section of the code table and add NMN denial. • Other codes for replacement components, inserts or modifications were re-arranged or re-ordered in the "No PA Required" section, but no changes to configuration.
Psychological and Neuropsychological Testing (All Lines of Business Except Medicare) MP274	**Policy Updates:** • No changes to criteria **Codes/PA:** • Add diagnosis codes F02.80, F02.81, and G3.00 to list of codes, reprocess back to 1/1/2021

Complementary and Alternative Medicine (CAM) Treatments (All Lines of Business Except Medicare) **MP260**	**Policy Updates:** • Add criteria for alternative therapies for Lyme disease, taken from the Lyme Disease policy that is being archived. **Codes/PA:** • Add codes for home infusion to policy (99601, 99602, S9494-S9504), no prior authorization required
Back: Sacroiliac Joint Fusion or Stabilization **MP24** *Previously: All lines of business except Medicare*	**Policy Updates:** • Change policy to All Lines of Business • Change denial from investigational to not medically necessary for open SI joint fusion **Codes/PA:** • No changes to codes/PA
Mechanical Stretching Devices for Joints of the Extremities **MP44**	**Policy Updates:** • Change denials from "investigational" to "not medically necessary" given state of evidence. **Codes/PA:** • Update codes to now deny "not medically necessary."

ARCHIVE

Effective 6/1/2022

Autologous Fat Transfer **MP9**	**Policy Updates:** • Archive policy **Codes/PA:** • Remove PA from 15679, 15771 and 15772 – these codes are addressed on "Gender Affirming Surgical Interventions" and "Cosmetic and Reconstructive Procedures" policies, which will be updated to reflect removal of PA.

Effective 7/1/2022

Lyme Disease **MP123**	**Policy Updates:** • Archive policy, moving alternative therapy criteria to the CAM policy. **Codes/PA:** • no changes to codes or PA
Back: Sacroiliac Joint Fusion or Stabilization (Medicare Only) **MP195**	**Policy Updates:** • The current *Back: Sacroiliac Joint Fusion or Stabilization (Medicare Only)* policy references a Wisconsin (WPS) LCD and LCA with coverage criteria; however, WPS is not the Medicare contractor (MAC) for our service area for **Part B** services. Noridian is our Part B MAC. With no Noridian LCD and/or LCA, it is recommended to use the PHP Commercial policy, which includes medical necessity criteria. Consolidating into a single "All Lines of Business" policy until such time Medicare decides to create a policy. **Codes/PA:** • Continue PA.

REIMBURSEMENT

Effective 6/1/2022

Inpatient Hospital Readmissions
 	
RP1
	Type of Update: New Reimbursement Policy
	Policy Updates:
	• New reimbursement policy addressing both unplanned and planned inpatient hospital readmissions.
	  • **Per the recommendation of RCGA and legal, the policy will only apply to participating and contracted facilities and will not apply to Medicaid/OHP.**
	  ○ **Phase II will explore OON facilities and application to OHP.**
	  • The criteria, first-and-foremost, are in-line with all relevant Medicare claims processing and benefit manuals. However, the Medicare language is rather vague, so supplemental review criteria were added based on the plan survey and an UpToDate® review on Hospital Readmissions.
	  • The policy first defines the criteria for readmission review. If readmission review criteria are met, either the unplanned or planned readmission criteria would then be applied.
	  ○ Criteria note added that even if the readmission is beyond 30 days it is still subject to MD review (RCGA confirmed that we have the ability to review any inpatient readmission, regardless of time period between admissions).

	• Current medical management policy states Leave of Absence (ie Planned Readmission) for Medicare is null/void if the time between discharge and readmission is greater than 60 days. ○ After consultation with RCGA, it was determined that we have the ability to review both planned and unplanned readmissions at any point in time (not just those that occur within 30 days or those that extend beyond 60 days). Thus, this language was removed and the criteria note mentioned above was added. • Current medical management policies, which will now be archived: 54.0 (HCS Facility Readmissions) **Reimbursement Methodology:** • Unplanned readmission—when criteria are met, the second inpatient stay is not reimbursable. • Planned readmission—when criteria are met, the initial and subsequent admissions will be combined into a single DRG payment. **Major Differences from Current Policy & Process:** • Current policy does not differentiate between planned and unplanned readmission • Today, we combine the two DRGs even if it's an unplanned readmission. • Plan to develop a proactive method for pending claims (vs maybe/maybe not catching them in CCR review)
Facility Routine Supplies and Services **RP2**	**Type of Update:** New Reimbursement Policy **Policy Updates:** • Creation of a new reimbursement policy around facility routine supplies and services that will be used to review IP claims not captured by the Optum high dollar review ($30-$99K claims) • The policy criteria outline supplies and services which are not separately reimbursable because they are considered incidental to the facility charge. • The policy is in-line with all relevant Medicare guidance around routine items or services and supplies billed in error. • Because the Medicare guidance is rather vague, extensive policy guidelines have been added to give examples of supplies and services which are not separately reimbursable. • Current medical management policies, which will now be archived: (maybe) 82.0—need to review with reimbursement team and Stephanie Asher. **Reimbursement Methodology:** Supplies or services which meet policy criteria will be considered not separately reimbursable.

VENDOR UPDATES

Clinical Alert: CMS Lung Cancer Screening update

Radiology: Lung Cancer Screening with Low-Dose CT (LDCT)

Background

The AIM Specialty Health® (AIM) guidelines for lung cancer screening with low-dose CT (LDCT) are aligned with U.S. Preventative Services Task Force (USPSTF) recommendations. In March 2021, the USPSTF updated their LDCT screening recommendations, lowering the starting age from 55 to 50 years, and reducing the threshold for tobacco smoking history from at least 30 pack-years to 20 pack-years. The upper age limit for screening as recommended by the USPSTF (80 years) remains unchanged.

AIM incorporated these updated eligibility parameters into our Chest Imaging guidelines in May 2021.

Recent CMS announcement for expanded LDCT coverage

On February 10, 2022, the Centers for Medicare & Medicaid Services (CMS) announced an update to the national coverage determination (NCD) for lung cancer screening with LDCT, in which these same starting age and smoking history parameters will be adopted as part of the eligibility criteria.

The update also simplifies requirements for the counseling and shared decision-making visit and removes the requirement for the reading radiologist to document participation in continuing medical education. CMS also added a requirement back to the NCD criteria for radiology imaging facilities to use a standardized lung nodule identification, classification, and reporting system.

The upper age limit for screening per the NCD eligibility criteria (77 years) remains unchanged.

AIM plan of action

All Medicare requests for LDCT for lung cancer screening will continued to be reviewed against current NCD eligibility criteria, now including the updated parameters above.

Updates to AIM Advanced Imaging Clinical Appropriateness Guideline

Effective for dates of service on and after March 13, 2022, the following updates will apply to the AIM Advanced Imaging Clinical Appropriateness Guidelines. Part of the AIM guideline annual review process, these updates are focused on advancing efforts to drive clinically appropriate, safe, and affordable health care services

Updates by Guideline
Imaging of the Brain

- Acoustic neuroma – removed indication for CT brain and replaced with CT temporal bone
- Meningioma – new guideline establishing follow-up intervals
- Pituitary adenoma – removed allowance for CT following nondiagnostic MRI in macroadenoma
- Tumor, not otherwise specified – added indication for management; excluded surveillance for lipoma and epidermoid without suspicious features

Imaging of the Head and Neck

- Parathyroid adenoma – specified scenarios where surgery is recommended based on American Association of Endocrine Surgeons guidelines
- Temporomandibular joint dysfunction – specified duration of required conservative management

Imaging of the Heart

- Coronary CT Angiography Removed indication for patients undergoing evaluation for transcatheter aortic valve implantation/replacement who are at moderate coronary artery disease risk

Imaging of the Chest

- Pneumonia – removed indication for diagnosis of COVID-19 due to availability and accuracy of lab testing
- Pulmonary nodule – aligned with Lung-RADS for follow-up of nodules detected on lung cancer screening CT

Imaging of the Abdomen and Pelvis

- Uterine leiomyomata – new requirement for US prior to MRI; expanded indication beyond uterine artery embolization to include most other fertility-sparing procedures
- Intussusception – removed as a standalone indication
- Jaundice – added requirement for US prior to advanced imaging in pediatric patients
- Sacroiliitis – defined patient population in whom advanced imaging is indicated (predisposing condition or equivocal radiographs)
- Azotemia – removed as a standalone indication
- Hematuria – modified criteria for advanced imaging of asymptomatic microhematuria based on AUA guideline

Oncologic Imaging

- National Comprehensive Cancer Network (NCCN) recommendation alignments for Breast Cancer, Hodgkin & Non Hodgkin Lymphoma, Neuroendocrine Tumor, Melanoma, Soft Tissue Sarcoma, Testicular Cancer, and Thyroid Cancers.
- Cancer Screening: new age parameters for Pancreatic Cancer screening; new content for Hepatocellular Carcinoma screening
- Breast Cancer: clinical scenario clarifications for Diagnostic Breast MRI and PET/CT

For questions related to guidelines, please contact AIM via email at aim.guidelines@aimspecialtyhealth.com. Additionally, you may access and download a copy of the current and upcoming guidelines here.

AIM Authorization Request Update

The following codes had a planned authorization request start date of 3/13/2022 through AIM, the date for requiring authorization has been moved out to 6/11/2022.

0633T
0633T
0634T
0635T
0636T
0637T
0638T
0648T
0649T
0042T

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

Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting April 1, 2022
Go-Live Date: Wednesday, June 01, 2022, unless otherwise noted

Special Updates:

Pneumococcal Vaccinations

Based on the updated recommendations from the Advisory Committee on Immunization Practices (ACIP) for use of pneumococcal vaccinations, the following changes to coverage of these vaccines will be **effective 7/1/2022**:

- PCV15 (Vaxenuvance®) and PCV20 (Prevnar 20®) will be covered for one dose for adult patients. These vaccines are not be covered for patients less than 19 years of age.
- PCV13 (Prevnar 13®) will not be covered for patients over 19 years of age.
- PPSV23 (Pneumovax®) will require prior authorization for all patients. This vaccine will only be covered if the patient has a previous vaccination history with PCV15 or PCV13 while an adult. Second doses of PPSV23 may be covered subject to review

Table of Contents:

New Drugs and Combinations:

1. **Tralokinumab-ldrm (Adbry) Syringe**
   a. **Indication**: For the treatment of moderate to severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
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	2 syringes per 28 days	2 syringes per 28 days	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: Dupilumab (Dupixent®)			

   c. **Prior Authorization Criteria for Commercial/Medicaid** :

PA PROGRAM NAME	Adbry
MEDICATION NAME	Adbry 150 mg/ml syringe
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Concurrent use with another therapeutic immunomodulator agent utilized for the same indication (such as dupilumab, upadacitinib, and abrocitinib)
REQUIRED MEDICAL INFORMATION	<u>For initial authorization, must meet all of the following criteria:</u> 1. Diagnosis of moderate to severe atopic dermatitis despite use of therapies outlined in criterion number 2 below, as defined by all the following: a. Patient has a minimum body surface area (BSA) involvement of at least 10% (or hand, foot or mucous membrane involvement) b. Patient has severe symptoms such as erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification

	c. Chronic condition, affecting patient for more than one year d. For Medicaid (OHP) only: Documentation that patient is having functional impairment due to atopic dermatitis (such as inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction) 2. Documented trial and failure of an adequate treatment course with at least one agent from all the following conventional treatment modalities: a. Moderate to high potency topical corticosteroids (such as clobetasol 0.05%, betamethasone dipropionate 0.05%, triamcinolone 0.5%) applied once daily for at least two weeks b. Topical calcineurin inhibitor (such as tacrolimus ointment) applied twice daily for at least one month c. For Medicaid only: Systemic immunomodulatory agents (such as cyclosporine, azathioprine, methotrexate, mycophenolate, or oral corticosteroids) for at least two months unless contraindicated 3. For Commercial only: Documented trial and failure, intolerance, or contraindication to dupilumab (an adequate treatment course is defined as at least three months) *For Reauthorization, all of the following criteria must be met:* 1. Documentation of reduction or stabilization from baseline of flares, pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, lichenification or affected BSA 2. If the request is for four (4) – 150 mg syringes per 28 days, one of the following must be met: a. Patient has not achieved clear or almost clear skin in the last 6 months b. Individual weighs greater than 100 kg
AGE RESTRICTIONS	Age 18 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a dermatologist, allergist, or immunologist
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for one year.

2. **Abrocitinib (Cibinqo) Tablet**

a. **Indication**: For the treatment of adults with refractory, moderate-to-severe atopic dermatitis (AD) whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable

b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
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	1 tablet per day	1 tablet per day	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: dupilumab (Dupixent®), upadacitinib (Rinvoq®)			

c. **Prior Authorization Criteria for Commercial/Medicaid**:

PA PROGRAM NAME	Cibinqo
MEDICATION NAME	Cibinqo 50 mg tablet Cibinqo 100 mg tablet Cibinqo 200 mg tablet
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Concurrent use with another therapeutic immunomodulator agent utilized for the same indication (such as dupilumab, upadacitinib, and tralokinumab)
REQUIRED MEDICAL INFORMATION	<u>For initial authorization, must meet all of the following criteria:</u> 1. Diagnosis of moderate to severe atopic dermatitis despite use of therapies outlined in criterion number 2 below, as defined by all of the following: a. Patient has a minimum body surface area (BSA) involvement of at least 10% (or hand, foot, or mucous membrane involvement)

	b. Patient has severe symptoms such as erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification c. Chronic condition, affecting patient for more than one year d. For Medicaid (OHP) only: Documentation that patient is having functional impairment due to atopic dermatitis (such as inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction) 2. Documented trial and failure of an adequate treatment course with at least one agent from all the following conventional treatment modalities: a. Moderate to high potency topical corticosteroids (such as clobetasol 0.05%, betamethasone dipropionate 0.05%, triamcinolone 0.5%) applied once daily for at least two weeks b. Topical calcineurin inhibitor (such as tacrolimus ointment) applied twice daily for at least one month c. For Medicaid only: Systemic immunomodulatory agents (such as cyclosporine, azathioprine, methotrexate, mycophenolate, or oral corticosteroids) for at least two months unless contraindicated 3. For Commercial only: Documented trial and failure,intolerance, or contraindication to upadacitinib (an adequate treatment course is defined as at least three months) *For Reauthorization, all of the following criteria must be met*: Documentation of reduction or stabilization from baseline of flares, pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, lichenification or affected BSA
AGE RESTRICTIONS	Age 18 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a dermatologist, allergist, or immunologist
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for one year.

2. **Cagbotegravir (Apretude) Suser Vial**
   a. **Indication**: Indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to initiating cabotegravir (with or without an oral lead-in with oral cabotegravir) for HIV-1 PrEP.
   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	Yes	N/A	N/A
Utilization Management Edits	N/A	N/A	N/A
Quantity Limit	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: Descovy®, emtricitabine/tenofovir disoproxil fumarate			

3. **Ropeginterferon alfa-2B-njft (Besremi) Syringe**
   a. **Indication**: For the treatment of adults with polycythemia vera (PV).
   b. **Decision**:

	Commercial	**Medicaid**	**Medicare**
Formulary Status*	Non-formulary	Non-formulary	Part D: Formulary Part B: Medical
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	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: hydroxyurea, Pegasys®, Jakafi®			

c. **Prior Authorization Criteria for Commercial/Medicaid**: Added to the Injectable Anti-Cancer Medications policy
d. **Prior Authorization Criteria for Medicare Part B**: Added to the Injectable Anti-Cancer Medications policy

4. **Lonapegsomatropin-tcgd (Skytrofa) Cartridge**
   a. **Indication**: Indicated for the treatment of pediatric patients one year and older who weight at least 11.5 kg and have growth failure due to endogenous growth hormone deficiency (GHD).
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Specialty Medication	Yes	Yes	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit			
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives (varies depending on LOB): Genotropin®, Nutropin AQ®, Norditropin®, Omnitrope®			

   c. **Prior Authorization Criteria for Commercial/Medicaid:**

PA PROGRAM NAME	Human Growth Hormones or Pediatrics
MEDICATION NAME	Skytrofa
PA INDICATION INDICATOR	3 - All Medically-Accepted Indications
OFF-LABEL USES	None
EXCLUSION CRITERIA	Treatment of idiopathic short stature.
REQUIRED MEDICAL INFORMATION	For Medicaid: Coverage is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services

	For initial authorization: I. Documented evidence of open epiphyses AND II. For non-preferred growth hormone (GH) request, documentation that the patient has intolerance, FDA labeled contraindication, or hypersensitivity to preferred growth hormone product(s) that is not expected to occur with the requested non-preferred agent (medical record required). Request of lonapegsomatropin to improve compliance or to reduce dosing frequency is considered not medically necessary. Please see Table 1 for preferred products. AND III. Meet criteria listed below for each specific diagnosis: A. Growth Hormone Deficiency (GHD): must meet criteria for one of the following: i. Newborn with hypoglycemia and both of the following criteria: 1. Serum GH level less than or equal to 5 micrograms per liter (5 mcg/L) 2. One of the following: a. One additional pituitary hormone deficiency (other than growth hormone) or b. Classical imaging triad (ectopic posterior pituitary and pituitary hypoplasia with abnormal stalk) ii. Patient with extreme short stature [defined as height standard deviation score (SDS) of more than 3 SDS below the mean for chronological age/sex] and all of the following: 1. Insulin-like growth factor (IGF)-1 level at least 2 SDS below normal 2. Insulin-like growth factor binding protein-3 (IGFBP-3) at least 2 SDS below normal 3. Delayed bone age, defined as bone age that is 2 SDS below the mean for chronological age iii. Patient has pituitary abnormality (secondary to a congenital anomaly, tumor, or irradiation) and meets both of the following criteria: 1. One additional pituitary hormone deficiency (other than growth hormone) 2. Evidence of short stature/growth failure by one of the following: a. Height standard deviation score (SDS) of more than 3 SD below the mean for chronological age/sex b. Height for age/sex is below the 3rd percentile (or greater than 2 SD below the mean) AND untreated growth velocity (GV) is below the 25th percentile (must have at least 1 year of growth data) c. Severe growth rate deceleration (GV measured over one year of more than 2 SD below the mean for age/sex) iv. All other patients with suspected GHD must meet all of the following criteria: 1. Evidence of short stature/growth failure using criteria III.A.iii.2. above 2. Documented biochemical GHD by one of the following: a. Two GH stimulation tests (using a provocative agent such as arginine, clonidine, glucagon, insulin or levodopa) showing peak GH concentrations of less than 10 ng/ml

	b. One GH stim test level less than 15ng/ml and insulin-like growth factor (IGF)-1 and IGFBP-3 levels below normal for bone age/sex ***Criteria omitted for non-GHD diagnoses*** For Reauthorization, all of the following criteria has been met: I. Evidence of growth velocity (GV) of greater than 2.5 cm/year AND II. Evidence of open epiphyses
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by a pediatric endocrinologist or pediatric nephrologist.
COVERAGE DURATION	Initial authorization and reauthorization will be approved for up to one year

5. **Vosoritide (Voxzogo) Vial**
   a. **Indication**: To increase linear growth in pediatric patients with ACH who are 5 years of age and older with open epiphyses. (1)
      i. The application for vosoritide was approved under the accelerated approval pathway based on an improvement in annualized growth velocity observed in the clinical trial. Continued approval for this indication is contingent upon verification of clinical benefit in confirmatory trial(s).
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	One vial per day	One vial per day	
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: None			

c. **Prior Authorization Criteria for Commercial/Medicaid**:

PA PROGRAM NAME	Voxzogo
MEDICATION NAME	Voxzogo
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	
EXCLUSION CRITERIA	• History of bone-related surgery or fracture of long bone or spine within the previous six months • Planned bone surgery
REQUIRED MEDICAL INFORMATION	For Medicaid: Coverage is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services For initial authorization, ALL the following criteria must be met: 1. Documentation of confirmed diagnosis of achondroplasia (ICD-10 Q77.4) through genetic testing **AND** 2. Documentation of a baseline annual growth velocity (AGV) **AND** 3. Current annual growth velocity greater than or equal to 1.5 cm/year (0.6 in/year) **AND** 4. Evidence of open epiphyses, defined as follows: a. Tanner stage less than 4 **OR** b. Bone age less than 16 years in male or less than 14 years in female. Bone age must be obtained annually when chronologic age reaches 15 years in male or 13 years in female **AND** 5. Person is ambulatory and able to stand without assistance For reauthorization, ALL the following criteria must be met: 1. Documentation of *an improvement* in annual growth velocity of greater than or equal to 1.0 cm/year from baseline (for example, if baseline AGV is 2.0 cm/year, 3.0 cm/year is required for reauthorization) **AND** 2. Current growth velocity greater than or equal to 1.5 cm/year (0.6 in/year) **AND**

	3. One of the following: a. Tanner stage less than 4 **OR** b. Bone age less than 16 years in male or less than 14 years in female. Bone age must be obtained annually when chronologic age reaches 15 years in male or 13 years in female
AGE RESTRICTIONS	Approved for ages 5 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a pediatric endocrinologist or other prescriber specialized in the care of patients with achondroplasia or skeletal dysplasia.
COVERAGE DURATION	Initial authorization and reauthorization will be approved for one year. Shorter reauthorization period may be approved based on slowing of growth velocity or bone age approaching epiphyseal closure.

6. **Maribavir (Livtencity) Tablet**
   a. **Indication**: For treatment of post-transplant cytomegalovirus (CMV) infection/disease that is refractory to treatment with ganciclovir, valganciclovir, cidofovir, or Foscarnet.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
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	4 tablets per day	4 tablets per day	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives (no prior authorization): valganciclovir; Medical Drugs (no prior authorization): ganciclovir, cidofovir, foscarnet			

   c. **Prior Authorization Criteria for Commercial/Medicaid**:

PA PROGRAM NAME	Livtencity

MEDICATION NAME	Livtencity
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	Initial authorization: 1. Documentation of history of hematopoietic stem cell or solid organ transplant 2. Documentation of post-transplant cytomegalovirus (CMV) infection/disease with CMV DNA of 2730 IU/mL or greater in whole blood or ≥910 IU/mL or greater in plasma 3. Documentation that patient is refractory (with or without genotypic resistance), or has an intolerance or contraindication to, treatment with ganciclovir, valganciclovir, cidofovir, or foscarnet Reauthorization: 1. Documentation is provided to support continued therapy as evidenced by incomplete resolution of clinical symptoms, incomplete virologic clearance, or relapse in CMV infection.
AGE RESTRICTIONS	May be approved for 12 years and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a transplant surgeon, infectious disease specialist, oncologist, hematologist
COVERAGE DURATION	Initial authorization and reauthorization will be approved for 8 weeks.

7. **Tixagevimab-cilgavimab vial (Evusheld [EUA])**
   a. **Indication**: Emergency use authorization (EUA) for the pre-exposure prophylaxis of COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40kg)
   b. **Decision**: N/A - Informational monograph only. Formulary status and utilization management will likely be re-assessed after the public health emergency has ended and upon FDA approval.

8. **nirmatrelvir and ritonavir kit (Paxlovid) [EUA] tablet**
   a. **Indication**: For the emergency use for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.
   b. **Decision**: N/A - Informational monograph only. Formulary status and utilization management will likely be re-assessed after the public health emergency has ended and upon FDA approval.

9. **Molnupiravir (EUA) capsule**
   a. **Indication**: For the emergency use for treatment of mild-to moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.
   b. **Decision**: N/A - Informational monograph only. Formulary status and utilization management will likely be re-assessed after the public health emergency has ended and upon FDA approval.

10. **Efgartigimod alfa-fcab (Vyvgart) Vial**
    a. **Indication**: For treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) 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	N/A	N/A	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: pyridostigmine, prednisone			

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

PA PROGRAM NAME	Vyvgart
MEDICATION NAME	Efgartigimod alfa (Vyvgart®)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For Generalized Myasthenia Gravis (gMG), all the following must be met: 1. Anti-acetylcholine receptor (anti-AChR) antibody positive

	AND 2. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV AND 3. Myasthenia Gravis - Activities of Daily Living (MG-ADL) total score of five or greater AND 4. History of failure of at least two immunosuppressive agents over the course of at least 12 months (such as azathioprine, methotrexate, cyclosporine, or mycophenylate) or has an intolerance or contraindication to these therapies AND 5. Dose and frequency is in accordance with FDA-approved labeling Reauthorization for Generalized Myasthenia Gravis (gMG): 1. Documentation of improvement in MG-ADL by at least two points from baseline 2. Dose and frequency is in accordance with FDA-approved labeling
AGE RESTRICTIONS	Age 18 and older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a neurologist or rheumatologist
COVERAGE DURATION	Initial authorization approved for six months. Reauthorization approved for one year.

11. **Inclisiran sodium (Leqvio) Syringe**
    a. **Indication**: For the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C).
    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
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: Praluent®, Repatha®			

c. **Prior Authorization Criteria for Commercial**:

PA PROGRAM NAME	PCSK9 Inhibitors
MEDICATION NAME	Leqvio® (inclisiran syringe) Praluent® (alirocumab injection) Repatha® (evolocumab injection)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Concomitant use with another PCSK9 inhibitor
REQUIRED MEDICAL INFORMATION	*For initial authorization* 1. One of the following: a. Provider attestation of a trial and failure of at least eight weeks of therapy with a high-intensity statin therapy (i.e., atorvastatin 40-80 mg or rosuvastatin 20-40 mg daily), defined as failure to achieve desired LDL-C lowering **OR** b. Provider attestation of statin intolerance, defined as one of the following: i. Rhabdomyolysis ii. Skeletal muscle related symptoms while on atorvastatin or rosuvastatin, and resolution of symptoms after discontinuation iii. Elevated liver enzymes **OR** c. The patient has an FDA labeled contraindication to a statin 2. Must meet listed criteria below for each specific diagnosis: a. For **familial hypercholesterolemia (FH),** one of the following must be met: i. A “possible” diagnosis of FH via Simon Boome criteria or a “probable” diagnosis of FH via Dutch Lipid Clinic Network Criteria score of greater than or equal to 6 (see appendix) OR ii. Genetic mutation in one of the following genes: low-density lipoprotein receptors (LDLR), apolipoprotein B gene (APOB), or proprotein convertase subtilisin kexin type 9 (PCSK9), or ARH adaptor protein 1/LDLRAP1 OR iii. LDL-C greater than 190 mg/dL (pretreatment or highest level while on treatment) and secondary causes have been ruled out. Secondary causes may include hypothyroidism, nephrosis, or extreme dietary patterns OR iv. Presence of xanthomas

	b. For **ASCVD**, attestation of LDL-C greater than or equal to 70 mg/dL and history of clinical ASCVD, defined as one of the following: i. Acute coronary syndromes ii. History of myocardial infarction iii. Stable/unstable angina iv. Coronary or other arterial revascularization v. Stroke or transient ischemic attack vi. Peripheral artery disease presumed to be of atherosclerotic origin vii. Clinically significant multi-vessel coronary heart disease presumed to be of atherosclerotic origin 3. For Praluent® or Leqvio®: a. Documented trial and failure, intolerance, or contraindication to evolocumab (Repatha®) *For initial reauthorization*: Provider attestation of response to therapy, defined as a decrease in LDL-C levels from pre-treatment levels.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	For ASCVD: Must be prescribed by, or in consultation with, a cardiologist For FH: Must be prescribed by, or in consultation with, a cardiologist, endocrinologist, or board certified lipidologist
COVERAGE DURATION	Initial authorization for one year. Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

d. **Prior Authorization Criteria for Medicaid**:

PA PROGRAM NAME	PCSK9 Inhibitors
MEDICATION NAME	Leqvio® (inclisiran syringe) Praluent® (alirocumab injection) Repatha® (evolocumab injection)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	*For initial authorization* 1. For all indications must have documentation of: a. One of the following:

i. Current use of high-intensity statin therapy for at least three months, defined as atorvastatin 80 mg daily or rosuvastatin 40 mg daily, OR
ii. Documented statin intolerance to low dose atorvastatin or rosuvastatin (atorvastatin 10 mg daily or rosuvastatin 5 mg daily) and any other statin at any dose. Statin intolerance is defined as intolerable muscle side effects or biomarker changes (such as elevations of creatinine kinase) that decrease or resolve after discontinuation of therapy with statin.

AND

2. Current use of ezetimibe 10 mg daily for at least three months, or documented intolerance/contraindication to its use. If patient is more than 30% above the goal low-density lipoprotein (LDL) level outlined in the hyperlipidemia criteria below, this criterion for ezetimibe may be waived.

AND

3. Must meet listed criteria below for each specific diagnosis:
   a. For **familial hypercholesterolemia (FH)**, both of the following:
      i. Confirmed diagnosis by one of the following:
         1. Genetic mutation in one of the following genes: low-density lipoprotein receptors (LDLR), apolipoprotein B gene (APOB), or proprotein convertase subtilisin kexin type 9 (PCSK9)OR
         2. Low density lipoprotein cholesterol (LDL-C) greater than 330 mg/dL OR
         3. LDL-C greater than 190 mg/dL and two of the following:
            a. Presence of tendon xanthomas in patient or in first- or second-degree relatives
            b. Personal history of premature atherosclerotic cardiovascular disease (ASCVD) in men less than 55 years or women less than 60 years
            c. First-degree relative with premature ASCVD (men less than 55 years, women less than 60 years)
      ii. Documentation of current (within previous three months) LDL-C greater than 100 mg/dL, taken after at least three months of continuous therapy with statin and ezetimibe outlined in criterion 1 above

   b. For **ASCVD**, both of the following:
      i. Documentation of current (within previous three months) LDL-C greater than 70 mg/dL, taken after at least three months of continuous therapy with statin and ezetimibe outlined in criterion 1 above
      ii. Documentation of very high-risk clinical ASCVD, defined as history of multiple ASCVD events [i.e., acute coronary syndrome (ACS) within previous 12 months,

	history of myocardial infarction, history of ischemic stroke, symptomatic peripheral artery disease] OR one ASCVD event and multiple of the following high-risk conditions: 1. Age 65 years and older 2. Heterozygous familial hypercholesterolemia 3. History of coronary revascularization (CABG or PCI) 4. Diabetes mellitus 5. Hypertension 6. Chronic kidney disease 7. Current smoking 8. Persistently elevated LDL-C above 100 despite maximally tolerated statin therapy and ezetimibe 9. History of congestive heart failure **Initial Reauthorization**: Documentation of response to therapy, defined as a decrease in LDL-C levels of at least 40% from pre-treatment levels.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	For ASCVD: Must be prescribed by, or in consultation with, a cardiologist For FH: Must be prescribed by, or in consultation with, a cardiologist, endocrinologist, or board certified lipidologist
COVERAGE DURATION	Initial authorization for six months. Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

e. **Prior Authorization Criteria for Medicare Part B**:

PA PROGRAM NAME	PCSK9 INHIBITORS
MEDICATION NAME	Leqvio® (inclisiran syringe)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Concomitant use with another PCSK9 inhibitor
REQUIRED MEDICAL INFORMATION	*For initial authorization* 1. One of the following: a. Provider attestation of a trial and failure of at least eight weeks of therapy with a high-intensity statin therapy (i.e., atorvastatin 40-80 mg or rosuvastatin 20-40 mg daily), defined as failure to achieve desired LDL-C lowering **OR** b. Provider attestation of statin intolerance, defined as one of the following:

	i. Rhabdomyolysis ii. Skeletal muscle related symptoms while on atorvastatin or rosuvastatin, and resolution of symptoms after discontinuation iii. Elevated liver enzymes **OR** c. The patient has an FDA labeled contraindication to a statin 2. Must meet listed criteria below for each specific diagnosis: a. For **familial hypercholesterolemia (FH),** one of the following must be met: i. A "possible" diagnosis of FH via Simon Boome criteria or a "probable" diagnosis of FH via Dutch Lipid Clinic Network Criteria score of greater than or equal to 6 (see appendix) OR ii. Genetic mutation in one of the following genes: low-density lipoprotein receptors (LDLR), apolipoprotein B gene (APOB), or proprotein convertase subtilisin kexin type 9 (PCSK9), or ARH adaptor protein 1/LDLRAP1 OR iii. LDL-C greater than 190 mg/dL (pretreatment or highest level while on treatment) and secondary causes have been ruled out. Secondary causes may include hypothyroidism, nephrosis, or extreme dietary patterns OR iv. Presence of xanthomas b. For **ASCVD**, attestation of LDL-C greater than or equal to 70 mg/dL and history of clinical ASCVD, defined as one of the following: i. Acute coronary syndromes ii. History of myocardial infarction iii. Stable/unstable angina iv. Coronary or other arterial revascularization v. Stroke or transient ischemic attack vi. Peripheral artery disease presumed to be of atherosclerotic origin vii. Clinically significant multi-vessel coronary heart disease presumed to be of atherosclerotic origin *For initial reauthorization*: Provider attestation of response to therapy, defined as a decrease in LDL-C levels from pre-treatment levels.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	For ASCVD: Must be prescribed by, or in consultation with, a cardiologist

	For FH: Must be prescribed by, or in consultation with, a cardiologist, endocrinologist, or board certified lipidologist
COVERAGE DURATION	Initial authorization for one year. Reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

New Drug Strengths and Formulations:

1. **Varenicline tartrate (Tyrvaya) Spray Metr**
   a. **Indication**: For the treatment of signs and symptoms of dry eye disease (DED).
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Non-formulary Part B: N/A
Tier**	N/A	N/A	N/A
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	N/A	N/A	N/A
Quantity Limit	4.2 ML/30 days	4.2 ML/30 days	N/A
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: Restasis, Xiidra, Lacrisert			

2. **Pilocarpine hcl (Vuity) Drops**
   a. **Indication**: For the treatment of presbyopia in adults.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Non-formulary	Non-formulary	Part D: Formulary Part B: N/A
Tier**	N/A	N/A	Non-preferred Drug
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A

Quantity Limit			
* Recommendations for placement may differ between lines of business due to regulatory requirements. ** Medications will be placed on recommended tier above for the base formulary; tier placement for custom formulary(ies) will be based on designation above. For example, Commercial Tier 6 designation above means that the medication will be placed on the highest cost-sharing tier on the respective formulary(ies).			
Formulary Alternatives: None			

c. **Prior Authorization Criteria for Commercial/Medicaid**:

PA PROGRAM NAME	Vuity
MEDICATION NAME	Vuity
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	Pilocarpine 1.25% ophthalmic solution (Vuity) is not considered medically necessary and will not be covered as corrective lenses (reading glasses) are available over-the-counter (OTC) or covered through vision benefit, if available.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	N/A

Other Formulary Changes:

Drug Name	Recommendation	Policy Name
Omnipod Dash	Add to Medicare Part D formulary: Formulary, Tier 4, Prior Authorization, Quantity Limit (10 pods per 30 days)	Disposable Insulin Pumps

PA PROGRAM NAME	Disposable Insulin Pumps
MEDICATION NAME	Omnipod 5 Pack/Omnipod Dash/Omnipod Starter
PA INDICATION INDICATOR	3 - All Medically-Accepted Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A

REQUIRED MEDICAL INFORMATION	One of the following: 1. Patient has Type 1 diabetes, or 2. Documentation that the patient requires multiple daily doses of rapid- or short-acting insulin (Humalog®, Humulin R®, Humulin® mix) therapy and has any of the following while on their current therapy for diabetes a. Documented need for more than five daily injections of insulin. b. Inadequate glycemic control, defined as glycosylated hemoglobin level (HbA1C) greater than 7%, c. Recurring episodes of significant hyperglycemia, d. Severe glycemic fluctuations e. Documented hypoglycemia unawareness or recurring, symptomatic hypoglycemia episodes Requests for additional pods may be covered when the patients' total daily dose of insulin is more than 65 units per day. The quantity will be limited to the appropriate number of pods per month based on insulin utilization (each pod can hold 200 units of insulin and must be changed every 72 hours)
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Authorization will be approved until no longer eligible with the plan

Cinacalcet hcl Tablet	Down-tier for Commercial/Medicaid: • Commercial Standard: Tier 2 (from Tier 6) • Commercial Cost-Based: Tier 4 (from Tier 6) • Medicare Part D: Tier 4 (from Tier 6)	N/A
Glycopyrrolate (Dartisla) Tab Rapdis	New dosage form; • Commercial/Medicaid: Non-Formulary, Quantity Limit (4 tablets per day) • Medicare Part D: Non-Formulary, FDA Max (4 tablets per day)	N/A
Doxylamine succinate 25 mg Tablet	Added to Medicaid Formulary	N/A
Levocetirizine dihydrochl Powder	Remove from Commercial and Medicaid Formularies	N/A

Pneumococcal 20-valent conjugate vaccine (diphtheria crm)/pf (Prevnar 20) Syringe	New entity; • All lines of business: Medical Benefit, Prior Authorization (patients <19 years), Quantity Limit (One dose per lifetime) EFFECTIVE: 07/01/2022	Pneumococcal Vaccines
Pneumococcal 15-valent conjugate vaccine (diphtheria crm)/pf (Vaxneuvance) Syringe	New formulation; All lines of business: Medical Benefit, Prior Authorization (patients <19 years), Quantity Limit (One dose per lifetime) EFFECTIVE: 07/01/2022	Pneumococcal Vaccines
Pneumococcal 13-valent conjugate (Prevnar 13)	Add Prior Authorization for patients aged 19 years and older for all lines of business EFFECTIVE: 07/01/2022	Pneumococcal Vaccines
Pneumococcal vaccine polyvalent (Pneumovax 23®)	Add Prior Authorization for patients aged 3 years and older for all lines of business EFFECTIVE: 07/01/2022	Pneumococcal Vaccines
Pyridoxine 25 mg hcl Tablet	Added to Medicaid Formulary	N/A
Budesonide (Tarpeyo) Capsule DR	New strength (4mg); • Commercial/Medicaid: Non-Formulary, Prior Authorization, Quantity Limit (4 capsules per day) • Medicare Part D: Non-Formulary	• Commercial/Medicaid: Tarpeyo • Medicare Part D: N/A
Fremanezumab-vfrm (Ajovy) Syringe/Auto Injct	Add to Commercial formulary: Formulary, Tier 3, Prior Authorization	Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists
Cyclosporine (Restasis) Droperette	New authorized generic. Non-Formulary for all lines of business	N/A
Relugolix/estradiol/ norethindr (Myfembree) Tablet	Commercial/Medicaid: Add Quantity Limit (1 tablet per day) EFFECTIVE: 07/01/2022	GnRH Antagonists
Elagolix (Orilissa)	Add Quantity Limit for Commercial/Medicaid: • 150 mg: 1 tablet per day • 200 mg: 2 tablets per day EFFECTIVE: 07/01/2022	GnRH Antagonists

Elagolix/Estradiol/ norethindrn (Oriahnn) Cap Seq	Commercial/Medicaid: Add Quantity Limit (2 capsules per day) EFFECTIVE: 07/01/2022	GnRH Antagonists
Somatropin (Omnitrope) Cartridge/ Vial	Medicaid: Remove from formulary	Human Growth Hormones for Adults
• **Chorionic Gonadotropin** • **Follitropin Beta, Recomb (Follistim AQ)** • **Ganirelix Acetate Syringe** • **Chorionic Gonadotropin, Human (Novarel)** • **Menotropins (Menupur®)**	Add to Commercial formulary, Tier 5, Prior Authorization:	Fertility and Related Medications
Nebivolol hcl Tablet	Down-tier generic • Commercial/Medicare Part D: Change from Tier 4 to Tier 3	N/A
Setmelanotide acetate (Imcivree) Vial	Remove from Medicaid formulary, as treatment is for below-the-line indication	Imcivree
Teriparatide (Forteo) Pen Injctr	Remove from Medicaid formulary	Osteoanabolic Agents
Vibegron (Gemtesa) Tablet	Remove from Commercial and Medicaid Formularies	N/A
Fesoterodine fumarate (Toviaz) Tab ER 24H	Remove from Commercial and Medicaid Formularies	N/A
Testosterone (Androgel) 20.25/1.25 Gel MD PMP	Add to Commercial and Medicaid Formularies. • Commercial: Tier 2 • Commercial Cost-Based: Tier 4	N/A
Sapropterin tablet and powder packet	Down-tier the generic for Commercial to Tier 5 from Tier 6	Kuvan
Calcitonin,salmon,synthetic (Miacalcin)	Remove from the Commercial formulary and retire policy due to low risk of over utilization	N/A

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 / Program Name
Rivaroxaban (Xarelto) Susp Recon	New dosage form (Susp Recon) and strength (1 mg/ml). Line extend with Xarelto; • Commercial: Formulary, Tier 3 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 3	N/A
Upadacitinib (Rinvoq) Tab ER 24H	New strength. Line extend with Rinvoq ER 15mg; • Commercial: Formulary, Tier 5, Prior Authorization, Quantity Limit (1 tablet per day) • Medicaid: Formulary, Prior Authorization, Quantity Limit (1 tablet per day) • Medicare Part D: Formulary, Tier 5, Prior Authorization	• Commercial: Therapeutic Immunomodulators – Comm • Medicaid: Therapeutic Immunomodulators – Medicaid • Medicare Part D: Therapeutic Immunomodulators
Lidocaine hcl/collagen (Proxivol) Gel	New dosage form (gel). Line extend as Medical; • Medical benefit for all lines of business	N/A
Pemetrexed (Pemfexy) Vial	New formulation (vial). Line extend with Alimta; • Medical benefit for all lines of business	N/A
Diphtheria, Pertussis (Acell), Tetanus, Polio Vaccine/PF (Quadracel DTAP-IPV) Syringe	New Dosage Form (syringe) and Strength (15-48.5-62); Line extend with Quadracel vial • Commercial: Preventive, Quantity Limit (0.5 ml per day) • Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 3	N/A
Lanadelumab-flyo (Takhzyro) Syringe	New dosage form (syringe). Line extend with Takhzyro vial; • Commercial: Formulary, Tier 6, Prior Authorization, Quantity Limit (4 ml per 28 days)	• Commercial/Medicaid: Prophylactic Hereditary Angioedema Therapy • Medicare Part D: Hereditary Angioedema Therapy

	• Medicaid: Formulary, Prior Authorization, Quantity Limit (4 ml per 28 days) • Medicare Part D: Formulary, Tier 5, Prior Authorization, Quantity Limit (4 ml per 28 days	
Talazoparib tosylate (Talzenna) Capsule	New strengths (0.5mg, 0.75mg). Line extend with Talzenna 0.25mg, 1mg capsules; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	• Commercial/Medicaid: Oral Anti-Cancer Medications • Medicare Part D: Anti-Cancer Agents
Vasopressin (Vasostrict) Infus. bottle	New dosage form (Infusion bottle) and strength (40 units/100ml). Line extend with Vaosctrict vial; • Commercial: Medical Benefit • Medicaid/Medicare Part D: Non-Formulary	N/A

New Generics:

Drug Name	Action Taken	Policy Name
Dexlansoprazole dr (Dexlansoprazole) Cap DR BP	First generic (Dexilant). Line extend as generic; • Commercial Standard: Formulary, Tier 2, Step Therapy • Commercial Cost-Based: Formulary, Tier 4, Step Therapy • Medicaid: Formulary • Medicare Part D: Formulary, Tier 4, Step Therapy	• Commercial: Proton Pump Inhibitors Step Therapy • Medicaid: N/A • Medicare Part D: Nexium Packet/Dexilant
Lanreotide acetate Syringe	Marketed under NDA (Somatuline Depot). Line extend as generic;	• Commercial/Medicaid: Somatostatin Analogs

	• Commercial/Medicaid: Medical Benefit, Prior Authorization • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit, Prior Authorization	• Medicare Part B: Somatostatin Analogs – Medicare Part B
Glycopyrrolate (Solution)	First generic (Cuvposa). Line extend as generic; • Commercial Standard: Formulary, Tier 2 • Commercial Cost-Based: Formulary, Tier 4 • Medicaid: Formulary • Medicare Part D: Non-Formulary	N/A
Lidocaine (Ziloval) Kit	First generic (LidoPac). Line extend as generic; • Non-Formulary for all lines of business	N/A
Brimonidine Tartrate-Timolol Drops	Marketed under NDA. Line extend as generic; • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Formulary, Tier 4	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Vasopressin Vial	First generic medical. Line extend as generic; • Medical benefit for all lines of business	N/A
Betaine (Betaine Anhydrous) Scoop Powder	First generic (Cystadane). Line extend as generic; • Commercial Standard: Formulary, Tier 2, Specialty • Commercial Cost-Based: Formulary, Tier 4, Specialty • Medicaid: Non-Formulary, Specialty • Medicare Part D: Formulary, Tier 5	N/A
Maraviroc Tablet	First generic (Selzentry). Line extend as generic; • Commercial Standard: Formulary, Tier 2	N/A

	• Commercial Cost-Based: Formulary, Tier 3 • Medicaid: /Formulary • Medicare Part D: Formulary, Tier 5	
Amphotericin B Liposome Vial	First generic (Ambisome). Line extend as generic; • Commercial/Medicaid: Medical Benefit • Medicare Part D: Formulary, Tier 5 • Medicare Part B: Medical Benefit	N/A
Artesunate Vial	First generic. Line extend as generic; • Medical benefit for all lines of business	N/A
Deferiprone Tablet	First generic (Ferriprox). Line extend as generic; • Commercial: Formulary, Tier 6 • Medicaid: Non-Formulary, Specialty • Medicare Part D: Non-Formulary	N/A

Clinical Policy Changes:

PHARMACY CLINICAL POLICIES – MAJOR CHANGES	
Policy Name	**Summary of Change**
Crysvita	Exclusion criteria were added to limit use in patients with poor renal function.
Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists	Ajovy® is being added as a preferred therapy.
Disposable Insulin Pumps	Quantity Limits were updated to clarify when more Omnipod® insulin pods would be required based on patient's insulin utilization. Also updated to allow without other criteria for patients with Type 1 diabetes.
Enzyme Replacement Therapy	Age restrictions were added to ensure appropriate utilization of therapies.
Fertility and Related Medications	Clarified coverage of therapies for different benefit structures.
GnRH Antagonists	Updated policy criteria to define trial and failure duration of hormonal contraceptives as three months
Human Growth Hormones for Adults	Updated criteria for trial of preferred products over non-preferred products

Human Growth Hormones for Pediatrics	Skytrofa®, a new growth hormone (GH) product, added to the policy as non-preferred GH product. Policy criteria added for SHOX deficiency and updated criteria for Pader-Wili Syndrome (PWS) to include short stature as not all patients with this will have associated growth hormone deficiency. Reauthorization criteria updated to require trial and failure of preferred GH product.
Imcivree	Policy reviewed and updated to include statement that for Medicaid, obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency is considered below the line
Kuvan	Policy reviewed and updated to include trial and failure, intolerance, or contraindication to generic sapropterin dihydrochloride in policy criteria.
Medical Nutrition – Medicaid	Updated oral nutrition criteria to align with recommendations of the Oregon Health Authority.
Medical Nutrition - Medicare Part B	Updated policy criteria to align with the revised Centers for Medicare & Medicaid Services (CMS) Local Coverage Determination L38955 guidance.
Medically Infused Therapeutic Immunomodulators (Tims) – Comm	Clarified that preferred infliximab products are required for initial authorization and for patients established on therapy.
Natpara	1. Updated pre-treatment required vitamin D level to be "sufficient per laboratory reference range - generally 20 ng/mL" from specific value of 30 ng/mL to align with product monograph and commonly used reference ranges, 2. Added that vitamin D supplementation (used in combination with calcium as first line treatment) should be the active form such as calcitriol, if available, to align with standard of care for hypocalcemia due to hypoparathyroidism and 3. Increased initial authorization period to one year to better align with our reauthorization criteria.
Overactive Bladder Medications Step Therapy	Remove darifenacin from policy due to availability of low-cost generic and added as a trial medication for other products on this policy. Will only require one step through med for all policy medications.
Osteoanabolic Agents	Retired Evenity, Forteo, and Tymlos policies and combined them into this new Osteoanabolic Agents policy.
Pituitary Disorder Therapies	Retired Oral Octreotide, Signifor LAR and Somavert and combined them into this new Pituitary Disorder Therapies policy.
Pneumococcal Vaccines	This is a new policy to outlined coverage for the various pneumococcal vaccines that are now approved for use in various populations. Criteria aligns with CDC/ACIP guidelines
Prophylactic Hereditary Angioedema Therapy	Reviewed and updated preferred drug criteria - will require a trial of Haegarda® prior to approval of Cinryze®.
Radicava	Updated duration of approval for reauthorization to one year given high approval rates. In addition, clarified that on-going coverage would require that patient is responding to therapy and is not experiencing rapid progression of disease.
Self-Administered Drug Exclusion	This is a new policy to outline when drugs that are considered to be self-administrable would be covered for administration by a healthcare professional.

SGLT-2 Inhibitors	Updated criteria for coverage of canagliflozin in diabetic nephropathy to allow for albuminuria greater than 200 mg/day instead of 300 mg/day.
SGLT-2 Inhibitors – Medicaid	Criteria were added to allow for coverage for empagliflozin for patients with diabetes and established cardiovascular disease, without require trial of metformin.
Somatostatin Analogs – Medicare Part B	1. Removed prerequisite trial of short-acting octreotide for acromegaly, carcinoid syndrome and VIP tumors. NCCN lists either short acting octreotide, octreotide LAR or lanreotide as appropriate first line agent and the Endocrinology Society Guidelines for acromegaly list octreotide LAR or lanreotide as appropriate first line medication therapy. 2. Removed pituitary irradiation as prerequisite for acromegaly as per guidelines radiotherapy is consider third line after surgery and medication therapy.
Strensiq	1. Changed initial authorization to require only clinical symptoms OR radiographic features of hypophosphatasia prior to age 18 instead of both. Multiple requests were going the Medical Director for lack of documentation of radiographic features and this criterion was being waived. This also reflects the PA criteria for many other health plans. 2. Adult subsequent reauthorizations only to require stabilization in criteria not continued improvement. 3. Reauthorization increased to 12 months given specific reauthorization criteria that may not be fully assessed every 6 months.
Tarpeyo	New Policy for Commercial and Medicaid to ensure use is a Food and Drug Administration approved indication.
Tepezza	Updated criteria to reflect new guideline recommendations that include use of mycophenylate in combination with intravenous (IV) glucocorticoid (GC) therapy or high-dose IVGC therapy. In addition, Tepezza® is not recommended to be used in patients with sight-threatening disease.
Testosterone Replacement Therapy (TRT)	Added generic testosterone 1.62% pump as a trial and failure option given reduction in cost.
Testosterone Replacement Therapy (TRT) - Medicare Part B	Added generic testosterone 1.62% pump as a trial and failure option given reduction in cost. In addition, add quantity limitation and diagnostic criteria to align with the CMS local coverage determination (LCD).
Therapeutic Immunomodulators – Comm	Several of the agents on this policy were recently granted new FDA-approved indications. The Janus Kinase (JAK) inhibitors are now labeled behind tumor necrosis factor inhibitors (anti-TNFs) due to updates to their label for safety concerns.
Therapeutic Immunomodulators (TIMs) - Medicaid	Clarified that preferred infliximab products are required for initial authorization and for patients established on therapy.
Tolvaptan	Simplified diagnosis criteria as diagnosis of autosomal dominant polycystic kidney disease (ADPKD) is complex patient and technique specific. This algins with many other health plans. Added Mayo imaging classification method as option for defining rapidly progressing ADPKD as it is being used
Total Parental Nutrition - Medicare Part B	Updated policy criteria to align with the revised Centers for Medicare & Medicaid Services (CMS) Local Coverage Determination L38953 guidance.

New Indications:

Therapies with Prior Authorization Policies (Non-oncology)

1. **RITUXAN® (**rituximab)
    a. New indication approved 12/02/2021:
        i. Pediatric patients aged 6 months and older with mature B-cell NHL and mature B-cell acute leukemia (B-AL)
            1. Previously untreated, advanced stage, CD20-positive, diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. The FDA approved indications section for Commercial, Medicaid, and Medicare Part B Rituximab prior authorization policies will be updated. No updates to criteria warranted.

2. **ZEPATIER® (**elbasvir and grazoprevir)
    a. New indication approved 12/09/2021:
        i. for treatment of chronic HCV genotype 1 or 4 infection in adult and pediatric patients 12 years of age and older or weighing at least 30 kg
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. The FDA approved indications section for Commercial and Medicaid Hepatitis C Direct Acting Antivirals prior authorization policies will be updated. No updates to criteria warranted.

3. **LASTACAFT® (**alcaftadine)
    a. New indication approved 12/10/2021:
        i. Alcaftadine ophthalmic solution will be over-the-counter
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Alcaftadine ophthalmic solution will be removed from the Commercial formulary and the policy below.

Prior Authorization for Commercial

PA PROGRAM NAME	Bepreve®, Lastacaft®, Zerviate®
MEDICATION NAME	Lastacaft ®
COVERED USES	3 - All Medically-Accepted Indications
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For Bepreve®, ~~Lastacaft®,~~ Zerviate®**:** 1. Documented trial and failure, contraindication or intolerance to olopatadine 0.2% eye drops

	(generic for Pataday®) AND 2. Documented trial and failure, contraindication or intolerance to azelastine opthalmic solution (Optivar®**)**

4. **XELJANZ/XELJANZ XR® (**tofacitinib)
    a. New indication approved 12/02/2021:
        i. treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers
        ii. treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers
    b. New indication approved 12/14/2021:
        i. treatment of adult patients with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers
    c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy for Commercial was updated by chair vote and included with the April 2022 P&T meeting materials. No updates to Medicaid or Medicare part D criteria warranted.

5. **RINVOQ® (**Upadacitinib)
    a. New indication approved 12/02/2021:
        i. for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers
    b. New indication approved 12/14/2021:
        i. adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers
    c. New indication approved 01/14/2022:
        i. Adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable
    d. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy for Commercial was updated by chair vote and included with the April 2022 P&T meeting materials. No updates to Medicaid or Medicare part D criteria warranted.

6. **ORENCIA® (**abatacept)
    a. New indication approved 12/15/2021:

i. the prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor.

b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy for Commercial was updated by chair vote and included with the April 2022 P&T meeting materials. No updates to Medicaid or Medicare part D criteria warranted.

7. **CAPLYTA® (**lumateperone)
   a. New indication approved 12/17/2021:
      i. Depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults, as monotherapy and as adjunctive therapy with lithium or valproate
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. The FDA approved indications section for Commercial Antipsychotic Step Therapy policy will be updated. No updates to criteria warranted.

8. **OXBRYTA® (**voxelotor)
   a. New indication approved 12/17/2021:
      i. for the treatment of sickle cell disease in adults and pediatric patients four years of age and older
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert and update prior authorization criteria for Commercial and Medicaid as outlined below:

Prior Authorization for Commercial/Medicaid:

PA PROGRAM NAME	Oxbryta
MEDICATION NAME	Oxbryta
COVERED USES	Sickle cell disease, subject to criteria outlined
AGE RESTRICTIONS	May be approved for patients four years of age and older

9. **OTEZLA® (**apremilast)
   a. New indication approved 12/20/2021:
      i. Adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy
   b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy for Commercial was updated by chair vote and included with the April 2022 P&T meeting materials. No updates to Medicaid or Medicare part D criteria warranted.

10. **COSENTYX® (**secukinumab)
    a. New indication approved 12/22/2021:
       i. active psoriatic arthritis (PsA) in patients two years of age and older

ii. active enthesitis-related arthritis (ERA) in patients four years of age and older

b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy for Commercial was updated by chair vote and included with the April 2022 P&T meeting materials. No updates to Medicaid or Medicare part D criteria warranted.

11. **REXULTI® (**brexpiprazole)
    a. New indication approved 12/27/2021:
        i. Treatment of schizophrenia in adults and pediatric patients ages 13 years and older
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. The FDA approved indications section for Commercial Antipsychotic Step Therapy policy will be updated. No updates to criteria warranted.

12. **DESCOVY® (**emtricitabine and tenofovir alafenamide)
    a. New indication approved 01/07/2022:
        i. HIV treatment: in combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor for the treatment of HIV-1 infection in pediatric patients weighing at least 14 kg and less than 35 kg
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. The FDA approved indications section for Commercial and Medicaid Descovy prior authorization policies will be updated. No updates to criteria warranted.

13. **SKYRIZI® (**Risankizumab-rzaa)
    a. New indication approved 01/21/2022:
        i. active psoriatic arthritis in adults
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy for Commercial was updated by chair vote and included with the April 2022 P&T meeting materials. No updates to Medicaid or Medicare part D criteria warranted.

<u>Therapies with Prior Authorization Policies (Oncology)</u>

14. **KEYTRUDA® (**pembrolizumab)
    a. New indication(s) approved 12/03/2021:
        i. for the adjuvant treatment of adult and pediatric (12 years and older) patients with Stage IIB, IIC, or III melanoma following complete resection
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

15. **KISQALI® (**ribociclib)
    a. New indication(s) approved 12/10/2021:
        i. For treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-neative advanced or metastatic cancer in combination with fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy in postmenopausal women or in men
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

16. **KISQALI FEMARA CO-PACK® (**ribociclib, letrozole)
    a. New indication(s) approved 12/10/2021:
        i. Indicated as initial endocrine-based therapy for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2) negative advanced or metastatic breast cancer
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. Prior authorization policy coverage criteria are based on recommendations from the National Comprehensive Cancer Network (NCCN); no updates to the policy are warranted.

<u>Therapies Without Prior Authorization Policies</u>

17. **SIKLOS® (**hydroxyurea)
    a. New indication(s) approved 12/07/2021:
        i. indicated to reduce the frequency of painful crises and to reduce the need for blood transfusions in adult and pediatric patients, two years of age and older, with sickle cell anemia with recurrent moderate to severe painful crises
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

18. **ZYNRELEF® (**bupivacaine and meloxicam)
    a. New indication(s) approved 12/08/2021:
        i. indicated in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after foot and ankle, small-to-medium open abdominal, and lower extremity total joint arthroplasty surgical procedures.
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

19. **EPZICOM® (**abacavir and lamivudine)

a. New indication(s) approved 12/10/2021
    i. indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection
        1. Not recommended in patients with creatinine clearance less than 30 mL per minuted or patients with hepatic impairment
b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

20. **VEKLURY® (**remdesivir)
    a. New indication(s) approved 01/21/2022:
        i. for the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, who are:
            1. Hospitalized, or
            2. Not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

21. **SOLOSEC® (**secnidazole)
    a. New indication(s) approved 01/26/2022:
        i. Treatment of bacterial vaginosis in female patients 12 years of age and older.
        ii. Treatment of trichomoniasis in patients 12 years of age and older.
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

22. **PIFELTRO® (**doravirine)
    a. New indication(s) approved 01/27/2022:
        i. indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg:
            1. with no prior antiretroviral treatment history, OR
            2. 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 with no history of treatment failure and no known substitutions associated with resistance to doravirine
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

23. **DELSTRIGO® (**doravirine, lamivudine, and tenofovir disoproxil fumarate)
    a. New indication(s) approved 01/27/2022:
        i. indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg:
            1. with no antiretroviral treatment history, OR

2. 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 with no history of treatment failure and no known substitutions associated with resistance to the individual components of DELSTRIGO

b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

24. **GEODON® (**ziprasidone)
    a. New indication(s) approved 01/28/2022:
        i. Oral formulation: treatment of schizophrenia in adults
        ii. Injection formulation: acute treatment of agitation in schizophrenic patients in adults
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

25. **EDURANT® (**rilpivirine)
    a. New indication(s) approved 01/31/2022:
        i. indicated in combination with VOCABRIA (cabotegravir), for short-term treatment of HIV-1 infection in adults who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine
    b. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

26. **VOCABRIA ® (**cabotegravir)
    a. New indication(s) approved 12/20/2021:
        i. indicated in at-risk adults and adolescents weighing at least 35 kg for short-term pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to initiating VOCABRIA

RECOMMENDATION: Inform prescribers via Medical Policy Alert.

Drug Safety Monitoring:

FDA Drug Safety Communications

1. **Drug Name:** buprenorphine (tablets and films dissolved under the tongue)
    - **Date Posted:** 01-12-2022
    - **Safety Alert Title:** FDA warns about dental problems with buprenorphine medicines dissolved in the mouth to treat opioid use disorder and pain

- **Link to more information:** https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-dental-problems-buprenorphine-medicines-dissolved-mouth-treat-opioid-use-disorder
- **What safety concern is FDA announcing?**
  - The U.S. Food and Drug Administration (FDA) is warning that dental problems have been reported with medicines containing buprenorphine that are dissolved in the mouth. The dental problems, including tooth decay, cavities, oral infections, and loss of teeth, can be serious and have been reported even in patients with no history of dental issues. Despite these risks, buprenorphine is an important treatment option for opioid use disorder (OUD) and pain, and the benefits of these medicines clearly outweigh the risks.
  - Regular adherence to buprenorphine to treat OUD reduces withdrawal symptoms and the desire to use opioids, without causing the cycle of highs and lows associated with opioid misuse. The comprehensive approach of buprenorphine combined with counseling and other behavioral therapies is often one of the most effective ways to treat OUD. This approach, called medication-assisted treatment (MAT), is tailored to meet each patient's needs and can help sustain recovery and prevent or reduce opioid overdose. According to the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA), MAT has been shown to be effective in improving patient survival, decreasing opioid use, and allowing patients to live a self-directed life, including the ability to gain and maintain employment.
- **What is FDA doing?**
  - We are requiring a new warning about the risk of dental problems be added to the prescribing information and the patient Medication Guide for all buprenorphine-containing medicines dissolved in the mouth. The prescribing and patient information will also include strategies to maintain or improve oral health while undergoing treatment with these medicines. These strategies will include recommending that prescribers refer patients to dental care services and encourage them to have regular checkups while taking these products. Patients should tell the dentist about all medicines they take, including buprenorphine.
- **What should health care professionals do?**
  - Health care professionals should be aware the benefits of buprenorphine medicines clearly outweigh the risks and are an important tool to treat OUD. When combined with counseling and other behavioral therapies, this comprehensive MAT approach is often the most effective way for treating OUD, and can help sustain recovery and prevent or reduce opioid overdose.
  - Ask patients about their oral health history prior to prescribing treatment with a transmucosal buprenorphine medicine. These serious dental problems have been reported even in patients with no history of dental issues, so refer them to a dentist as soon as possible after starting transmucosal buprenorphine. Counsel patients about the potential for dental problems and the importance of taking extra steps after the medicine has completely dissolved, including to gently rinse their teeth and gums with water and then swallow. Patients should be advised to wait at least 1 hour before brushing their teeth. Dentists treating someone taking a transmucosal buprenorphine product should perform a baseline dental evaluation and caries risk assessment, establish a dental caries preventive plan, and encourage regular dental checkups.
- **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

Drug Recalls/Market Withdrawals

1. **Drug Name:** All drugs compounded at Edge Pharma, LLC
   - **Date of Recall:** December 04, 20221
   - **Reason for recall:** Process issues that could lead to a lack of sterility assurance for products intended to be sterile and could impact the safety and quality of non-sterile products
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/edge-pharma-llc-issues-voluntary-nationwide-recall-all-drug-products-due-lack-sterility-assurance
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.

2. **Drug Name:** Metformin HCL Extended-Release Tablets
   - **Date of Recall:** January 07, 2022
   - **Reason for recall:** N-Nitrosodimethylamine (NDMA) Impurity
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/viona-pharmaceuticals-inc-issues-voluntary-nationwide-recall-metformin-hcl-extended-release-tablets-0
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert.