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PharmNotes

Monthly Communications

December 2025

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Pharmacy Benefit Management
Expires: 12/01/2028

Table of Contents

Drug Safety Alert Notification

The Drug Safety Communications are provided by the U.S. Food and Drug Administration and are intended to offer important information to patients and health care providers about new safety issues regarding certain medications. This helps prescribers and health care professionals be informed so that decisions regarding the treatment of patients are made accordingly.

No drug safety alert was released during the month of December.

New FDA-Approved Drug Products

New Molecular Entity

Cardamyst (etripamil) nasal spray

FDA-Approved Indication

For the conversion of acute symptomatic episodes of paroxysmal supraventricular tachycardia (PSVT) to sinus rhythm in adults.

Dosage & Administration

Using one nasal spray device, administer one spray into each nostril for a total initial dose of 70 mg. If symptoms persist after 10 minutes, use the second nasal spray device to administer a second dose of one spray into each nostril.

Dosage Forms & Strengths

Nasal spray: 70 mg etripamil per device.

Contraindications

- Hypersensitivity to Cardamyst or any of its components
- Heart failure – NYHA Class II to IV
- Wolff Parkinson White, Lown Ganong Levine syndromes, or manifest pre-excitation (delta wave) on a 12-lead ECG
- Sick sinus syndrome (except in patients with a permanent pacemaker)
- Second degree atrioventricular Mobitz 2 block or higher degree of AV block

Common Adverse Reactions

Nasal discomfort, nasal congestion, rhinorrhea, throat irritation, and epistaxis.

Warnings & Precautions

- Syncope

Use in Specific Populations

- Lactation: A lactating woman should pump and discard breastmilk for 12 hours after Cardamyst administration.

Clinical Studies

The approval came from randomized, double-blind, placebo-controlled phase 3 RAPID study. Results showed that in patients with a confirmed episode of PSVT, 64% of those who used Cardamyst converted to sinus rhythm within 30 minutes compared with 31% of those who received placebo (hazard ratio 2.6 [95% CI, 1.7-4.2]; P <.001).

Place in Therapy

Cardamyst is the first and only rapid-acting, patient-controlled option that allows individuals to manage PSVT episodes outside of a traditional healthcare setting, potentially avoiding emergency room visits or calls to emergency services.

New FDA-Approved Drug Products

Orphan Drug | Specialty

New Molecular Entity

Yartemlea (narsoplimab-wuug) injection, for intravenous use

FDA-Approved Indication

For the treatment of adult and pediatric patients 2 years of age and older with hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA).

Dosage & Administration

Once weekly weight-based intravenous infusion.

Dosage Forms & Strengths

Injection: 370 mg/2 mL (185 mg/mL) in a single-dose vial.

Contraindications

- None

Common Adverse Reactions

Viral infections, sepsis, hemorrhage, diarrhea, vomiting, nausea, neutropenia, pyrexia, fatigue and hypokalemia.

Warnings & Precautions

- Serious Infection

Clinical Studies

The approval came the single-arm, open-label TA-TMA study, with an expanded access program. Results showed that 61% (95% CI, 40.6-78.5) of patients had TMA response, with 61% having an improvement in platelet count and 75% having an improvement in LDH. Improvement in organ function and freedom from red blood cell or platelet transfusion was observed in 74% and 48% of patients, respectively. Consistent responses were also observed during the expanded part of the study.

Place in Therapy

TA-TMA is a high-mortality complication of stem cell transplants. Yartemlea is the first and only therapy indicated for TA-TMA and also the first and only approved inhibitor of the lectin pathway of the complement system.

New FDA-Approved Drug Products

New Molecular Entity

Nuzolvence (zoliflodacin) for oral suspension

FDA-Approved Indication

For the treatment of uncomplicated urogenital gonorrhea due to *Neisseria gonorrhoeae* in adults and pediatric patients 12 years of age and older, weighing at least 35 kg.

Dosage & Administration

3 g (one packet) administered as a single dose orally.

Dosage Forms & Strengths

For oral suspension: 3 g of zoliflodacin in each unit-dose packet.

Contraindications

- Known history of hypersensitivity to Nuzolvence
- Concomitant use with moderate or strong CYP3A4 inducers

Common Adverse Reactions

Neutropenia, headache, leukopenia, dizziness, nausea, and diarrhea.

Warnings & Precautions

- Testicular Toxicity and Risks to Male Fertility
- Embryo-Fetal Toxicity
- Hypersensitivity Reactions
- *Clostridioides difficile* Infection

Clinical Studies

The approval came from an open-label, active-controlled phase 3 study. Study participants were randomly assigned 2:1 to receive a single dose of Nuzolvence or standard of care (SOC: a combination of a single intramuscular dose of ceftriaxone 500mg plus oral azithromycin 1g). Results showed Nuzolvence was noninferiority in achieving microbiological cure at the urogenital site of infection compared with SOC, with cure rates of 90.9% and 96.2%, respectively.

Place in Therapy

Nuzolvence could be reserved for the treatment of drug-resistant gonorrhea, including cases that do not respond to the current first-line treatment, ceftriaxone.

New FDA-Approved Drug Products

Specialty

New Molecular Entity

Lerochol (lerodalcibep-liga) injection, for subcutaneous use

FDA-Approved Indication

As an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH).

Dosage & Administration

300 mg administered subcutaneously once monthly.

Dosage Forms & Strengths

Injection: 300 mg/1.2 mL (250 mg/mL) solution in a single-dose prefilled syringe.

Contraindications

- None.

Common Adverse Reactions

Injection site reactions, nasopharyngitis, diarrhea, nausea and peripheral edema.

Clinical Studies

The approval came from 3 randomized, double-blind, placebo-controlled trials that enrolled patients who were on maximally tolerated statin therapy and who required additional LDL-C lowering. Lerochol demonstrated sustained LDL-C reductions of over 60% in patients with, or at very high or high risk of, cardiovascular disease and over 50% in those with HeFH who have more severe LDL-C elevations.

Place in Therapy

Lerochol joins the treatment landscape alongside Repatha (evolocumab), Praluent (alirocubmab) and Leqvio (inclisiran). Lerochol stands out primarily due to its low-volume administration and superior storage stability (room temperature stable for up to 3 months).

New FDA-Approved Drug Products

Specialty

New Molecular Entity

Exdensur (depemokimab-ulaa) injection, for subcutaneous use

FDA-Approved Indication

For add-on maintenance treatment of severe asthma characterized by an eosinophilic phenotype in adult and pediatric patients aged 12 years and older.

Dosage & Administration

100 mg administered once every 6 months by subcutaneous injection by a healthcare provider.

Dosage Forms & Strengths

Injection: 100 mg/mL solution in a single-dose, prefilled pen and syringe.

Contraindications

- None.

Common Adverse Reactions

Upper respiratory tract infection, allergic rhinitis, influenza, arthralgia, and pharyngitis.

Warnings & Precautions

- Hypersensitivity reactions, including anaphylaxis
- Do not abruptly discontinue systemic or inhaled corticosteroids upon initiation of therapy with Exdensur
- Treat pre-existing helminth infections before initiating therapy with Exdensur

Use in Specific Populations

- Pregnancy: Exdensur can cross the placenta during pregnancy.

Clinical Studies

The approval came from 2 randomized, double-blind, parallel-group, placebo-controlled replicate trials (SWIFT-1 and SWIFT-2). Results showed treatment with Exdensur resulted in a 58% reduction in the rate of annualized asthma exacerbations compared with placebo in SWIFT-1 (rate ratio, 0.42 [95% CI, 0.30-0.59]; P <.001). Similarly, Exdensur led to a 48% reduction in the rate of annualized asthma exacerbations versus placebo in SWIFT-2 (rate ratio, 0.52 [95% CI, 0.36-0.73]; P <.001).

Place in Therapy

Exdensur joins the treatment landscape alongside Tezspire (tezepelumab), Nucala (mepolizumab), Cinqair (reslizumab), Xolair (omalizumab), Dupixent (dupilumab), and Fasenra (benralizumab). Unlike other IL-5 inhibitors that require injections every 4 to 8 weeks, Exdensur is administered just once every 6 months.

New FDA-Approved Drug Products

Orphan Drug | Specialty

New Molecular Entity

Myqorzo (aficamten) tablets, for oral use

FDA-Approved Indication

For the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) to improve functional capacity and symptoms.

Dosage & Administration

The recommended starting dose is 5 mg orally once daily. Increase the dose every 2 to 8 weeks by 5 mg until a maintenance dose or the maximum recommended dose of 20 mg once daily is achieved.

Dosage Forms & Strengths

Film-coated tablets: 5 mg, 10 mg, 15 mg, 20 mg.

Contraindications

- Rifampin

Common Adverse Reactions

Hypertension.

Warnings & Precautions

- ***BBW***: *Risk of Heart Failure*
- Drug Interactions Leading to Increased Risk of Heart Failure or Loss of Effectiveness

Clinical Studies

The approval came from the randomized, double-blind, placebo-controlled phase 3 SEQUOIA-HCM. Adults with symptomatic NYHA class II and III oHCM were randomly assigned 1:1 to receive Myqorzo or placebo once daily for 24 weeks. Results showed Myqorzo led to a statistically significant improvement in exercise capacity compared with placebo (change from baseline in pVO_2: 1.7 mL/min/kg vs 0.0 mL/min/kg; least squares mean difference, 1.7 [95% CI, 1.0-2.4]; P <.0001). Also, 59% of patients receiving Myqorzo experienced an improvement in physical activity limitations compared to 24% of individuals receiving placebo.

Place in Therapy

Guideline recommended therapy generally includes beta blockers, calcium channel blockers, anti-arrhythmic drugs, heart failure drugs, and anticoagulants. Myqorzo joins the treatment landscape alongside Camzyos (mavacamten).

New FDA-Approved Drug Products

Specialty

New Molecular Entity

Fesilty (fibrinogen, human - chmt), lyophilized powder for reconstitution, for intravenous use

FDA-Approved Indication

For the treatment of acute bleeding episodes in pediatric and adult patients with congenital fibrinogen deficiency (CFD), including hypo- or afibrinogenemia.

Dosage & Administration

Intravenous infusion with the dose individualized for each patient; the target plasma fibrinogen level is 100 mg/dL for minor bleeding and 150 mg/dL for major bleeding.

Dosage Forms & Strengths

A sterile, lyophilized, white in color powder for solution for intravenous injection. Fesilty is provided as one single-dose glass vial containing nominally 1 gram of human fibrinogen and one 50 mL glass vial of Sterile Water for Injection, USP.

Contraindications

- Severe hypersensitivity reactions, including anaphylaxis

Common Adverse Reactions

Pain in extremity, back pain, hypersensitivity reactions, pyrexia, thrombosis, fibrin D dimer increased, headache, and vomiting.

Warnings & Precautions

- Hypersensitivity reactions
- Thrombotic events
- Fesilty is made from pooled human plasma and may carry the risk of transmitting infectious agents

Clinical Studies

The approval came from an open-label, single-arm phase 3 study 36 patients with CFD, 34 with congenital afibrinogenemia and 2 with severe hypofibrinogenemia. The primary efficacy endpoint was the overall hemostatic response based on a 4-point scale classified as excellent, good, moderate or none. Results showed that the bleeding events were successfully managed, with 86% of patients showing an excellent response after just one infusion, 13% as good, and 1% as moderate.

Place in Therapy

Fesilty is the third fibrinogen concentrate product approved for CFD, joining the treatment landscape alongside RiaSTAP and Fibryga.

New FDA-Approved Drug Products

Orphan Drug | Specialty

New Formulations, Combinations, and Line Extensions

Aqvesme (mitapivat) tablets, for oral use

FDA-Approved Indication

For the treatment of anemia in adults with alpha- or beta-thalassemia.

Dosage & Administration

100 mg orally twice daily.

Dosage Forms & Strengths

Tablets: 100 mg.

Contraindications

- None.

Common Adverse Reactions

Headache and insomnia.

Warnings & Precautions

- ***BBW***: *Hepatocellular Injury (REMS)*

Drug Interactions

- Strong CYP3A Inhibitors and Inducers
- Moderate CYP3A Inhibitors and Inducers
- Sensitive CYP3A substrates including hormonal contraceptives
- CYP2B6, CYP2C and UGT1A1 Substrates
- P-gp Substrates

Use in Specific Populations

- Hepatic Impairment: Avoid use in patients with cirrhosis.

Clinical Studies

The approval came from the double-blind, randomized, placebo-controlled, phase 3 ENERGIZE and ENERGIZE-T trials. In ENERGIZE, 55 patients in the Aqvesme group had a hemoglobin response, compared to 1 in the placebo group (least-squares mean difference, 41%; 95% CI, 32-50; *P* <.0001). In ENERGIZE-T, transfusion reduction response (defined as a ≥50% reduction in transfused RBC units and a reduction of ≥2 units of transfused RBCs in any consecutive 12-week period compared with baseline) was achieved in 30.4% of patients in the Aqvesme arm versus 12.6% in the placebo arm.

Place in Therapy

Prior to the approval of Aqvesme, there were limited treatment options for alpha thalassemia and non-transfusion–dependent beta thalassemia. Aqvesme joins the treatment landscape alongside Reblozyl (luspatercept-aamt), an injection administered by a healthcare professional subcutaneously every 3 weeks and that is only approved for beta-thalassemia (transfusion-dependent).

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Wegovy (semaglutide) tablets, for oral use

FDA-Approved Indication

[1] To reduce the risk of major adverse CV events in adults with established CV disease and either obesity or overweight; [2] To reduce excess body weight and maintain weight reduction long term in adults with obesity, or in adults with overweight in the presence of at least one weight-related comorbid condition.

Dosage & Administration

Initiate with a dosage of 1.5 mg once daily for 30 days. Then follow the dosage escalation schedule, titrating every 30 days to achieve the maintenance dosage. The recommended maintenance dosage is 25 mg orally once daily for cardiovascular risk reduction and weight reduction in adults.

Dosage Forms & Strengths

Tablets: 1.5 mg, 4 mg, 9 mg and 25 mg

Contraindications

- Personal or family history of MTC or in patients with MEN 2.
- Known hypersensitivity to semaglutide or any of the excipients

Common Adverse Reactions

Nausea, diarrhea, vomiting, constipation, abdominal pain, headache, fatigue, dyspepsia, dizziness, abdominal distension, eructation, hypoglycemia in patients with type 2 diabetes, flatulence, gastroenteritis, gastroesophageal reflux disease, and nasopharyngitis.

Drug Interactions

- May impact absorption of concomitantly administered oral medications.

Use in Specific Populations

- Pregnancy: May cause fetal harm.
- Lactation: Breastfeeding not recommended during treatment.
- Females and Males of Reproductive Potential: Discontinue at least 2 months before a planned pregnancy.

Warnings & Precautions

- ***BBW***: *Risk of Thyroid C-Cell Tumors*
- Acute Pancreatitis
- Acute Gallbladder Disease
- Hypoglycemia
- Acute Kidney Injury Due to Volume Depletion
- Severe Gastrointestinal Adverse Reactions
- Hypersensitivity Reactions
- Diabetic Retinopathy Complications in Patients with Type 2 Diabetes
- Heart Rate Increase
- Suicidal Behavior and Ideation
- Pulmonary Aspiration During General Anesthesia or Deep Sedation

Clinical Studies

The approval came from randomized, double-blind, placebo-controlled phase 3 OASIS 4 trial which included 307 patients. Results showed that oral Wegovy led to a -13.6% change from baseline in body weight compared with a -2.4% change in baseline with placebo (difference, -11.2 [95% CI, -13.6, -8.8]; P <.0001). There was not a separate trial of the Wegovy pill for the MACE indication; approval for this indication was based on the studies of the Wegovy injection.

Place in Therapy

Oral Wegovy offers an alternative to injectable treatments for long-term weight management in adults, used in conjunction with diet and exercise. The availability of an oral formulation may improve adherence to treatment for patients who prefer taking pills over injections.

New FDA-Approved Drug Products

New Biosimilar Product

Drug Name	Reference Product	Designations	Additional Information
Boncresa (denosumab-mobz)	Prolia	Biosimilar	Boncresa joins other Prolia biosimilars such as Jubbonti, Ospomyv, Stoboclo, Bildyos, among others.
Oziltus (denosumab-mobz)	Xgeva	Biosimilar	Oziltus joins other Xgeva biosimilars such as Wyost, Osenvelt, Bilprevda, among others.
Nufymco (ranibizumab-leyk)	Lucentis	Biosimilar interchangeable	Nufymco joins other Lucentis biosimilars such as Cimerli and Byooviz.

Other Notable New Approvals

Daybue Stix (trofinetide) for oral solution

- For the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older. Daybue Stix is a new formulation of the existing Daybue oral solution that provides greater flexibility to patients as it can be mixed with a variety of water-based liquids, allowing for modifications in taste and dose volume.

Orladeyo (berotralstat) oral pellets

- A plasma kallikrein inhibitor indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 2 years and older. The once-daily oral pellet formulation extends treatment to pediatric patients aged 2 to less than 12 years old. Previously, the drug was only approved for adults and adolescents aged 12 and older. This new formulation makes administration easier for children who cannot swallow the original capsule form.

Rybrevant Faspro (amivantamab and hyaluronidase-lpuj) injection, for subcutaneous use

- This is a subcutaneous formulation of amivantamab approved for all indications of the intravenous formulation. This new formulation can be administered in approximately five minutes and has lower rate of infusion-related reactions: 13% compared to the high 67% seen with the IV version in clinical trials.

Avance (acellular nerve allograft-arwx) for Surgical Implantation

- An acellular nerve scaffold indicated for the treatment of adult and pediatric patients aged one month and older with sensory nerve discontinuity. Avance is the first and only acellular nerve allograft to receive a Biologics License Application (BLA) approval from the FDA. It is a "processed" human nerve from a deceased donor.

Waskyra (etuvetidigene autotemcel) suspension, for intravenous use Gene/Cell Therapy

- An autologous hematopoietic stem cell-based gene therapy indicated for the treatment of pediatric patients aged 6 months and older and adults with Wiskott-Aldrich Syndrome (WAS) who have a mutation in the WAS gene for whom hematopoietic stem cell transplantation (HSCT) is appropriate and no suitable human leukocyte antigen (HLA)-matched related stem cell donor is available. Waskyra is the first cell-based gene therapy for the treatment of Wiskott-Aldrich syndrome, a rare, life-threatening genetic disease characterized by bleeding, eczema, recurrent infections, and increased susceptibility to autoimmunity and lymphoreticular malignancies.

New First-Time Generic Approvals

First-Time Generics are the first generic forms of brand name drugs. The generic version is formulated to work in the same way as the brand-name product and provides the same clinical benefit.

Product	Manufacturer	Generic For	Indication(s)	Estimated Availability Date*
Metformin Hydrochloride and Sitagliptin Phosphate Tablets 500 mg / 50 mg (base) and 1000 mg / 50 mg (base)	Sandoz, Inc.	Janumet	Type 2 Diabetes	05/2026
Estradiol Vaginal Insert 0.004 mg and 0.01 mg	Teva Pharmaceuticals USA, Inc.	Imvexxy	Dyspareunia	2031-2032
Loteprednol Etabonate and Tobramycin Ophthalmic Suspension/Drops 0.5% / 0.3%	Alembic Pharmaceuticals Limited	Zylet	Inflammatory Ocular Conditions	Not available (may be in 2026)
Beclomethasone Dipropionate Metered Aerosol Inhalation 0.04 mg/inh and 0.08 mg/inh	Amneal Limited	Qvar Redihaler	Asthma	2032-2033

**Note: Various legal factors may come into play, affecting the estimated availability date.*

New FDA-Approved Indications for Existing Drugs

The following table contains drugs that have gained FDA approval for the treatment of additional diseases or conditions.

Drug Name and Manufacturer	Previous Indication(s)	New Indication
Blujepa (gepotidacin) From: GSK	Uncomplicated urinary tract infections in female adult and pediatric patients 12 years of age and older weighing at least 40 kilograms.	Uncomplicated urogenital gonorrhea in adult and pediatric patients 12 years of age and older weighing at least 45 kilograms who have limited or no alternative treatment options.
Uplizna (inebilizumab-cdon) From: Amgen	[1] Neuromyelitis optica spectrum disorder in adult patients who are anti-aquaporin-4 antibody positive; [2] Immunoglobulin G4-related disease in adult patients.	Generalized myasthenia gravis in adult patients who are antiacetylcholine receptor or anti-muscle specific tyrosine kinase antibody positive.
Akeega (abiraterone acetate and niraparib) From: Johnson & Johnson	With prednisone for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated metastatic castration-resistant prostate cancer.	With prednisone for the treatment of adult patients with deleterious or suspected deleterious BRCA2-mutated metastatic castration-sensitive prostate cancer.
Addyi (flibanserin) From: Sprout Pharmaceuticals	For the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder as characterized by low sexual desire.	For the treatment of women less than 65 years of age with acquired, generalized hypoactive sexual desire disorder as characterized by low sexual desire that causes marked distress or interpersonal difficulty.
Enhertu (fam-trastuzumab deruxtecan-nxki) From: AstraZeneca	[1] As monotherapy for the treatment of adult patients with unresectable or metastatic HER2-positive (IHC 3+ or ISH+) breast cancer who have received a prior anti-HER2-based regimen either in the metastatic setting, or, in the neoadjuvant or adjuvant setting and have developed disease recurrence during or within six months of completing therapy; [2] HER2-Positive (IHC 3+) Unresectable or Metastatic Solid Tumors; [3] HER2-Positive Locally Advanced or Metastatic Gastric Cancer; [4] HER2-Mutant Unresectable or Metastatic Non-Small Cell Lung Cancer; [5] HER2-Low and HER2-Ultralow Metastatic Breast Cancer.	In combination with pertuzumab for the first-line treatment of adult patients with unresectable or metastatic HER2-positive (IHC 3+ or ISH+) breast cancer as determined by an FDA-approved test.
Jascayd (nerandomilast) From: Boehringer Ingelheim	The treatment of idiopathic pulmonary fibrosis in adult patients.	The treatment of progressive pulmonary fibrosis in adult patients.
Accrufer (ferric maltol)	For the treatment of iron deficiency in adults.	For the treatment of iron deficiency in adult and pediatric patients 10 years of age and older.

From: Shield Therapeutics		
Furoscix (furosemide) From: MannKind	For the treatment of edema in adult patients with chronic heart failure or chronic kidney disease, including the nephrotic syndrome.	For the treatment of edema in pediatric patients weighing 43 kg and above and in adult patients with chronic heart failure or chronic kidney disease, including the nephrotic syndrome.

Pipeline

The goals of the NDA (or BLA) are to provide enough information to permit FDA approval of a new pharmaceutical for sale and marketing in the U.S.

Drug Name and Manufacturer	Indication(s)	Additional Information	Impact
CagriSema (cagrilintide and semaglutide) From: Novo Nordisk	Weight Loss, Type 2 Diabetes	NDA submitted	High
Oxylanthanum carbonate From: Unicycive Therapeutics, Inc.	Hyperphosphatemia of Renal Failure	NDA resubmitted	Moderate

Pipeline Generics

This section describes generics that may possibly be available on the market in the next month. Various legal factors may come into play, affecting the date.

No relevant generics are expected to enter the market in the next month.