Pharmacy

Premera Formulary Newsletter

The latest monthly pharmacy news and announcements

April 2026

Latest News

Helping Members Save on Prescriptions with Rx Savings Solutions

Rising prescription drug costs continue to be a challenge for employers and members alike. To help make medications more affordable, Premera Blue Cross partners with Rx Savings Solutions, an innovative pharmacy savings tool designed to help members lower their out-of-pocket costs on prescription drugs.

What is Rx Savings Solutions?

Rx Savings Solutions uses real prescription pricing and a member's specific benefit information—including plan design and accumulators—to identify potential savings opportunities. When savings are available, eligible members are notified and guided on how they may be able to spend less on their prescriptions.

Savings opportunities may include:

- Switching to a pharmacy with lower out-of-pocket costs
- Using a generic or a different generic medication
- Learning about clinically appropriate therapeutic alternatives

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Members can also log in proactively to search for savings opportunities on their medications.

Who is eligible?

- Fully insured and OptiFlex groups have Rx Savings Solutions embedded as part of their plan.
- Self-funded groups may elect Rx Savings Solutions as a buy-up option and must have integrated pharmacy benefits with Premera.

How members access Rx Savings Solutions

Eligible members are invited to activate their account at myrxss.com/premera. Once enrolled, they can view personalized savings opportunities based on their prescription history.

How members are notified

Rx Savings Solutions contacts members when savings opportunities are identified using:

- Email
- Letters
- Text messages (after members verify their mobile number in the portal)

Notifications are based on prescription fill history and are not immediate. Members may see savings opportunities near their next refill or when they log into their Rx Savings Solutions account.

Members can opt out of notifications at any time, including for specific medications.

Support for prescription changes

If a savings opportunity of $20 or more is identified, members can choose to:

- Use the Rx Savings Solutions concierge team to help manage the change
- Contact their pharmacist directly

- Share a letter with their prescriber

For savings under $20, members can contact their pharmacist or provide a prescriber letter.

Member support

Members who need assistance can:

- Email support@rxss.com
- Call 800-268-4476 (TTY: 800-877-8973)

Formulary Updates

Premera regularly makes standard drug list updates to ensure that drug lists provide the best value for the dollar, bringing the best net cost, access and experience for members. These decisions are based on information and recommendations from Premera's Pharmacy & Therapeutics Committee, a group of independent clinicians and providers.

The following are notable decisions to drug lists that may include new brand launches, new generic launches, and updates to products on the market today. Copays and/or coinsurance, benefits, and coverage may differ based on selected plan designs. Refer to your benefit plan documents for additional information.

Name	Formulary						Programs				Notes
	Preferred 3 Tier (B3)	Preferred 4 Tier (B4)	Open (A2)	Metallic (M4)	Essentials 3 Tier (E3)	Essentials 4 Tier (E4)	Specialty	PA	ST	QL	
pomalidomide capsule	1	1	1	Formulary Tier 4	Formulary Tier 3	Formulary Tier 4	Yes	Yes	No	No	First time generic for POMALYST
ORLADEYO (berotralstat packet)	3	4	2	Non-Formulary Tier 4	Formulary Tier 3	Formulary Tier 4	Yes	Yes	No	30 packets per 30 days	New pellet in packet formulation for prophylaxis of hereditary angioedema.
rilpivirine tablet	1	1	1	Non-Formulary Tier 3	Formulary Tier 1	Formulary Tier 1	No	No	No	30 tablets per 30 days	First time generic for EDURANT

brivaracetam tablets	1	1	1	Non-Formulary Tier 3	Formulary Tier 3	Formulary Tier 3	No	No	Yes	60 tablets per 30 days	First time generic for BRIVIACT
tapentadol tablet	1	1	1	Non-Formulary Tier 3	Non-Formulary Tier 3	Non-Formulary Tier 4	No	Yes	No	181 tablets per fill	First time generic for NUCYNTA
DESMODA (desmopressin acetate oral solution)	3	4	2	Non-Formulary Tier 4	Non-Formulary Tier 3	Non-Formulary Tier 4	Yes	Yes	No	No	For the treatment of central diabetes insipidus

Brand drugs are capitalized. Generic drugs are in lower case. PA = Prior Authorization, ST = Step Therapy, QL = Quantity Limit, HCLV = High-Cost Low Value, SSB = Single-Source Brand, MSB = Multi-Source Brand, OPT = Optional Benefits.

Formulary Name	Tier
Preferred 3 Tier (B3)	1 = Generic, 2 = Preferred Brand, 3 = Non-Preferred Brand
Preferred 4 Tier (B4)	1 = Generic, 2 = Preferred Brand, 3 = Non-Preferred Brand, 4 = Specialty
Open (A2)	1 = Generic, 2 = Brand
Metallic (M4)	1 = Preferred Generic, 2 = Preferred Brand, 3 = Non-Preferred Drugs (Brand or Generic), 4 = Specialty
Essentials 3 Tier (E3)	1 = Preferred Generic, 2 = Preferred Brand, 3 = Non-Preferred Drugs
Essentials 4 Tier (E4)	1 = Preferred Generic, 2 = Preferred Brand, 3 = Preferred Specialty, 4 = Non-Preferred Drugs

Note that this is a summary only, as formularies may also undergo additional positive changes (example: moving to a lower cost tier). More details are available here: https://www.premera.com/visitor/drug-list-changes.

PRIOR AUTHORIZATION

Prior authorization may be required for certain medications to ensure medical necessity criteria is met. Providers will need to provide additional clinical information. Prior authorization in addition to other utilization management edits, such as quantity limits.

Drug Name	Update	Effective Date	Notes
pomalidomide	Add	Release date	
ORLADEYO (berotralstat packet)	Add	Release date	
QIVIGY (immune globulin)	Add	Release date	Medical benefit only
RYBREVANT FASPRO (amivantamab-hyaluronidase-lpuj)	Add	Release date	Medical benefit only
tapentadol tablet	Add	Release date	

STEP THERAPY

Drug Name	Update	Effective Date	Notes
brivaracetam tablet	Add	Release date	

QUANTITY LIMITS

Quantity limits may be added or removed from time to time that limits the amount of medication permitted per prescription or within a specified timeframe. Quantity limits are in addition to other utilization management edits, such as prior authorization or step therapy.

Drug Name	Update	Quantity Limit	Effective Date
ORLADEYO (berotralstat packet)	Add	1 packet once daily	Release date
brivaracetam tablet	Add	2 tablets per day	Release date
tapentadol tablet	Add	181 tablets per fill	Release date

NEW DRUGS

Bysanti (milsaperidone)

FDA APPROVAL DATE: February 20, 2026

INDICATION: An atypical antipsychotic indicated for the treatment of schizophrenia in adults and the acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.

STUDY INFORMATION: The effectiveness of Bysanti in the treatment of schizophrenia in adults has been established from adequate and well controlled studies of iloperidone tablets (referred to as "iloperidone" (iloperidone and milsaperidone rapidly interconvert in vivo)) in adults with schizophrenia. Iloperidone was studied in two placebo- and active-controlled short-term trials (a 6-week trial (Study 1) and a 4-week trial (Study 2)) and one long-term placebo-controlled randomized withdrawal trial (Study 3) in adult patients who met the DSM-III/IV criteria for schizophrenia. In Study 1, the primary endpoint was change from baseline on the BPRS total score at the end of treatment (Day 42). Both the 12 mg to 16 mg/day and the 20 mg to 24 mg/day iloperidone treatment groups were superior to the placebo group on the BPRS total score. The active control antipsychotic drug (risperidone) appeared to be superior to iloperidone in this trial within the first 2 weeks, a finding that may in part be explained by the more rapid titration that was possible for risperidone. Study 2 (n=604) compared one fixed-dose of iloperidone (24 mg/day) to placebo and an active control (ziprasidone). In Study 2, the primary endpoint was change from baseline on the PANSS total score at the end of treatment (Day 28). The 24 mg/day iloperidone treatment group was superior to the placebo treatment group in the PANSS total score. Study 3 included clinically stable adult outpatients (n=303) who met DSM-IV criteria for schizophrenia. After a one-week iloperidone titration, patients who remained clinically stable received 12 weeks of open-label treatment with a flexible iloperidone dosage (4 mg to 12 mg administered twice daily (8 mg to 24 mg per day, respectively). Based on the interim analysis in Study 3, an independent data monitoring committee decided the study should be discontinued early due to evidence of efficacy.

The effectiveness of BYSANTI in the acute treatment of manic or mixed episodes associated with bipolar I disorder has been established from an adequate and well-controlled study of iloperidone tablets (referred to as "iloperidone" (iloperidone and milsaperidone rapidly interconvert in vivo)) in adults with manic or mixed episodes associated with bipolar I disorder. Iloperidone was studied in one multicenter, randomized, double-blind, placebo-controlled, 4-week study (n=392) that enrolled adult patients who met the DSM-5 criteria for bipolar I disorder, manic or mixed type (Study 4; NCT04819776). The primary endpoint was change in YMRS total score from baseline to Day 28. The iloperidone group was superior to the placebo group on the primary endpoint.

COST: $$$ (anticipated)

TAKEAWAY: Another option to treat schizophrenia.

Loargys (pegzilarginase-nbln)

FDA APPROVAL DATE: February 23, 2026

INDICATION: An arginine specific enzyme indicated for the treatment of hyperargininemia in adult and pediatric patients 2 years of age and older with Arginase 1 Deficiency (ARG1-D), in conjunction with dietary protein restriction. This indication is approved under accelerated approval based on reduction of plasma arginine. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

STUDY INFORMATION: The effectiveness of LOARGYS for the treatment of hyperargininemia in adult and pediatric patients with ARG1-D was evaluated in Trial 1 which was a multicenter, double-blind, 24-week placebo-controlled trial with a long-term open-label extension period of up to 150 weeks. A total of 32 patients were randomized 2:1 to receive intravenous LOARGYS (n=21) or placebo (n=11) once weekly for 24 weeks.

The primary endpoint in Trial 1 was the change from baseline in plasma arginine at Week 24. LOARGYS-treated patients had a significant mean reduction in plasma arginine levels from baseline to Week 24. Additionally, 90% of LOARGYS-treated patients achieved target plasma arginine levels (below 200 µM) and normalized levels, compared to 0% of placebo-treated patients.

COST: $$$$

TAKEAWAY: The first disease modifying treatment for an ultra-rare condition.

Yuviwel (navepegritide)

FDA APPROVAL DATE: February 27, 2026

INDICATION: A C-type natriuretic peptide (CNP) analog indicated to increase linear growth in pediatric patients 2 years of age and older with achondroplasia with open epiphyses. This indication is approved under accelerated approval based on an improvement in annualized growth velocity. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

STUDY INFORMATION: The effectiveness of YUVIWEL has been established in a clinical trial of navepegritide consisting of a randomized, double-blind, placebo-controlled 52-week period, followed by a single-arm 52-week OLE period (Trial 1). Trial 1 enrolled 84

treatment-naïve pediatric patients with genetically confirmed achondroplasia: 57 patients received navepegritide 0.1 mg/kg administered subcutaneously once weekly, and 27 received placebo.

The primary efficacy endpoint was annualized growth velocity (AGV) at Week 52. Height Z-scores calculated using reference data from untreated children with achondroplasia (achondroplasia-specific height Z-score) and using reference data from the general population (CDC-based height Z-score) were also evaluated.

Treatment with once-weekly navepegritide for 52 weeks resulted in a least-squares mean treatment difference in AGV of 1.5 cm/year and a least-squares mean increase from baseline in achondroplasia-specific height Z-score of 0.3.

COST: $$$$ (anticipated)

TAKEAWAY: The second treatment for achondroplasia. Administered once weekly.

Lynavoy (linerixibat)

FDA APPROVAL DATE: March 17, 2026

INDICATION: An ileal bile acid transporter (IBAT) inhibitor for the treatment of cholestatic pruritus in adult patients with PBC.

STUDY INFORMATION: The approval is based on data from the global GLISTEN phase III trial which met both primary and key secondary endpoints, demonstrating significant, rapid (at week two) and sustained (over 24 weeks) improvements in cholestatic pruritus and itch-related sleep interference versus placebo.

COST: $$$$ (anticipated)

TAKEAWAY: Clinical trials showed statistical improvement, long-term clinical significance is still to be determined.

Icotyde (icotrokinra)

FDA APPROVAL DATE: March 17, 2026

INDICATION: An interleukin-23 (IL-23) receptor antagonist indicated for the treatment of moderate-to-severe plaque psoriasis in adults and pediatric patients 12 years of age and older who weigh at least 40 kg who are candidates for systemic therapy or phototherapy.

STUDY INFORMATION: The efficacy of ICOTYDE was evaluated in four multi-center, randomized, double-blind, placebo

and/or active comparator-controlled trials that included 2500 subjects (2428 adults and 72 pediatric subjects 12 years and older who weigh at least 40 kg) with moderate-to-severe plaque psoriasis who were eligible for systemic therapy or phototherapy.

ICOTYDE met primary efficacy endpoints and demonstrated a favorable safety profile across four Phase 3 studies including 2,500 patients. The approval is based on evidence from the ICONIC clinical development program, which simultaneously evaluated ICOTYDE in adults and adolescents, high impact sites such as scalp and genital PsO, and in duplicate head-to-head trials versus an active comparator. In the head-to-head superiority studies, approximately 70% of patients achieved clear or almost clear skin (IGA 0/1) and 55% of patients achieved a Psoriasis Area and Severity Index (PASI) 90 response at Week 16. Rates of adverse reactions for ICOTYDE treated patients were within 1.1% of placebo through Week 16 and no new safety signals were identified through Week 52.

COST: $$$$ (anticipated)

TAKEAWAY: The first oral IL-23 receptor antagonist approved for plaque psoriasis.

NEW BIOSIMILARS

None

FIRST TIME GENERICS

rilpivirine hydrochloride

Somerset Therapeutics launched an AB-rated generic for Edurant (rilpiviring hydrochloride) on February 10, 2026.

ceftaroline fosamil

Apotex Corp launched an AP-rated generic for Teflaro (ceftraoline fosamil injection) on February 11, 2026.

brivaracetam oral tablet, oral solution, and intravenous solution

Multiple manufacturers have launched AB-rated generic versions of Briviact (brivaracetam) oral tablets, oral solution, and intravenous solution on February 18, 2026.

NEW INDICATIONS

Leqvio (inclisiran sodium)

FDA APPROVAL DATE: February 12, 2026

INDICATION: New indication as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in pediatric patients aged 12 years and older with homozygous familial hypercholesterolemia (HoFH).

Also, expanded indication as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults and pediatric patients aged 12 years and older with heterozygous familial hypercholesterolemia (HoFH). It was previously approved in adults for this indication.

STUDY INFORMATION: The safety and effectiveness of LEQVIO as an adjunct to diet and other LDL-C-lowering therapies for the treatment of HeFH have been established in pediatric patients aged 12 years and older. Use of LEQVIO for this indication is based on data from a 12-month, randomized, placebo-controlled, double-blind study in 141 pediatric patients with HeFH. This indication is also supported by evidence from an adequate and wellcontrolled study in adults with HeFH. The safety profile reported in pediatric patients aged 12 years and older with HeFH was consistent with adult patients with hypercholesterolemia, with the exception of headache.

The safety and effectiveness of LEQVIO as an adjunct to diet and other LDL-C-lowering therapies for the treatment of HoFH have been established in pediatric patients aged 12 years and older. Use of LEQVIO for this indication is based on data from a 12-month, randomized, placebo-controlled, double-blind study in 13 pediatric patients with HoFH.

Enzeevu (aflibercept-abzv)

FDA APPROVAL DATE: February 12, 2026

INDICATION: Macular Edema Following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR).

STUDY INFORMATION: This biosimilar to Eylea (aflibercept) was approved via the 351k pathway which provided for the addition of the new indications.

Wakix (pitolisant)

FDA APPROVAL DATE: February 13, 2026

INDICATION: For the new indication of treatment of cataplexy in patients 6 years of age and older with narcolepsy.

STUDY INFORMATION: The recent expanded approval for cataplexy in children with narcolepsy was supported by a multicenter, randomized, double-blind, placebo-controlled study. In the study, which included 95 patients with a history of cataplexy, patients who were treated with pitolisant experienced a statistically significantly greater improvement in the average number of cataplexy attacks per week from baseline to end of treatment, compared to placebo.

Rapiblyk (landiolol)

FDA APPROVAL DATE: February 13, 2026

INDICATION: For the short-term reduction of ventricular rate in pediatric patients with supraventricular tachycardia.

STUDY INFORMATION: The safety and effectiveness of RAPIBLYK for the short-term reduction of ventricular rate in supraventricular tachycardia have been established in pediatric patients. Use of RAPIBLYK is supported by evidence from adequate and well-controlled studies in adults, with additional pharmacokinetic, pharmacodynamic and safety data from a descriptive single-arm, unblinded study that enrolled 60 pediatric patients from birth to <18 years of age. In this study, treatment with RAPIBLYK resulted in a >20% reduction in ventricular rate from baseline in patients with atrioventricular reentrant tachycardia (6/7, 85.7%), focal atrial tachycardia (4/8, 50%), junctional ectopic tachycardia (3/12, 25%), and in inappropriate sinus tachycardia (10/30, 33.3%).

Rybrevant Faspro (amivantamab and hyaluronidase-lpuj)

FDA APPROVAL DATE: February 13, 2026

INDICATION: New monthly subcutaneous dosing schedule in combination with Lazcluze (lazertinib) for the first-line treatment of adult patients with epidermal growth factor receptor (EGFR)-mutated non–small cell lung cancer (NSCLC).

STUDY INFORMATION: Support for the monthly dosing schedule was based on results from the phase 2 PALOMA-2 open-label, international, parallel-cohort study which demonstrated that the combination of Rybrevant Faspro and Lazcluze achieved a high objective response rate in patients with EGFR-mutated advanced NSCLC.

Calquence (acalabrutinib)

FDA APPROVAL DATE: February 19, 2026

INDICATION: For the use of acalabrutinib in combination with venetoclax as a new combination regimen (in combination with venetoclax) for the treatment of adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma.

STUDY INFORMATION: Results from the Phase 3, open-label AMPLIFY trial supported the approval. Patients with untreated CLL who did not harbor 17p deletions or TP53 mutations were randomized to receive acalabrutinib plus venetoclax or standard-of-care (SOC) chemoimmunotherapy. The median progression-free survival (PFS) follow-up duration was 42.6 months. Median PFS, the primary endpoint, was not estimable (95% CI, 51.1 to NE) in the acalabrutinib/venetoclax group and 47.6 months (95% CI, 43.3 to NE) in the SOC group (hazard ratio 0.65; 95% CI, 0.49 to 0.87; P = 0.0038). The safety and tolerability of the acalabrutinib/venetoclax combination in AMPLIFY were consistent with the agents' known safety profiles, with no new safety signals reported, according to news releases.

Elucirem (gadopiclenol)

FDA APPROVAL DATE: February 20, 2026

INDICATION: For adult and pediatric patients, including term neonates, for use with magnetic resonance imaging (MRI) to detect and visualize lesions with abnormal vascularity in the central nervous system (brain, spine, and associated tissues) and the body (head and neck, thorax, abdomen, pelvis, and musculoskeletal system).

STUDY INFORMATION: The safety and effectiveness of ELUCIREM for use with MRI to detect and visualize lesions with abnormal vascularity in the CNS (brain, spine, and associated tissues), and the body (head and neck, thorax, abdomen, pelvis, and musculoskeletal system) have been established in pediatric patients including term neonates.

Use of ELUCIREM in this age group is supported by evidence from adequate and well-controlled studies in adults, with additional pharmacokinetic and safety data from two open-label, single-arm, multicenter, single-dose studies (i.e., Trials 1 and 2) of ELUCIREM (0.05 mmol/kg) in 116 pediatric patients who underwent CNS and body MRI. Trial 1 included 80 pediatric patients aged 2 to 17 years, and Trial 2 included 36 pediatric patients aged 25 days to less than 2 years.

Dupixent (dupilimumab)

FDA APPROVAL DATE: February 23, 2026

INDICATION: For the treatment of adult and pediatric patients aged 6 years and older with allergic fungal rhinosinusitis (AFRS) who have a history of sino-nasal surgery.

STUDY INFORMATION: Approval was supported by the Phase 3 LIBERTY-AFRS-AIMS trial. A total of 6 pediatric subjects 6 to 17 years of age with allergic fungal rhinosinusitis (AFRS) were enrolled, including 3 subjects who received Dupixent 200 mg Q2W (≥30 to <60 kg) and 300 mg Q2W (≥60 kg).

At week 52, the mean ± SD observed steady-state trough concentration was 72.3 ± 28.8 mcg/mL, which was within the range of steady-state trough concentrations in adult subjects with AFRS who received Dupixent 300 mg Q2W. Dupixent reduced sinus opacification scores by 50% at Week 52 versus 10% with placebo, improved nasal symptoms and sense of smell, and reduced the risk of surgery or systemic steroid use by 92%.

Braftovi (encorafenib)

FDA APPROVAL DATE: February 24, 2026

INDICATION: For BRAF V600E Mutation-Positive Metastatic Colorectal Cancer (mCRC), BRAFTOVI is indicated, in combination with cetuximab and fluorouracil-based chemotherapy, for the treatment of adult patients with metastatic colorectal cancer (mCRC) with a BRAF V600E mutation, as detected by an FDA-authorized test. Previously the indication noted use with mFOLFOX6.

STUDY INFORMATION: BRAFTOVI in combination with cetuximab and mFOLFOX6 was evaluated in a randomized, active-controlled, open-label, multicenter trial (BREAKWATER CRC; NCT04607421). Eligible patients were required to have BRAF V600E mutation-positive metastatic colorectal cancer (CRC), as detected using the Qiagen therascreen BRAF V600E RGQ polymerase chain reaction (PCR) Kit. Other key eligibility criteria included no prior systemic treatment in the metastatic setting, absence of prior treatment with any selective BRAF inhibitor or EGFR inhibitor, tumor that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) unless the patient is ineligible to receive immune checkpoint inhibitors, tumor that is not RAS-mutated or for which RAS mutation status is unknown, and Eastern Cooperative Oncology Group (ECOG) performance status 0-1. Randomization was stratified by ECOG performance status (0 versus 1) and region (US/Canada versus Europe versus Rest of World).

Patients were initially randomized 1:1:1 to one of the following treatment arms, and then 1:1 after discontinuation of enrollment of the BRAFTOVI+cetuximab arm (158 patients):

• BRAFTOVI 300 mg orally once daily in combination with cetuximab 500 mg/m2 IV infusion every 2 weeks (BRAFTOVI+cetuximab arm)

• BRAFTOVI 300 mg orally once daily in combination with cetuximab 500 mg/m2 IV infusion every 2 weeks and mFOLFOX6 every 2 weeks (BRAFTOVI+cetuximab+mFOLFOX6 arm)

• mFOLFOX6 (every 2 weeks), or FOLFOXIRI (every 2 weeks), or CAPOX (every 3 weeks), each with or without bevacizumab (administered per prescribing instructions).

BRAFTOVI in combination with cetuximab and mFOLFOX6 demonstrated statistically significant improvements in ORR, PFS, and OS compared to the active comparator."

RizaFilm (rizatriptan benozate)

FDA APPROVAL DATE: February 26, 2026

INDICATION: New patient population includes those pediatric patients and adults 6 years of age and older for the acute treatment of migraine with or without aura. This was previously approved for those 12 years of age and older.

STUDY INFORMATION: "The safety and effectiveness of RizaFilm for the acute treatment of migraine have been established in pediatric patients 6 years of age and older based on an adequate and well-controlled study with rizatriptan benzoate tablets. The incidence of adverse reactions reported for pediatric patients in the acute clinical trial was similar in patients who received rizatriptan benzoate tablets to those who received placebo. The adverse reaction pattern in pediatric patients is expected to be similar to that in adults.

Hernexeos (zongertinib)

FDA APPROVAL DATE: February 26, 2026

INDICATION: New indication removed "who have received prior systemic therapy." Thus, HERNEXEOS is indicated for the treatment of adult patients with unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations, as detected by an FDA-authorized test.

STUDY INFORMATION: "For previously Untreated Unresectable or Metastatic Non-Squamous NSCLC: The efficacy population included 72 patients with unresectable or metastatic, non-squamous NSCLC with HER2 (ERBB2) tyrosine kinase domain (TKD) mutations based on prospective local testing, who had not received prior systemic therapy for advanced disease. Of those, tumor tissue samples from 60% (43/72) of patients were retrospectively tested using Oncomine™ Dx Target Test (Life Technologies Corporation, Tissue-test). While 86% (37/43) of samples were positive for HER2 (ERBB2) TKD mutations; 14% (6/43) were unevaluable.

The baseline demographic and disease characteristics of the efficacy population were: 67 years (range: 35 to 88); 50% female, 47% Asian, 42% White, 1.4% Black or African American; 10% had unknown race data; 6% were of Hispanic or Latino ethnicity; 44% Eastern Cooperative Oncology Group (ECOG) performance status (PS) 0 and 56% ECOG PS 1; 65% never smoked; 100% had metastatic disease; and 31% had brain metastases.

Objective Response Rate was 76% (95% CI: 65, 86) and the Duration of Response was 1.4, 18 + (range, months).

Prezcobix (cobicistat/darunavir ethanolate)

FDA APPROVAL DATE: February 27, 2026

INDICATION: PREZCOBIX is indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV-1) in treatment-naïve and treatment experienced adults and pediatric patients 3 years of age and older weighing at least 15 kg with no darunavir resistance-associated substitutions (V11I, V32I, L33F, I47V, I50V, I54L, I54M, T74P, L76V, I84V, L89V). Prezcobix was previously indicated for those weighing at least 25 kg.

STUDY INFORMATION: The safety and effectiveness of PREZCOBIX and PREZCOBIX PED for the treatment of HIV-1 in pediatric patients 3 years of age and older weighing at least 15 kg was established through a trial with components of PREZCOBIX and PREZCOBIX PED. Use of PREZCOBIX or PREZCOBIX PED in this group is supported by evidence from adequate and well-controlled studies in adults with additional pharmacokinetic, safety, and virologic data from a study of components of PREZCOBIX or PREZCOBIX PED (Trial GS-US-216-0128) in pediatric participants with HIV-1 aged 3 to less than 18 years.

The safety and effectiveness of PREZCOBIX or PREZCOBIX PED have not been established in pediatric patients weighing less than 15 kg. Darunavir, a component of PREZCOBIX and PREZCOBIX PED is not recommended in pediatric patients below 3 years of age because of toxicity and mortality observed in juvenile rats dosed with darunavir.

Palynziq (pegvaliase-pqpz)

FDA APPROVAL DATE: February 27, 2026

INDICATION: To reduce blood phenylalanine concentrations in adult and pediatric patients 12 years of age and older with phenylketonuria (PKU) who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management. Palynziq was previously only indicated for adults.

STUDY INFORMATION: The safety and effectiveness of PALYNZIQ to reduce blood phenylalanine concentrations have been established in pediatric patients 12 years and older with PKU who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management. Use of PALYNZIQ for this indication is supported by evidence from Study 4, an open label randomized 2-arm study in patients who are 12 to less than 18 years of age.

In Study 4, 16 out of 36 (44%) pegvaliase-treated patients experienced eosinophilia. Incidence of eosinophil levels higher than upper limit of normal was more frequent during the induction/titration phase and decreased during the maintenance phase.

Sogroya (somapacitan-beco)

FDA APPROVAL DATE: February 27, 2026

INDICATION: SOGROYA is indicated for the treatment of pediatric patients aged 2.5 years and older with short stature born small for gestational age (SGA) and with no catch-up growth by 2 years of age, growth failure associated with Noonan syndrome (NS), and idiopathic Short Stature (ISS).

STUDY INFORMATION: The safety and effectiveness of SOGROYA have been established in pediatric patients 2.5 years of age and older for the treatment of:

• Short stature born SGA with no catch-up growth by 2 years of age. The use of SOGROYA® for this indication is supported by evidence from a multi-center, randomized open-label, active-comparator, phase 3 basket study in 142 pediatric patients aged 2.6 to 10.7 years with short stature born SGA with no catch-up growth by 2 years of age. • Growth failure associated with NS. The use of SOGROYA® for this indication is supported by evidence from a multi-center, randomized open-label, active-comparator, phase 3 basket study in 77 pediatric patients aged 2 to 11.1 years with growth failure associated with NS .

• ISS. The use of SOGROYA® for this indication is supported by evidence from a multi-center, randomized open-label, active-comparator, phase 3 basket study in 88 pediatric patients aged 2.8 to 10.8 years with ISS.

Juxtapid (lomitapide)

FDA APPROVAL DATE: February 27, 2026

INDICATION: JUXTAPID is indicated as an adjunct to a low-fat diet and exercise and other low density lipoprotein cholesterol (LDL-C) therapies to reduce LDL-C in adults and pediatric patients aged 2 years and older with homozygous familial hypercholesterolemia (HoFH). Juxtapid was previously only approved for adult populations.

STUDY INFORMATION: A single-arm, open label, multinational, 104-week trial was conducted in 43 pediatric patients with HoFH aged 5 to 17 years. Thirty-nine of the patients completed the trial. The dose of JUXTAPID was escalated from an age-dependent starting dose to a maximum tolerated dose (MTD) as applicable to the pediatric age group and based on acceptable safety and tolerability criteria, in addition to LDL-C goals.

The primary endpoint was percent change in LDL-C from baseline to Week 24. At Week 24, the mean percent change in LDL-C from baseline was -49% (95% CI: -59%, -38%).

Tecvayli (teclistamab-cqyv)

FDA APPROVAL DATE: March 5, 2026

INDICATION: TECVAYLI is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma in combination with daratumumab hyaluronidase-fihj in patients who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent.

STUDY INFORMATION: The efficacy of TECVAYLI in combination with subcutaneous daratumumab hyaluronidase-fihj compared with investigator's choice of either daratumumab hyaluronidase-fihj, pomalidomide and dexamethasone (DPd) or daratumumab hyaluronidase-fihj, bortezomib and dexamethasone (DVd) was evaluated in adult patients with relapsed or refractory multiple myeloma in a randomized, open-label, multi-center study (MajesTEC-3). The study included patients who had previously received one to three prior lines of therapy including a proteasome inhibitor and lenalidomide. Patients who had received only one prior line of therapy must have been refractory to lenalidomide. Patients who had disease refractory to a prior anti-CD38 monoclonal antibody therapy, or who had received any prior BCMA-directed therapy were excluded.

Overall response rate was 68 (95% CI 52.1, 70.9). The median time to first response was 1.2 months (range: 0.2 to 5.5 months). With a median follow-up of 7.4 months among responders, the estimated duration of response (DOR) rate was 90.6% (95% CI: 80.3%, 95.7%) at 6 months and 66.5% (95% CI: 38.8%, 83.9%) at 9 months.

Sotyktu (deucravacitinib)

FDA APPROVAL DATE: March 6, 2026

INDICATION: SOTYKTU is indicated for the treatment of active psoriatic arthritis in adults.

STUDY INFORMATION: The efficacy and safety of SOTYKTU were assessed in two multicenter randomized, double-blind, placebo-controlled trials (Trial PsA-1 and Trial PsA-2 in subjects 18 years and older with active psoriatic arthritis (PsA) (≥3 swollen joints, ≥3 tender joints, a C-reactive protein (CRP) level of ≥3 mg/L) and with active or a history of plaque psoriasis.

Subjects in both trials at baseline had a diagnosis of psoriatic arthritis for at least 3 months and met the Classification criteria for Psoriatic Arthritis (CASPAR) at screening. In Trial PsA-1, subjects also had presence of at least one bone erosion on X-ray of hands and/or feet. Trial PsA-2 included an active safety reference treatment arm (apremilast).

The efficacy of SOTYKTU was assessed in 1,294 subjects up to Week 16. Trial PsA-1 evaluated 670 subjects who were randomized to placebo or SOTYKTU 6 mg once daily. Trial PsA-2 evaluated 624 subjects who were randomized to placebo or SOTYKTU 6 mg once daily. In addition, 105 subjects were randomized to apremilast 30 mg twice daily in Trial PsA-2. In both trials, subjects randomized to placebo were switched to SOTYKTU at Week 16.

The primary endpoint in both trials were the percentage of subjects who achieved an American College of Rheumatology (ACR) 20 response at Week 16. In both trials, treatment with SOTYKTU resulted in statistically significant improvement in disease activity, as measured by ACR 20, compared to placebo at Week 16. Improvement in disease activity was also demonstrated as measured by ACR 50/70 compared with placebo at Week 16. In both trials, ACR20 responses at Week 16 were consistent regardless of concomitant DMARD use, age, gender, race, or baseline disease characteristics in patients receiving SOTYKTU. In Trial PsA-2, similar ACR response rates were seen regardless of prior anti-TNF alpha therapy. Improvements in ACR 20 and individual ACR components from baseline were observed in subjects treated with SOTYKTU at Week 16. Similar responses were seen in Trial PsA-2 up to Week 16.

Wellcovorin (leucovorin calcium)

FDA APPROVAL DATE: March 12, 2026

INDICATION: WELLCOVORIN is indicated for the treatment of cerebral folate transport deficiency in adult and pediatric patients who have a confirmed variant in the folate receptor 1 gene (FOLR1-CFTD).

STUDY INFORMATION: FOLR1-CFTD is a very rare neurological syndrome. No clinical trials have been conducted to examine the efficacy and safety of leucovorin in patients with FOLR1 variants. Evidence for the efficacy and safety of leucovorin in patients with FOLR1-CFTD was derived from the published literature. Forty-six patients with FOLR1-CFTD who received leucovorin treatment via various administration routes were identified in 26 published case reports and case reviews through 2024. Thirty cases were described in more than one publication.

CSF 5-MTHF measurements were collected at varying, unspecified time points across patients, with timing broadly categorized as before or after treatment initiation in most cases. In the subset of 27 FOLR1-CFTD patients who received oral leucovorin only, pre-treatment 5-MTHF levels were very low (<10 nmol/L in 17 of 21 patients with observed levels) compared to reported reference ranges from 40 up to 240 nmol/L. A subset of 7 patients had CSF 5-MTHF levels measured both before and after leucovorin initiation. All 7 patients experienced an increase in CSF 5-MTHF levels following treatment initiation, with 5 achieving normalization above 40 nmol/L.

Cosentyx (secukinumab)

FDA APPROVAL DATE: March 12, 2026

INDICATION: COSENTYX is indicated for the treatment of moderate to severe hidradenitis suppurativa (HS) in adults and pediatric patients 12 years of age and older.

STUDY INFORMATION: The safety and effectiveness of COSENTYX have been established for the treatment of moderate to severe HS in pediatric patients 12 years of age and older who weigh 30 kg or more. Use of COSENTYX for this indication is supported by safety and efficacy data from adequate and well controlled trials in adult subjects with moderate to severe HS.

Additional evidence includes population pharmacokinetic modeling and simulation based on data from adult subjects with PsO and HS and pediatric subjects with PsO, as well as safety data from clinical trials in pediatric subjects with PsO and JIA (JPsA and ERA).

The safety and effectiveness of COSENTYX in pediatric patients with HS below the age of 12 years old or with a body weight less than 30 kg have not been established.

Arexvy (respiratory syncytial virus vaccine, adjuvanted)

FDA APPROVAL DATE: March 17, 2026

INDICATION: AREXVY is a vaccine indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older and individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV. This approval expands the range to those 18 through 49 years of age.

STUDY INFORMATION: Safety and effectiveness was supported by an open-label Phase 3 study conducted in Australia, Canada, Germany, Japan, South Africa and the U.S., in participants 18 through 49 years of age with pre-specified, stable, chronic medical conditions leading to an increased risk for LRTD caused by RSV defined as chronic pulmonary disease, chronic cardiovascular disease, diabetes, chronic kidney or liver disease, or neurological or neuromuscular disease (N = 1,029). The study also enrolled participants 60

years of age and older (N = 429). All study participants received 1 dose of AREXVY. The study demonstrated a non-inferior immune response in high-risk adults aged 18-49 years of age compared to adults 60 years of age and older.

SAFETY UPDATES

FDA Adverse Event Monitoring System (AEMS)

FDA DATE: March 11, 2026

FDA implemented the Adverse Event Monitoring System (AEMS) to consolidate multiple disparate reporting systems currently used across all FDA-regulated product categories, including medical products, vaccines, devices, tobacco, food, cosmetics, and veterinary medicines.

This unified platform is designed to enhance data quality and consistency through standardized reporting protocols, streamline reporting processes to reduce administrative burden on both internal FDA staff and external stakeholders, and strengthen safety surveillance capabilities through advanced case processing workflows, AI-based redaction and digitization tools, enhanced analytics, and comprehensive cross-product surveillance.

Beyond adverse event reporting, AEMS will serve as a centralized platform for managing consumer complaints, regulatory misconduct reports, and whistleblower submissions across all FDA centers. This comprehensive approach will enable more effective safety monitoring, facilitate trend identification across diverse product categories, and support timely regulatory decision-making to protect public health through improved data integration and analysis capabilities.

Isotretinoin REMS Modification

RECALLS

None

DRUG DISCONTINUATIONS

Roctavian (valoctocogene roxaparvovec-rvox)

Biomarin announced a business decision to discontinue Roctavian for reasons not related to safety or effectiveness.

Tazverik (tazemetostat)

Ipsen announced that it is voluntarily withdrawing Tazverik in all indications based on emerging data from the ongoing Phase Ib/III SYMPHONY-1 trial. The Independent Data Monitoring Committee (IDMC) advised that, based on adverse events of secondary hematologic malignancies, the risks may outweigh potential benefits for patients within this treatment regimen.

adalimumab-ryvk (Quallent)

Quallent announced a business decision to discontinue adalimumab-ryvk (Quallent) for reasons not related to safety or effectiveness. This product will no longer be available on the market by June 2026. Members may continue to refill at this time. Premera is working with Accredo to transition members to a preferred formulary alternative. Current alternatives include adalimumab-aaty, adalimumab-adbm (non-Quallent NDCs), and adalimumab-adaz.

Questions?

Please contact your Premera representative for more information.