PROVIDENCE Health Plan

PROVIDENCE Health Assurance

Healthcare Services Medical & Pharmacy Policy Alerts

Number 268

March 1, 2022

This is the March 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 4/1/2022

Surgical Site of Service **MP184**	**Policy Updates:** • Criteria added for total hip arthroplasty (THA) for inpatient settings. Criteria are based largely on current total knee arthroplasty criteria. • Two-part prior authorization process will be established: THA's will be reviewed first for medical necessity per the "Hip: Total Joint Arthroplasty" policies, then if approved, for inpatient site of service, per this policy. • References to Medicare guidance documents added addressing site of service criteria. **Codes/PA:** • No coding changes; PA still required.
Hip: Total Joint Arthroplasty (All Lines of Business Except Medicare) **MP130**	**Policy Updates:** • Add note referencing site of service criteria for total hip arthroplasty procedures. • Remove "not medically necessary" note regarding robotic surgical assistance, per coding policy. **Codes/PA:** • **Two-part PA:** THA's will be reviewed first for medical necessity, then if approved, for inpatient site of service criteria on the "Surgical Site of Service" policy. • No changes to codes/PA per this policy. See "Surgical Site of Service" update above for additional information.
Hip: Total Joint Arthroplasty (Medicare Only) **MP133**	**Policy Updates:** • No change to criteria (continue to apply Noridian LCD for general medical necessity criteria), but the following revisions were made to the policy: ○ In addition to the general medical necessity criteria in this policy, **one** (1) hip arthroplasty CPT code (27130) will **also** be subject to surgical site of service (SOS) review, using the All Lines of Business SOS policy. A note with this direction was added to this THA policy, as well as added to the "Billing Guidelines" section. ○ For this single CPT code, there is a **two-part PA process required:** Total hip arthroplasties (THAs) are reviewed first for medical necessity. If approved, CPT code 27130 will also undergo review using inpatient site of service criteria on the "Surgical Site of Service" policy. Remaining codes are not subject to SOS policy criteria for Medicare only. **Codes/PA:** • No coding or configuration changes required codes. Continue PA per this policy.

Gastroesophageal Reflux Disease: Endoscopic Treatments (Medicare Only) **MP197**	**Policy Updates:** • Cover transoral incisionless fundoplication (TIF) when criteria are met without PA or review for Medicare lines of business. **Codes/PA:** • CPT 43210: Remove PA, allow code to adjudicate per member benefits and provider contract.
Blood Counts **(All Lines of Business Except Medicare)** **MP208**	**Policy Updates:** • Add additional dx codes to list that deny as not medically necessary when billed with a CPT code for blood counts (per Medicare NCD Coding Policy Manual and Change Report.) • Diagnosis codes related to antenatal screening (Z360 -Z365 and Z3681-Z3689) will now pay when billed with a CPT code for blood counts.

MEDICAL
Effective 5/1/2022

Premature Rupture of Membranes (PROM) Testing **MP97**	**Policy Updates:** • No recommended changes to criteria • Code 0066U (for PartoSure) will now deny as investigational (member responsibility).

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.

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

PROVIDENCE Health Plan

PROVIDENCE Health Assurance

Pharmacy & Therapeutics (P&T) Committee

Oregon Region P&T Committee Meeting February 4, 2022
Go-Live Date: Friday, April 01, 2022, unless otherwise noted

Table of Contents:

New Drugs and Combinations:

1. **Finerenone (Kerendia) Tablet**
   a. To reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease, cardiovascular death, nonfatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2DM)
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 4	N/A	
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	One tablet per day	One tablet per day	One tablet 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: ACE-I/ ARBs, SGLT2 inhibitors

c. Prior Authorization Criteria:

PA PROGRAM NAME	Kerendia
MEDICATION NAME	Finerenone tablet (Kerendia®)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	N/A
REQUIRED MEDICAL INFORMATION	For initiation of therapy: 1. Patient has a diagnosis of type 2 diabetes 2. Patient has evidence of diabetic nephropathy, defined as one of the following: a. Estimated glomerular filtration rate (eGFR) of 60 mL/min/1.73m2 or less for at least three months b. Persistent moderate to severe albuminuria [urine albumin-to-creatinine ratio (UACR) 30 mg/g or greater, or 0.113 mg/mmol or greater] for at least three months c. Moderate to severe proteinuria [urine protein-to-creatinine ratio (UPCR) 200 mg/g or greater] for at least three months 3. Documentation that patient is on a maximally tolerated Angiotensin Converting Enzyme inhibitor (such as lisinopril) or an Angiotensin Receptor Blocker (such as losartan), unless all agents in these classes are contraindicated 4. Documentation of trial, contraindication, or intolerance to a Sodium Glucose Co-transporter-2 inhibitor (such as empagliflozin or dapagliflozin)
AGE RESTRICTIONS	Approved for patients 18 years of age and older
PRESCRIBER RESTRICTIONS	N/A
COVERAGE DURATION	Initial authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes

2. **Avacopan (Tavneos) Capsule**
   - **a.** Indicated as an adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids. Avacopan does not eliminate glucocorticoid use.
   - **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	6 capsules/day	6 capsules/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: glucocorticoids			

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

PA PROGRAM NAME	Avacopan (Tavneos®)
MEDICATION NAME	Avacopan capsule
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Cirrhosis
REQUIRED MEDICAL INFORMATION	For initial authorization, all the following criteria (1-5) must be met: 1. Confirmed diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis or microscopic polyangiitis)

	2. Documentation that patient is currently receiving standard therapy (cyclophosphamide or rituximab) including glucocorticoids for induction of remission, unless clinically significant adverse effects are experienced or are contraindicated 3. Documentation of organ-threatening or life-threatening disease (such as active glomerulonephritis, pulmonary hemorrhage, cerebral vasculitis, progressive peripheral or cranial neuropathy, orbital pseudotumor, scleritis, gastrointestinal bleeding due to vasculitis, cardiac disease due to vasculitis [pericarditis, myocarditis]) despite standard therapy outlined above 4. Documentation of estimated glomerular filtration rate (eGFR) equal to or greater than 15 mL/min/1.72m2 5. Documentation of baseline liver function tests (ALT, AST, alkaline phosphatase, total bilirubin) For reauthorization, all the following must be met: 1. Documentation of clinical benefit of therapy defined as one of the following: a. Improved or sustained renal function b. Documentation of decreased glucocorticoid dose
AGE RESTRICTIONS	18 years of age or older
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a rheumatologist or nephrologist
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for six months.

3. **Asciminib hydrochloride (Scemblix) Tablet** reviewed by Jane Hoh, PharmD.
   a. **Indication**: For the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs) and Ph+ CML in CP with the T315I mutation.
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Formulary	Formulary	Part D: Formulary Part B: N/A
Tier**	Tier 6 - Non-Preferred Specialty	N/A	Specialty
Affordable Care Act Eligible	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	Prior Authorization
Quantity Limit	2 tablets/day	2 tablets/day	2 tablets/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: ponatinib (Iclusig®; oral tablet), omacetaxine (Synribo®; SQ)

c. **Prior Authorization Criteria for Commercial/Medicaid**: Added to Oral Anti-Cancer Medications Policy
d. **Prior Authorization Criteria for Medicare Part D**: Added to Anti-Cancer Agents Program

4. **Maralixibat chloride (Livmarli) Solution** reviewed by Jessica Niculcea, PharmD.
   a. **Indication**: For the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) one year of age and older.
   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	FDA max dose: 3 mL/day	FDA max dose: 3 mL/day	FDA max dose: 3 mL/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: ursodiol, cholestyramine, rifampin			

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

PA PROGRAM NAME	Cholestatic Pruritus Agents
MEDICATION NAME	Maralixibat chloride solution (Livmarli®) Odevixibat (Bylvay®)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A

EXCLUSION CRITERIA	1. History of liver transplant 2. Decompensated cirrhosis 3. History of surgical interruption of enterohepatic circulation, such as partial external biliary diversion surgery (For Livmarli® only) 4. Molecular genetic testing indicates PFIC type 2 with *ABCB11* variants encoding for nonfunction or absence of BSEP-3 protein (For Bylvay® only)
REQUIRED MEDICAL INFORMATION	For initial authorization, all the following criteria must be met: 1. Documentation of moderate-to-severe pruritus AND 2. Documentation that drug-induced pruritis has been ruled out AND 3. Documentation of trial and failure, contraindication, or intolerance to ALL of the following systemic medications for pruritis associated with cholestasis: a. Ursodiol b. Cholestyramine c. Rifampin 4. Indication-specific criteria, as outlined below: a. For Cholestatic pruritus in patients with confirmed diagnosis of **Alagille syndrome (ALGS)**, Livmarli® may be approved with documentation of cholestasis, as indicted by at least one of the following: i. Total serum bile acid greater than three times the upper limit of normal (ULN) for age, **or** ii. Conjugated bilirubin greater than 1 mg/dL, or iii. Fat soluble vitamin deficiency that is otherwise unexplainable, or iv. Gamma Glutamyl Transferase (GGT) greater than three times ULN for age, or v. Intractable pruritus explainable only by liver disease b. For Progressive **Familial Intrahepatic Cholestasis (PFIC)**, Bylvay® may be approved when the following criteria are met: i. Documentation of genetically confirmed PFIC type 1 or 2 (formerly known as Byler disease or syndrome) (note: gene mutations affiliated with PFIC include the ATP8B1 gene, ABCB11 gene, ABCB4 gene, TJP2 gene, NR1H4 gene, and MYO5B gene) AND ii. Documentation that serum bile acids at least 100 micromol/L For reauthorization: documentation of response to therapy, defined as both of the following: 1. Improvement in pruritus 2. Reduction in serum bile acids from baseline, defined as:

	a. For Livmarli®: at least 50% reduction b. For Bylvay®: at least 70% reduction
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	Must be prescribed by, or in consultation with, a hepatologist or gastroenterologist
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved for one year.

5. **Atogepant (Qulipta) Tablet** reviewed by Savanna Muravez, PharmD., BCPS
   a. **Indication**: For the preventive treatment of episodic migraine in adults.
   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: Aimovig®, Emgality®			

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

PA PROGRAM NAME	Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists

MEDICATION NAME	Atogepant (Qulipta®)
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	• Concomitant use of more than one calcitonin gene-related (CGRP) agent • Concomitant use of CGRP agent for migraine prophylaxis with botulinum toxin for cluster headaches or migraine headaches that do not meet criteria outlined
REQUIRED MEDICAL INFORMATION	1. For initial authorization, the following indication-specific criteria must be met: a. For **migraine prophylaxis (chronic and episodic)**, Emgality®, Aimovig®, Ajovy®, Vyepti®, Nurtec ODT®, or **Qulipta®** may be covered if the following criteria are met: i. Diagnosis of migraine headaches with at least four headache days per month, AND ii. One of the following: 1. Trial and inadequate response to at least six weeks of at least one prophylactic medication from one of the following categories: a. Anticonvulsants, specifically divalproex, valproate, or topiramate b. Beta-blockers, specifically metoprolol, propranolol, or timolol c. Antidepressants, specifically amitriptyline or venlafaxine 2. Documented intolerance or contraindication to an anticonvulsant, a beta blocker, AND an antidepressant listed above iii. The patient has been evaluated for, and does not have, medication overuse headache iv. For non-preferred CGRP prophylactic agents (Ajovy®, Vyepti®, Nurtec ODT®, **Qulipta®**): Trial and failure, intolerance, or contraindication to two of the preferred CGRP agents (Aimovig® and Emgality®) v. For patients established on botulinum toxin for migraine prophylaxis, combination therapy may be considered medically necessary if the following criteria are met: 1. The patient has been established on, and adherent to botulinum toxin for at least six months and has a documented 30% reduction in headache days from baseline 2. Patient continues to have at least four headache days per month with headaches lasting four hours or longer, despite use of botulinum toxin prophylaxis monotherapy

	3. Combination therapy is prescribed by, or in consultation with, a neurologist 2. For patients established on the requested therapy, the following criteria must be met. Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy: a. For migraine prophylaxis: Documented reduction in the severity or frequency of headaches. b. For acute treatment of migraines: Documentation of treatment success, as demonstrated by a reduction of migraine pain or freedom from migraine symptoms 3. For quantity limit exception requests: a. For migraine prophylaxis: doses above the FDA maximum recommended dose will not be covered. i. Nurtec ODT® will be allowed at a quantity of 18 tablets per 30 days if coverage for migraine prophylaxis is approved. ii. **Qulipta® will be allowed at a quantity of one tablet per day if coverage for migraine prophylaxis is approved.** b. For acute treatment of migraines: i. The safety and efficacy of treating more than eight migraine headaches per month with ubrogepant (Ubrelvy®) has not been established; quantities to treat more than eight migraine headaches (16 tablets) will not be covered. ii. Quantities of up to 18 tablets per month of rimegepant (Nurtec ODT®) may be covered if the patient is on prophylactic therapy with a non-CGRP agent (e.g., divalproex, valproate, topiramate, metoprolol, propranolol, timolol, amitriptyline, or venlafaxine) and the patient is still experiencing more than two headache days per week.
AGE RESTRICTIONS	N/A
PRESCRIBER RESTRICTIONS	N/A for migraine prophylaxis
COVERAGE DURATION	Initial authorization will be approved for six months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

d. Prior Authorization Criteria for Medicaid: Add to Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists Policy

New Drug Strengths and Formulations:

1. **Sirolimus protein-bound (Fyarro) Vial** reviewed by Jane Hoh, PharmD.
   a. **Indication**: For the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa)
   b. **Decision**:

	Commercial	Medicaid	Medicare
Formulary Status*	Medical	Medical	Part D: Non-formulary Part B: Medical
Tier**	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: oral sirolimus and everolimus			

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

2. **Ruxolitinib Phosphate (Opzelura) Cream** reviewed by Momoka Abe, PharmD.
   a. **Indication**: For the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis (AD) in non-immunocompromised patients 12 years of age and older 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	No	N/A	N/A
Utilization Management Edits	Prior Authorization	Prior Authorization	N/A
Quantity Limit	One tube (60 g) per 30 days	One tube (60 g) per 30 days	FDA Max: 240 g per 28 days
* 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: Crisaborole (Eucrisa®), tacrolimus ointment (Protopic®), pimecrolimus cream (Elidel®)			

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

PA PROGRAM NAME	Opzelura
MEDICATION NAME	Opzelura
PA INDICATION INDICATOR	1 - All FDA-Approved Indications
OFF-LABEL USES	N/A
EXCLUSION CRITERIA	Concurrent use with biologics, other JAK inhibitors or potent immunosuppressants
REQUIRED MEDICAL INFORMATION	For Initial authorization, must meet all of the following criteria: 1. Diagnosis of mild to moderate atopic dermatitis despite use of therapies outlined in criterion number 2 below, as defined by all of the following: a. Patient has a body surface area (BSA) involvement of 3% to 20% b. Chronic condition, affecting patient for at least two years AND 2. Documentation of trial and failure of an adequate treatment course with at least one agent from all each of the following treatment modalities: a. Moderate to high potency topical corticosteroids (e.g., clobetasol 0.05%, betamethasone dipropionate 0.05%, triamcinolone 0.5%) applied once daily for at least two weeks b. Topical calcineurin inhibitor (e.g., tacrolimus ointment) applied twice daily for at least one month AND 3. For Medicaid only:

	a. Documentation that condition is causing functional impairment such as inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction AND b. Documentation of one of the following i. At least 10% of body surface area involved OR ii. Hand, foot, or mucous membrane involvement Reauthorization requires documentation of reduction or stabilization from baseline of flares, pruritis, erythema, edema, xerosis, erosions/excoriation, oozing/crusting, lichenification of affected BSA
AGE RESTRICTIONS	Approved for patients 12 years of age 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 until no longer eligible with the plan, subject to formulary or benefit changes.

Other Formulary Changes:

Drug Name	Action Taken	Policy Name
Clobetasol Propionate 0.05% Foam	Add to Formulary for all lines of business: • Commercial Standard: Tier 2 • Commercial Cost-Based: Tier 3 • Medicaid: Formulary • Medicare Part D: Tier 4	N/A
Diclofenac Potassium Tablet	• Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Celecoxib (Elyxyb) Solution	New dosage form (solution) and strength (120 mg/4.8 ml); • Non-formulary for all lines of business	N/A

Topiramate (Eprontia) Solution	New dosage form (solution); • Commercial/Medicaid: Non-Formulary • Medicare Part D: Formulary, Tier 4	N/A
Diclofenac Potassium (Lofena) Tablet	New to Market Generic • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Doxycycline Hyclate (Lymepak) Tablet	New Branded product: • Commercial/Medicaid: Non-Formulary, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial/Medicaid: New Medications and Formulations without Established Benefit • Medicare Part D: N/A
Opium Tincture 10 mg/ml Tincture	Add to Medicare Part D Formulary, Tier 4	N/A
Everolimus (Afinitor/Afinitor Disperz) Tablet	Commercial: Move generic formulation to Tier 5 from Tier 6	Oral Anti-Cancer Medications
Abiraterone Acetate (Zytiga) 250 mg Tablet	• Generic formulation: No change: • Brand Zytiga: Commercial/Medicaid: Remove from Formulary Effective: 05/15/2022	• Commercial/Medicaid (generic): Oral Anti-Cancer Medications • Commercial/Medicaid (Brand): Brand Over Generic
Abiraterone Acetate (Zytiga) 500 mg Tablet	• Commercial/Medicaid: Remove from Formulary Effective: 05/15/2022	• Commercial/Medicaid (generic): Oral Anti-Cancer Medications • Commercial/Medicaid (Brand): Brand Over Generic
Sertraline hcl Capsule	New dosage form (capsule); • Commercial: Non-Formulary, Prior Authorization • Medicaid/Medicare Part D: Non-Formulary	• Commercial: New Medications and Formulations without Established Benefit • Medicaid/Medicare Part D: N/A
Mitotane (Lysodren) Tablet	Limited Distribution drug: • Commercial: Change from Tier 3 to Tier 6, and add Prior Authorization • Medicaid: Add Prior Authorization, Specialty	Oral Anti-Cancer Medications

	Effective: 05/15/2022	
Doxylamine succinate/pyridoxine (vitamin B6) (Bonjesta/Diclegis) Tablet IR DR	Remove from Medicaid formulary Effective: 05/15/2022	N/A
Dengue tetravalent vaccine, live, vero cell/pf (Dengvaxia) Vial	New entity; • Commercial/Medicaid: Medical Benefit • Medicare Part D: Non-Formulary	N/A
Pneumococcal 20-valent conjugate vaccine (diphtheria crm)/pf (Prevnar 20) Syringe	New entity; • Commercial/Medicaid: Defer decision, awaiting CDC recommendations • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit	N/A
Pneumococcal 15-valent conjugate vaccine (diphtheria crm)/pf (Vaxneuvance) Syringe	New formulation; • Commercial/Medicaid: Defer decision, awaiting CDC recommendations • Medicare Part D: Non-Formulary • Medicare Part B: Medical Benefit	N/A
Wellbutrin XL Tab ER 24h	Remove brand formulation from Commercial formulary and add Prior Authorization • Commercial Brand: Non-Formulary, Prior Authorization Effective: 05/15/2022	Brand Over Generic Policy
Multivitamins Formulations (DEKAs Plus)	Add to Medicaid formulary	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 Name**
Glecaprevir/Pibrentasvir (Mavyret) Pelet Pack	Correction from December P&T: • Medicaid: Change from Non-Formulary to Formulary	• Medicaid: Hepatitis C - Direct Acting Antivirals – Medicaid

Sofosbuvir/Velpatasvir (Epclusa) Pellet Pack	New dosage form (Pellet) and strength (150-37.5mg). Line extend with Epclusa tablets; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Non-Formulary	• Commercial: Hepatitis C - Direct Acting Antivirals • Medicaid: Direct Acting Antivirals – Medicaid • Medicare Part D: N/A
Glucagon (Gvoke) Vial	New dosage dorm (vial). Line extend with Gvoke syringe/auto-inject; • Commercial/Medicare Part D: Formulary, Tier 3 • Medicaid: Formulary	N/A
Bictegravir Sodium/Emtricitabine/Tenofovir Alafenamide Fumar (Biktarvy) Tablet	New strength. Line extend with Biktarvy 50/200/25mg; • Commercial: Formulary, Tier 3 • Medicaid: Formulary • Medicare Part D: Formulary, Tier 5	N/A
Voxelotor (Oxbryta) Tab Susp	New dosage form (Tab Susp) and strength (300mg); Line extend with Oxybyta 500mg; • Commercial/Medicaid: Non-Formulary, Specialty, Prior Authorization, Quantity Limit (8 tablets per day) • Medicare Part D: Non-Formulary	Commercial/Medicaid: Oxbryta

New Generics:

NEW GENERICS		
Drug Name	**Action Taken**	**Policy Name**
Nelarabine Vial	First generic (Arranon). Line extend as generic; • Medical benefit, with prior authorization for all lines of business	Injectable Anti-Cancer Medications
Everolimus Tablet	First generic (Zortress); Line extend as generic;	N/A

	• Commercial: Formulary, Tier 6 • Medicaid: Formulary, Specialty • Medicare Part D: Formulary, Tier 5, Prior Authorization (B vs D), Quantity Limit (two tablets per day)	
Oxycodone-Acetaminophen Solution	First generic (Prolate). Line extend as generic; • Commercial/Medicaid: Non-Formulary, Quantity Limit (90MME) • Medicare Part D: Non-Formulary	N/A
Carglumic Acid Tab Disper	First generic (Carbaglu). Line extend as generic; • Commercial: Formulary, Tier 6, Prior Authorization • Medicaid: Formulary, Specialty, Prior Authorization • Medicare Part D: Formulary, Tier 5, Prior Authorization	Medications For Rare Indications
Adapalene-Benzoyl Peroxide Gel W/Pump	First generic (Epiduo Forte). Line extend as generic; • Non-formulary for all lines of business	N/A
Naloxone hcl Spray	Line extend as generic; • Commercial: Formulary, Tier 2 • Medicaid: Formulary • Medicare Pard D: Formulary Tier 3	N/A

Clinical Policy Changes:

PHP CLINICAL POLICIES – MAJOR CHANGES	
Policy Name	**Summary of Change**
Antipsychotics Step Therapy	Policy was updated to clarify that drugs will be covered for FDA approved or compendia-supported indications and that prerequisites requirements are for generic, atypical antipsychotic medications. In addition, Fanapt® will be added to this policy
Brand Over Generic	Added two branded drugs to the policy: Wellbutrin XL® and Zytiga®

Cambia	Policy was updated to clarify the specific therapies required for trial and failure.
CAR-T	New indication review for Tecartus- updated policy criteria to include coverage for Tecartus in the setting of adult relapsed/refractory acute lymphoblasic leukemia. Policy aligns with FDA label, National Comprehensive Cancer Network (NCCN) guidelines, and clinical trial
Gonadotropin Releasing Hormone Agonists	Criteria for uterine fibroids updated to remove requirement for use of therapy to lessen surgical burden, as guidelines do not recommend that any longer. Vantas® was removed as a preferred agent for Medicaid due to manufacturer discontinuation.
Gonadotropin Releasing Hormone Agonists - Medicare Part B	Criteria for uterine fibroids updated to remove requirement for use of therapy to lessen surgical burden, as guidelines do not recommend that any longer.
Oral Anti-Cancer Medications	Criteria were added to require use of abiraterone 250 mg tablets instead of the 500 mg tablets due to same efficacy and large disparity in costs.
Oxbryta	Policy was updated to include medical necessity criteria for use of the tablets for oral suspension.
Rituximab **Rituximab - Medicare Part B**	Updated prescriber restrictions to include hematologist and removed trial of Simponi Aria® from the rheumatoid arthritis criteria, as no longer a preferred drug. In addition, updated reauthorization coverage duration to be approved until no longer eligible with the plan.

New Indications:

Therapies with Prior Authorization Policies (Non-oncology)

1. **DUPIXENT® (**dupilumab)

a. Previous Indication(s):
   i. for the treatment of patients aged six years and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. DUPIXENT can be used with or without topical corticosteroids.
   ii. as an add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma.
   iii. as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP)

b. New indication approved 10/01/2021:
   i. as an add-on maintenance treatment of patients aged six years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma

c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert and update prior authorization criteria for Commercial, Medicaid, Medicare Part B, and Medicare Part D as outlined below.

Prior Authorization for Commercial/Medicaid/Medicare Part B:

PA PROGRAM NAME	Dupixent
MEDICATION NAME	Dupixent
COVERED USES	1 - All FDA-Approved Indications
AGE RESTRICTIONS	• Moderate-to-severe atopic dermatitis: Age six years and older • Eosinophilic and corticosteroid dependent asthma: Age six years and older • Chronic rhinosinusitis with nasal polyposis: Age 18 years and older

Prior Authorization for Medicare Part D:

PA PROGRAM NAME	Dupixent
MEDICATION NAME	Dupixent
AGE RESTRICTIONS	For atopic dermatitis, patient is six years of age or older. For asthma, patient is six years of age or older. For chronic rhinosinusitis with nasal polyposis, patient is 18 years of age or older.

2. **TECARTUS® (**brexucabtagene autoleucel)

a. Previous Indication(s):
   i. Adult patients with relapsed or refractory mantle cell lymphoma (MCL)
b. New indication approved 10/01/2021:
   i. Adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. This new indication is being reviewed along with the policy for February 2022 ORPTC.

3. **RUXIENCE® (**rituximab-pvvr)

a. Previous Indication(s):
   i. Non-Hodgkin's Lymphoma (NHL)

1. Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent.
2. Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy.
3. Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy.
4. Previously untreated diffuse large B-cell, CD20-positive NHL in combination with (cyclophosphamide, doxorubicin, vincristine, and prednisone) (CHOP) or other anthracycline-based chemotherapy regimens.

ii. Chronic Lymphocytic Leukemia (CLL): Previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC)
iii. Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in combination with glucocorticoids

b. New indication approved 11/15/2021:
   i. Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to severely-active RA who have inadequate response to one or more TNF antagonist therapies
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert. No updates to criteria warranted.

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

4. **TECENTRIQ® (**atezolizumab)

a. New indication(s) approved 10/15/2021:
   i. for the first-line treatment of adult patients with metastatic NSCLC whose tumors have high PD-L1 expression (PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 10%]), as determined by an FDA approved test, with no EGFR or ALK genomic tumor aberrations
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.

5. **VERZENIO® (**abemaciclib)

a. New indication(s) approved 10/12/2021:
   i. in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence and a Ki-67 score ≥20% as determined by an FDA approved test

ii. in combination with an aromatase inhibitor as initial endocrine based therapy for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.
iii. in combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy.

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.

6. **KEYTRUDA® (**pembrolizumab)

a. New indication(s) approved 10/13/2021:
i. in combination with chemotherapy, with or without bevacizumab, for the treatment of patients with persistent, recurrent, or metastatic cervical cancer whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test.
ii. as a single agent for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test.

b. New indication(s) approved 10/13/2021:
i. for the adjuvant treatment of patients with RCC at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions

c. **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.

7. **MVASI® (**bevacizumab-awwb)

a. New indication(s) approved 11/15/2021:
i. Epithelial ovarian, fallopian tube, or primary peritoneal cancer:
1. in combination with carboplatin and paclitaxel, followed by MVASI as a single agent, for stage III or IV disease following initial surgical resection
2. in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for platinum-resistant recurrent disease who received no more than 2 prior chemotherapy regimens
3. in combination with carboplatin and paclitaxel or carboplatin and gemcitabine, followed by MVASI as a single agent, for platinumsensitive recurrent disease

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.

8. **KYPROLIS® (**carfilzomib)

a. New indication(s) approved 11/30/2021:

i. for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy in combination with Daratumumab and hyaluronidase-fihj and dexamethasone

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.

9. **DARZALEX FASPRO® (**daratumumab and hyaluronidase-fihj)

a. New indication(s) approved 11/30/2021:
   i. List indication
   ii. For the treatment of adult patients with multiple myeloma in combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy
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.

Therapies Without Prior Authorization Policies

10. **DEXTENZA® (**dexamethasone ophthalmic insert)

a. Previous Indication(s):
   i. The treatment of ocular inflammation and pain following ophthalmic surgery
b. New indication(s) approved 10/07/2021:
   i. The treatment of ocular itching associated with allergic conjunctivitis
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

11. **BIKTARVY® (**bictegravir, emtricitabine, and tenofovir alafenamide)

a. Previous Indication(s):
   i. the treatment of HIV-1 infection in adults and pediatric patients weighing at least 25 kg who have no antiretroviral treatment history or 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 BIKTARVY
b. New indication(s) approved 10/07/2021:
   i. the treatment of HIV-1 infection in adults and pediatric patients weighing at least 14 kg who have no antiretroviral treatment history or 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 BIKTARVY
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

12. **VIMPAT® (**lacosamide)

a. Previous Indication(s):
   i. Treatment of partial-onset seizures in patients 4 years of age and older
   ii. Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients 4 years of age and older
b. New indication(s) approved 10/14/2021:
   i. Treatment of partial-onset seizures in patients 1 month of age and older
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

13. **WELCHOL® (**colesevelam hydrochloride)

a. Previous Indication(s):
   i. reduce elevated low-density lipoprotein cholesterol (LDL-C) in adults with primary hyperlipidemia
   ii. reduce LDL-C levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia (HeFH)
   iii. improve glycemic control in adults with type 2 diabetes mellitus
b. New indication(s) approved 10/20/2021:
   i. reduce LDL-C levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia (HeFH), unable to reach LDL-C target levels despite an adequate trial of diet and lifestyle modification
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

14. **INJECTAFER® (**ferric carboxymaltose injection)

a. Previous Indication(s):
   i. for the treatment of iron deficiency anemia (IDA) in adult patients:
      1. who have intolerance to oral iron or have had unsatisfactory response to oral iron, or
      2. who have non-dialysis dependent chronic kidney disease
b. New indication(s) approved 11/19/2021:
   i. for the treatment of iron deficiency anemia (IDA) in:
      1. Adults and pediatric patients 1 year of age and older who have either intolerance to oral iron or an unsatisfactory response to oral iron.
      2. Adult patients who have non-dialysis dependent chronic kidney disease.
c. **RECOMMENDATION:** Inform prescribers via Medical Policy Alert.

<u>Therapies With Indication(s) Removed</u>

15. **TECENTRIQ® (**atezolizumab)

a. Indication(s) removed 10/06/2021:

i. in combination with paclitaxel protein-bound for the treatment of adult patients with unresectable locally advanced or metastatic TNBC whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] of any intensity covering ≥ 1% of the tumor area), as determined by an FDA approved test. This indication is approved under accelerated approval based on progression free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

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.

Drug Safety Monitoring:

FDA Drug Safety Communications

None available

Drug Recalls/Market Withdrawals

1. **Drug Name:** Irbesartan, Irbesartan and hydrochlorothiazide
   - **Date of Recall:** October 14, 2021
   - **Reason for recall:** API batches above the specification limit for the impurity, N-nitrosoirbesartan
   - **Link to more information:** https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lupin-pharmaceuticals-inc-issues-voluntarily-nationwide-recall-all-irbesartan-tablets-and-irbesartan
   - **Health Plan Recommendation:** Notify providers via Medical Policy Alert. The health plan took action by mailing member and provider specific letters to advise those who may be affected by the recall.