

Pharmacy

# Premera Formulary Newsletter

The latest monthly pharmacy news and announcements

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March 2026

## Latest News

### Biosimilars

Biosimilars are highly similar versions of existing biologic medicines (known as reference products) that have already been proven safe and effective. Because biologics are complex therapies made from living cells, biosimilars must meet rigorous regulatory standards to demonstrate they have no clinically meaningful differences from the reference product in terms of safety, quality, and effectiveness. In practice, this means patients and providers can expect the same therapeutic outcomes they trust from the original biologic.

From a cost-management perspective, biosimilars play a critical role in expanding access to high-value therapies. By introducing competition into categories that have traditionally been dominated by single, high-cost biologics, biosimilars help lower overall drug spend for health plans, employers, and patients. These savings can be reinvested to improve coverage, reduce patient out-of-pocket costs, and support broader access to innovative treatments.

For clients focused on balancing clinical excellence with financial stewardship, biosimilars represent a smart, sustainable solution. They allow decision makers to maintain high standards of care while managing budgets responsibly—without compromising patient outcomes. As adoption continues to grow, biosimilars are becoming an essential tool in delivering affordable, high-quality care.

## High-Cost, Low-Value Drugs

### Understanding Premera's High Cost, Low Value Drugs - applicable only to the Incentive formulary

Managing prescription drug costs while ensuring access to effective care is a shared priority. One of the ways Premera supports this balance is through the High Cost, Low Value (HCLV) Drug List that identifies medications that are:

- Significantly more expensive, and
- Not shown to provide meaningful clinical benefit compared to other available treatment options.

In many cases, lower-cost alternatives—such as therapeutically equivalent medications or different formulations—are available and provide similar outcomes for most patients.

#### *How does it work?*

Medications are reviewed through Premera's established clinical and formulary evaluation process, which considers:

- The strength and quality of clinical evidence
- Comparative effectiveness versus other therapies
- Overall cost and value

When a drug is designated as high cost, low value, it may be excluded from the formulary or subject to utilization management, depending on the plan design. Clinically appropriate alternatives remain available, and exception processes are in place when medication is medically necessary.

#### *Example*

If a high-priced brand-name drug enters the market but does not demonstrate improved outcomes compared to existing, lower-cost therapies, it may be placed on the HCLV Drug List. In these cases, members and providers are encouraged to use effective alternatives that help reduce unnecessary spending without compromising care.

## Key Takeaways

You can take a few simple steps to maximize the value of this program:

- Review your formulary to understand how HCLV drugs are handled under your plan
- Communicate with employees about coverage changes and available alternatives
- Partner with your Premera account team for education, resources, and benefit strategy support

Premera remains committed to helping you balance affordability, access, and quality. The High Cost, Low Value Drug List helps better manage pharmacy costs, supports evidence-based prescribing, and promotes sustainable benefit designs over time. This is one of several tools designed to support smarter pharmacy spending while maintaining high standards of care.

## 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 formulary drug lists that may include new brand or generic launches and updates to products on the market today. Cost shares (i.e., copays or coinsurance), benefits, and coverage may differ based on 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	
MYQORZO (aficamten)	3	4	2	Non-Formulary Tier 4	Formulary Tier 3	Formulary Tier 4	Yes	Yes	No	30 tablets per 30 days	For the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy
PIVYA (pivmecillinam hcl)	3	3	2	Non-Formulary Tier 3	Non-Formulary Tier 3	Non-Formulary Tier 4	Yes	Yes	No	21 tablets per fill	For the treatment of uncomplicated urinary tract infections
sodium oxybate 500mg/mL oral solution	1	1	1	Non-Formulary Tier 4	Formulary Tier 3	Formulary Tier 4	Yes	Yes	No	3 bottles per 30 days	First time generic for Xyrem

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	
ZYCUBO (copper histidinate subcutaneous vial)	3	4	2	Non-Formulary Tier 4	Non-Formulary Tier 3	Non-Formulary Tier 4	Yes	Yes	No	1 vial per day	For the treatment of Menkes disease in pediatric patients

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
ITVISMA (onasemnogene abeparvovec-brve)	Add	Release date	Medical benefit only
MYQORZO (aficamten)	Add	Release date	
YARTEMLEA (narsoplimab-wuug)	Add	Release date	Medical benefit only
PIVYA (pivmecillinam hcl)	Add	Release date	
sodium oxybate	Add	Release date	

## STEP THERAPY

Drug Name	Update	Effective Date	Notes
LEVETIRACETAM (branded levetiracetam tablet for oral suspension)	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
ACTEMRA (tocilizumab)	Add	4 auto-injectors or syringes per 28 days	6/1/2026
adalimumab (Humira & all biosimilars)	Add	2 auto-injectors or syringes per 28 days	6/1/2026
ADBRY (tralokinumab-ldrm)	Add	2 auto-injectors or syringes per 28 days	6/1/2026
BIMZELX (bimekizumab-bkzx)	Add	160mg: 2 auto-injectors or syringes per 56 days 320mg: 1 auto-injector or syringe per 56 days	6/1/2026
CIMZIA (certolizumab pegol)	Add	2 syringes per 28 days	6/1/2026
COSENTYX (secukinumab)	Add	75mg: 1 syringe per 28 days 150mg 2 pens or syringes per 28 days 300mg: 1 pen per 28 days	6/1/2026
DUPIXENT (dupilumab)	Add	2 pens or syringes per 28 days	6/1/2026
ENBREL (etanercept)	Add	25mg: 8 syringes or vials per 28 days 50mg: 4 auto-injectors or syringes per 28 days	6/1/2026
ENTYVIO (vedolizumab)	Add	2 pens per 28 days	6/1/2026
ILUMYA (tildrakizumab-asmn)	Add	1 syringe per 84 days	6/1/2026
KEVZARA (sarilumab)	Add	2 syringes per 28 days	6/1/2026

KINERET (anakinra)	Add	28 syringes per 28 days	6/1/2026
MYQORZO (aficamten)	Add	30 tablets per 30 days	Release date
PIVYA (pivmecillinam)	Add	21 tablets per Rx	Release date
SDAMLO (amlodipine powder for oral solution)	Add	30 bottles per 30 days	Release date
LITFULO (ritlecitinib)	Add	28 capsules per 28 days	6/1/2026
LOPRESSOR (metoprolol tartrate 12.5 mg)	Add	30 tablets per 30 days	Release date
NEMLUVIO (nemolizumab-ilto)	Add	2 pens per 28 days	6/1/2026
OLUMIANT (baricitinib)	Add	30 tablets per 30 days	6/1/2026
OMVOH (mirikizumab-mrkz)	Add	2 pens or syringes per 28 days	6/1/2026
ORENCIA (abatacept)	Add	4 auto-injectors or syringes per 28 days	6/1/2026
OTEZLA (apremilast)	Add	60 tablets per 30 days	6/1/2026
RINVOQ ER (upadacitinib)	Add	15mg & 30mg: 30 tablets per 30 days 45mg: 56 tablets per 365 days	6/1/2026
RINVOQ LQ (upadacitinib)	Add	360mL per 28 days	6/1/2026
SILIQ (brodalumab)	Add	2 syringes per 28 days	6/1/2026
SIMPONI (golimumab)	Add	1 auto-injector or syringe per 28 days	6/1/2026
SKYRIZI (risankizumab-rzaa)	Add	1 syringe or cartridge per 56 days	6/1/2026
sodium oxybate	Add	3 bottles per 30 days	Release date
SOTYKTU (deucravacitinib)	Add	30 tablets per 30 days	6/1/2026
TALTZ (ixekizumab)	Add	1 auto-injector or syringe per 28 days	6/1/2026
TREMFYA (guselkumab)	Add	100mg: 1 auto-injector or pen per 56 days 200mg: 1 pen or syringe er 28 days	6/1/2026
ustekinumab (Stelara & all biosimilars)	Add	45mg: 1 syringe or vial per 84 days 90mg: 1 syringe per 56 days	6/1/2026
VELSIPITY (etrasimod)	Add	30 tablets per 30 days	5/1/2026
XELJANZ (tofacitinib)	Add	Solution: 480mL per Rx Tablets: 60 tablets per 30 days	5/1/2026
XELJANZ XR (tofacitinib)	Add	30 tablets per 30 days	5/1/2026

ZEPBOUND KWIKPEN (tirzepatide pen injector)	Add	1 pen per 28 days	Release date
ZYCUBO (copper histidinate)	Add	1 vial per day	Release date
ZYMFENTRA (infliximab-dyyb)	Add	2 pens or syringes per 28 days	6/1/2026

## Clinical Information

### NEW DRUGS

#### Adquey (difamilast 1% ointment)

**FDA APPROVAL DATE:** February 12, 2026

**INDICATION:** A phosphodiesterase 4 inhibitor indicated for the topical treatment of adults and pediatric patients 2 years of age and older with mild to moderate atopic dermatitis.

**STUDY INFORMATION:** Efficacy was evaluated in pediatric patients with Menkes disease (age at treatment initiation ranges 0.1 to 31.4 months) receiving 3 years of copper histidinate treatment in two open label, single-arm clinical trials. Data from copper histidinate-treated patients in these two trials were compared to data from an untreated contemporaneous external control cohort as collected under a protocol amendment of Trial 2.

Efficacy was assessed in three multicenter, randomized, double-blind parallel-group, vehicle-controlled trials that treated a total of 612 patients. In these trials, patients were randomized one to one to received Adquey or vehicle ointment that was applied topically to the entire treatment area twice daily for at least 4 weeks. The primary efficacy endpoint was the proportion of patients who achieved Investigator's Global Assessment (IGA) success which was defined as an IGA grade of clear or almost clear and with a 2-grade or greater improvement from baseline, at week 4. In trial 1, 9 Adquey patients achieved IGA success compared to 1 with vehicle. In trial 2, 70 Adquey patients achieved IGA success compared to 23 with vehicle. In trial 3, 40 Adquey patients achieved IGA success compared to 15 with vehicle.

### NEW BIOSIMILARS

None

### FIRST TIME GENERICS

## sodium oxybate oral solution

Camber and Amneal launched generic version of Xyrem (sodium oxybate) oral solution for the treatment of cataplexy or excessive daytime sleepiness in patients with narcolepsy on January 26, 2026 and January 29, 2026.

## NEW INDICATIONS

### Noxafil (posaconazole injection), Noxafil (posaconazole tablet), Noxafil PowderMix Kit (posaconazole kit)

**FDA APPROVAL DATE:** January 27, 2026

**INDICATION:** The new indications include expansion to a new patient population (2 year olds weighing > 10 kilograms) for the treatment of invasive aspergillosis and prophylaxis of invasive aspergillus and candida infections.

#### Treatment of Invasive Aspergillosis

Noxafil is indicated for the treatment of invasive aspergillosis as follows:

- Noxafil injection: adults and pediatric patients 2 years of age and older who weigh 10 kg or greater
- Noxafil delayed-release tablets: adults and pediatric patients 2 years of age and older who weigh greater than 40 kg
- Noxafil PowderMix for delayed-release oral suspension: pediatric patients 2 years of age and older who weigh 10 to 40 kg

#### Prophylaxis of Invasive Aspergillus and Candida Infections

Noxafil is indicated for the prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy as follows:

- Noxafil injection: adults and pediatric patients 2 years of age and older who weigh 10 kg or greater

- Noxafil delayed-release tablets: adults and pediatric patients 2 years of age and older who weigh greater than 40 kg
- Noxafil oral suspension: adults and pediatric patients 13 years of age and older
- Noxafil PowderMix for delayed-release oral suspension: pediatric patients 2 years of age and older who weigh 10 kg to 40 kg

**STUDY INFORMATION:** The safety and effectiveness of Noxafil (injection and delayed-release tablets) have been established for the treatment of invasive aspergillosis in pediatric patients 2 years of age and older. The safety and effectiveness of Noxafil PowderMix have been established for the treatment of invasive aspergillosis in pediatric patients 2 years of age and older who weigh 10 kg to 40 kg. Use of Noxafil and Noxafil PowderMix for these pediatric indications is supported by evidence from adequate and well-controlled studies of Noxafil in adults and safety and pharmacokinetic (PK) data from two pediatric studies. The safety of Noxafil and Noxafil PowderMix in pediatric patients for these pediatric indications was consistent with the known safety profile of Noxafil in adults.

## Caldolor (ibuprofen injection)

**FDA APPROVAL DATE:** January 23, 2026

**INDICATION:** For the treatment of postoperative pain.

**STUDY INFORMATION:** A study of orthopedic surgical pain confirmed the findings of the study of abdominal surgical pain. A total of 185 patients were randomized and treated with CALDOLOR 800 mg or placebo administered every 6 hours (started pre-operatively) and morphine administered on an as-needed basis. Efficacy was demonstrated as a statistically significant greater reduction in pain intensity over 24 hours post-operatively for patients treated with CALDOLOR as compared to those receiving placebo.

## Darzalex Faspro (daratumumab and hyaluronidase-fihj)

**FDA APPROVAL DATE:** January 27, 2026

**INDICATION:** In combination with bortezomib, lenalidomide, and dexamethasone (VRd) for adults with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant (ASCT).

**STUDY INFORMATION:** Efficacy was evaluated in CEPHEUS (NCT03652064), an open-label, randomized, active-controlled trial in patients with newly diagnosed multiple myeloma who were ineligible for ASCT or refused ASCT as initial therapy. The effectiveness of DARZALEX FASPRO-VRd has not been established in patients who refused ASCT as initial therapy.

A total of 395 patients were randomized: 197 to the Darzalex Faspro-VRd arm and 198 to the VRd arm. The major efficacy outcome measures were overall minimal residual disease (MRD) negativity rate and progression-free survival (PFS) by independent review committee (IRC) based on International Myeloma Working Group (IMWG) response criteria. The MRD negativity rate was 52.3% in the Darzalex Faspro-VRd arm and 34.8% in the VRd arm (p-value 0.0005). The PFS hazard ratio was 0.60 [95% CI: 0.41, 0.88]; p-value 0.0078].

## Noxafil (posaconazole injection), Noxafil (posaconazole tablet), Noxafil PowderMix Kit (posaconazole kit)

**FDA APPROVAL DATE:** January 27, 2026

**INDICATION:** The new indications include expansion to a new patient population (2 year olds weighing > 10 kilograms) for the treatment of invasive aspergillosis and prophylaxis of invasive aspergillus and candida infections.

### Treatment of Invasive Aspergillosis

Noxafil is indicated for the treatment of invasive aspergillosis as follows:

- Noxafil injection: adults and pediatric patients 2 years of age and older who weigh 10 kg or greater
- Noxafil delayed-release tablets: adults and pediatric patients 2 years of age and older who weigh greater than 40 kg
- Noxafil PowderMix for delayed-release oral suspension: pediatric patients 2 years of age and older who weigh 10 to 40 kg

### Prophylaxis of Invasive Aspergillus and Candida Infections

Noxafil is indicated for the prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy as follows:

- Noxafil injection: adults and pediatric patients 2 years of age and older who weigh 10 kg or greater
- Noxafil delayed-release tablets: adults and pediatric patients 2 years of age and older who weigh greater than 40 kg
- Noxafil oral suspension: adults and pediatric patients 13 years of age and older
- Noxafil PowderMix for delayed-release oral suspension: pediatric patients 2 years of age and older who weigh 10 kg to 40 kg

**STUDY INFORMATION:** The safety and effectiveness of Noxafil (injection and delayed-release tablets) have been established for the treatment of invasive aspergillosis in pediatric patients 2 years of age and older. The safety and effectiveness of Noxafil PowderMix have been established for the treatment of invasive aspergillosis in pediatric patients 2 years of age and older who weigh 10 kg to 40 kg. Use of Noxafil and Noxafil PowderMix for these pediatric indications is supported by evidence from adequate and well-controlled studies of Noxafil in adults and safety and pharmacokinetic (PK) data from two pediatric studies. The safety of Noxafil and Noxafil PowderMix in pediatric patients for these pediatric indications was consistent with the known safety profile of Noxafil in adults.

## Keytruda (pembrolizumab) and Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph)

**FDA APPROVAL DATE:** February 10, 2026

**INDICATION:** In combination with paclitaxel, with or without bevacizumab, for adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma whose tumors express PD-L1 (CPS $\geq$ 1) as determined by an FDA-authorized test, and who have received one or two prior systemic treatment regimens.

**STUDY INFORMATION:** "Approval was based on results from the Phase 3 KEYNOTE-B96 study. Patients were randomized 1:1 to receive either Keytruda plus paclitaxel with or without bevacizumab or placebo plus paclitaxel with or without bevacizumab. In the population of patients whose tumors expressed PD-L1, the median progression-free survival (PFS) was 8.3 months in the Keytruda arm versus 7.2 months in the placebo arm (hazard ratio [HR], 0.72; P = 0.0014), and the median overall survival (OS) was 18.2 months in the Keytruda arm versus 14.0 months in the placebo arm (HR, 0.76; P = 0.0053).

Keytruda and Keytruda Qlex are the first programmed cell death protein 1 (PD-1) inhibitors approved for this indication.

## SAFETY UPDATES

### Xeloda (capecitabine) and fluorouracil Label Updates

**FDA DATE:** February 5, 2026

Recent updates to the product labeling of capecitabine (Xeloda) and fluorouracil (5-FU) related to risks associated with dihydropyrimidine dehydrogenase (DPD) deficiency. All healthcare providers should be aware of the risks of DPD deficiency, inform patients prior to treatment about the potential for serious and life-threatening toxicities due to DPD deficiency, and test patients for genetic variants of DPYD prior to initiating treatment with capecitabine or 5-FU unless immediate treatment is necessary.

The DPYD gene encodes the enzyme DPD, which breaks down >80% of fluorouracil. Patients with certain homozygous or compound heterozygous variants in the DPYD gene, known to result in complete or near complete absence of DPD activity (complete DPD deficiency), are at increased risk for acute early-onset toxicity and serious, including fatal, adverse reactions (e.g., mucositis, diarrhea, neutropenia, and neurotoxicity) when exposed to capecitabine or fluorouracil. Patients with partial DPD activity (partial DPD deficiency) may also have an increased risk of serious, including fatal, adverse reactions.

The Boxed Warning now highlights the risk of serious adverse reactions or death in patients with complete DPD deficiency. It also advises DPYD testing prior to initiating capecitabine or 5-FU, unless immediate treatment is necessary, and recommends avoiding use in patients with certain homozygous or compound heterozygous DPYD variants that result in complete DPD deficiency.

### Isotretinoin REMS Modification

**FDA DATE:** February 10, 2026

FDA Approves iPLEDGE REMS Modification. The modifications approved include changes outlined in the November 2023 FDA notification to isotretinoin manufacturers. These modifications to the REMS will go into effect 180 days after the February 9, 2026 approval. Until that time, FDA continues to exercise enforcement discretion regarding pregnancy testing requirements as described in the Agency's October 2023 update.

### Yescarta (axicabtagen ciloleucel) Prescribing Information Update

**FDA DATE:** February 6, 2026

The FDA has approved an update to the prescribing information for axicabtagene ciloleucel (axi-cel; Yescarta), removing the prior Limitations of Use for patients with relapsed/refractory primary central nervous system lymphoma (PCNSL).

## Hormone Replacement Therapy Label Updates

**FDA DATE:** February 12, 2026

The FDA has approved drug labeling changes to six menopausal hormone therapy products, also known as hormone replacement therapy (HRT), to clarify risk considerations for these drugs. Specifically, risk statements related to cardiovascular disease, breast cancer and probable dementia were removed from the “boxed warning,” the agency’s most prominent safety-related warning.

The FDA initiated the removal of these warnings in November 2025, following a comprehensive review of the scientific literature. At the FDA’s request, 29 drug companies have submitted proposed labeling changes. This first batch of six products with approved labeling changes includes products from each of the four categories of HRT for menopausal women:

- Systemic combination therapy (estrogen and progestogen)
- Systemic estrogen-alone therapy
- Systemic progestogen-alone therapy for women with a uterus using systemic estrogen
- Topical vaginal estrogen therapy

## Enoby (denosumab-qbde) and Ospomyv (denosumab-qbde) REMS Program Update

**FDA DATE:** February 12, 2026

The FDA issued safety updates under the REMS program for the biosimilars denosumab-qbde (Enoby) and denosumab-dssb (Ospomyv), which both reference denosumab (Prolia).” The REMS updates for both biosimilars “emphasize the increased risk for severe hypocalcemia following administration in patients with advanced chronic kidney disease, defined as those with estimated glomerular filtration rate levels below 30 mL/min/1.73 m<sup>2</sup>, including patients dependent on dialysis. Furthermore, the “updates note that cases of severe hypocalcemia resulting in life-threatening events, hospitalization, and death have been reported.

## RECALLS

None

## DRUG DISCONTINUATIONS

None

## Questions?

Please contact your Premera representative for more information.

