New Drug Update 2025: CV, Respiratory, GI, ID, Endocrine & Renal

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OHIO PHARMACISTS ASSOCIATION

Disclosure Statement

- Karen L. Kier has no relevant financial relationships with ineligible companies to disclose.
  and
- None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.

Learning Objectives

At the completion of this activity, the participant will be able to:

1. review the pharmacology and therapeutics of selected prescription medications released to the market within the past year;
2. state the indications and clinical applications of the medications presented, and how they compare to current therapies;
3. list the most common adverse effects, toxicities, and significant drug-drug and drug-food interactions reported; and
4. explain important patient/caregiver counseling information for these medications.

Cardiovascular

Losartan potassium (Arbli) Oral Suspension

High Blood Pressure, Diabetic Kidney Disease

March 13, 2025 Scienture Holdings

- Oral liquid formulation of angiotensin II receptor blocker losartan for treatment of hypertension and diabetic nephropathy
- Ready-to-use suspension 10mg/ml (165ml)
- Peppermint flavor
- 6 years of age and older
- Shake well for 20 seconds before use
- Administer with an accurate measuring device

Chlorthalidone (HemiClor) Tablets

High Blood Pressure

March 17, 2025 PRM Pharma

- Thiazide-like diuretic for treatment of hypertension in adults
- 12.5 mg chlorthalidone
- 12.5 mg as the recommended starting dose in current hypertension treatment guidelines
- Other companies dosages include 15mg (higher bioavailability—not equal to other doses), 25mg, 50mg
- Mixed evidence comparing chlorthalidone and HCTZ

Amlodipine, indapamide and telmisartan (Widaplik) Tablets - formerly GMRx2

High Blood Pressure

June 5, 2025 George Medicines

- Single pill, triple combination therapy for hypertension, including initiation of treatment
- RCT: significantly improved blood pressure and control rates vs comparators
- Comparators placebo and dual therapy
- Telmisartan 10 to 20mg, amlodipine 1.25 to 2.5mg, and indapamide 0.625 to 1.25mg once daily
- Dose may be titrated after 2 weeks of therapy to max daily dose of telmisartan 40 mg/amlodipine 5 mg/indapamide 2.5 mg
- Do to chew, crush, or split
- 10mg/1.25mg/0.625mg or 20mg/2.5mg/1.25mg or40mg/5mg/2.5mg tablets

Ramipril (Vostally) Oral Solution

High Blood Pressure, Cardiovascular Risk Reduction

July 23, 2025 Rosemont Pharmaceuticals

- Oral solution formulation of angiotensin converting enzyme (ACE) inhibitor ramipril for treatment of hypertension and to reduce the risk of cardiovascular events
- Once daily dosing
- 1 mg/mL oral solution
- Peppermint flavor
- Contains sucralose
- Availability early 2026??

Clonidine hydrochloride (Javadin) Oral Solution

High Blood Pressure

October 23, 2025 Azurity Pharmaceuticals

- Oral solution formulation of central alpha-2 adrenergic agonist clonidine for treatment of hypertension
- Approved in adults
- 0.02 mg/mL (250 mL), 5mL = 0.1 mg
- Berry-flavored, clear, colorless oral solution
- Immediate release liquid with BP lowering in 30-60 minutes

Bumetanide (Enbumyst) Nasal Spray

Edema

September 15, 2025 Corstasis Therapeutics

- Nasal spray loop diuretic for treatment of edema associated with congestive heart failure, hepatic and renal disease, and nephrotic syndrome in adults
- Clinical studies showed rapid absorption and predictable diuretic response, with a similar effect on diuresis, natriuresis and urinary potassium excretion when compared to IV bumetanide
- 0.5 to 2 mg once daily with max total daily dose of 2 mg/day
- Convert to oral diuretics as soon as possible
- Bumetanide intranasal 1 mg = furosemide 40 mg oral or furosemide 20 mg IV
- Each unit (0.5 mg) is for single use only
- 0.5mg/0.1mL
- Do not prime or attempt to reuse for more than 1 administration
- Administer directly into the nose, not against the wall
- When using multiple sprays, alternate between right and left nostril

Furosemide (Lasix ONYU) Injection

Edema

October 7, 2025 SQ Innovation

- Loop diuretic drug-device combination indicated for edema in adults with chronic heart failure
- SQ infusion of furosemide outside the healthcare setting
- 80mg per 2.67 mL
- Reusable unit with charger that can be used for 48 treatments and a plastic sterile single-use unit that is discarded after treatment
- Clinical studies found Lasix ONYU demonstrated complete bioavailability (112%) resulting in similar diuresis (115%) and natriuresis (117%) when compared to the same dose given by IV bolus
- Biphasic release so more sustained
- Another on body furosemide available on market (Furoscix (on-body infusor))

Furosemide (Lasix ONYU) Injection

- Administer in a setting where the pt can limit activity (limit bending; do not wear while riding in a car or flying) for the duration of administration and has access to a bathroom (for at least 8 hours); not for use in an MRI setting
- Select a clean, dry, hairless or nearly hairless area of the abdomen above the beltline and to the left or right of the belly button; do not apply lotions, oils, or ointments to the area where infusor will be applied
- Wipe the area where infusor will be applied with an alcohol wipe and allow to dry
- Rotate sites between the left and right with each administration
- Remove the adhesive liner and apply infusor so the start/stop button and status light are facing up and can be seen
- Press and hold the start/stop button to begin administration; a solid blue status light and a long beep will be heard when administration is complete
- Keep infusor dry; do not shower, swim, or do activities causing sweating while wearing the infusor
- Do not use infusor within 12 inches of mobile phones, tablets, computers, or wireless accessories (eg, TV remote control, Bluetooth computer keyboard, or Bluetooth mouse)
- Use within 7 hours of assembling; infusion will last about 5 hours. For single use only; dispose of the infusor in a sharps container after use.

Aficamten (Myqorzo) Tablets

Hypertrophic Cardiomyopathy

December 19, 2025 Cytokinetics

- cardiac myosin inhibitor for treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy to improve functional capacity and symptoms
- REMS program
- 5 mg, 10 mg, 15 mg, 20 mg tablets
- 5 mg once daily then increase dose by 5 mg every 2 to 8 weeks until a maintenance dose or max dose of 20 mg daily
- Boxed warning for the risk of heart failure
- ADRs: hypertension, reduced EF
- CYP3A4 interactions are possible
- Genomic testing for CYP2C9 could be helpful
  - CYP2C9 (Major with inhibitors), CYP2C9 (Minor with inducers)

Aficamten (Myqorzo) Tablets

- Echocardiogram assessments required prior to and during treatment to monitor for systolic dysfunction
- Initiation in patients LVEF <55% is not recommended
- Decrease the dose if LVEF <50% and ≥40%
- Interrupt the dose if LVEF <40% or if the patient experiences heart failure symptoms or worsening clinical status due to systolic dysfunction
- Patient journey program called Myqorzo & You™
- Phase 3 clinical trial, SEQUOIA-HCM, demonstrated robust efficacy, safety, and clinically meaningful benefits across symptoms, exercise capacity, hemodynamics, and biomarker endpoints
- At 24 weeks significant improved exercise capacity compared to placebo, increasing peak oxygen uptake (pVO_2)
- Treatment effect was consistent across all prespecified subgroups, including age, sex, patient baseline characteristics, and in patients receiving or not receiving background beta-blocker therapy

Etripamil (Cardamyst) Nasal Spray

Paroxysmal Supraventricular Tachycardia

December 12, 2025 Milestone Pharmaceuticals

- calcium channel blocker nasal spray indicated for the conversion of acute symptomatic episodes of paroxysmal supraventricular tachycardia to sinus rhythm in adults
- First rapid acting drug for PSVT administered in the outpatient setting
- One spray = 35 mg, each device contains 2 doses
- One spray into each nostril using one device = total dose of 70 mg
- May repeat after 10 minutes with a second (new) device; if symptoms do not improve within 20 minutes of second dose, seek medical assistance
- Maximum dose: 140 mg/day (2 devices)
- PKIN: 7 minutes to peak blood levels

Etripamil (Cardamyst) Nasal Spray

- Administer in safe place, sitting down (due to fainting)
- Store at room temperature (68°F to 77°F)
- ADRs: Nose or throat irritation, stuffy nose, runny nose, nosebleeds, fainting, low heart rate, low BP, tearing eyes
- Avoid in patients with HF, WPW, sick sinus syndrome without pacemaker, 2nd or 3rd degree AV block
- Clinical trial program based on safety data from more than 1,800 participants and more than 2,000 episodes of PSVT
- Phase 3 RAPID, randomized, double-blind comparison of etripamil vs. placebo
- Patients were 2 times more likely to convert symptomatic PSVT to sinus rhythm and more than 3 times faster compared with placebo
- Primary endpoint: 64% converting from SVT to sinus rhythm within 30 minutes compared to 31% on placebo

Plozasiran (Redemplo) Injection

Familial Chylomicronemia Syndrome

November 18, 2025 Arrowhead Pharmaceuticals

- apolipoprotein C-III directed small interfering ribonucleic acid (siRNA) indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS)
- FCS is a severe, rare disease, with an estimated 6,500 people in the U.S. living with genetic or clinical FCS, characterized by triglyceride levels 10 to 100 times higher than normal
- Low fat diet of less than 20 grams per day
- Self-administered, 25 mg SQ injection once every 3 months
- ADRs: headache, GI distress, hyperglycemia (monitor)
- Prefilled syringe warm to room temperature for 30 minutes prior to administration
- Solution should be clear and colorless to yellow
- Intended for use under supervision of a health care provider; self-injection or administration by a caregiver may occur after proper training
- Administer into the abdomen, front of the thigh, or upper arm (if administered by a caregiver or health care provider)
- Insert needle into pinched skin at a 45- to 90-degree angle

Plozasiran (Redemplo) Injection

- Phase 3 PALISADE study, a randomized, double-blind, placebo-controlled trial in adults with confirmed FCS
- Demonstrating significant reductions in triglycerides and APOC3
- 25 mg plozasiran achieved durable reductions in triglycerides, with a median change from baseline of -80% versus -17% in placebo group, and a lower numerical incidence of acute pancreatitis compared with placebo
- Available only via a specialty pharmacy

Lerodalcibep-liga (Lerochol) Injection

High Cholesterol

December 12, 2025 LIB Therapeutics

- proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor for treatment of adults with hypercholesterolemia
- Novel, third-generation PCSK9 inhibitor
- SQ adjunct to diet and exercise to reduce LDL-C
- Once monthly injection, small volume, 300mg/1.2mL
- Store for 3 months at room temperature, amber colored solution in prefilled, single-dose syringe
- ADRs: Injection site reactions, neutralizing antibodies (11-15%), peripheral edema, nasopharyngitis
- More ADRs were seen in patients with HF (not excluded)

Lerodalcibep-liga (Lerochol) Injection

- Spring 2026 availability
- Phase 3 LIBerate Clinical Trial Program, over 2,900 patients with CVD, without CVD at very high and high risk for CVD, including heterozygous and homozygous familial hypercholesterolemia
- 300mg once monthly for up to 52 weeks in placebo-controlled trials, and over 2,400 patients continued in the 72-week open-label extension
- Demonstrated sustained LDL-C reductions of ≥60% in patients with, or at very high or high risk of CV and ≥50% in those with HeFH who have more severe LDL-C elevations

Respiratory

Treprostinil (Yutrepia) Inhalation Powder

Pulmonary Arterial Hypertension; Pulmonary Hypertension Associated with Interstitial Lung Disease

May 23, 2025 Liquidia Technologies

- Inhaled dry powder formulation of the prostacyclin mimetic treprostinil for pulmonary arterial hypertension and pulmonary hypertension associated with interstitial lung disease
- first and only prostacyclin dry-powder formulation enabled by Liquidia's PRINT™ technology, which yields uniform, free-flowing particles designed to enhance deep-lung delivery via an easy-to-use, low-effort device requiring less inspiratory effort
- Phase 3 INSPIRE trial which evaluated patients who were naïve to treprostinil and those transitioning to Yutrepia from nebulized treprostinil

Treprostinil (Yutrepia) Inhalation Powder

- 26.5 mcg, or 53 mcg, 79.5 mcg per capsule
- Delivered by Specialty Pharmacy

Nerandomilast (Jascayd) Tablets

Idiopathic Pulmonary Fibrosis

October 7, 2025 Boehringer Ingelheim Pharmaceuticals

- Phosphodiesterase 4 (PDE4) inhibitor for treatment of pulmonary fibrosis
- New adding IPF and a novel mechanism of action that exerts both antifibrotic and immunomodulatory effects, thereby slowing the decline in lung function in IPF patients
- 18 mg every 12 hours (can reduce to 9 mg)
- Max daily dose is 36 mg/day
- Comes as 9 mg and 18 mg tablets
- FIBRONEER™-IPF was the absolute change from baseline in Forced Vital Capacity (FVC) at week 52, smaller decline than placebo
- ADRs: decrease appetite, URI, diarrhea
- DDI: Significant CYP3A4 strong inducers

Clesrovimab-cfor (Enflonsia) Injection

RSV Vaccination and Immunization

June 9, 2025 Merck

- Respiratory syncytial virus (RSV) F protein-directed fusion inhibitor for passive immunization for the prevention of RSV lower respiratory tract disease in neonates and infants who are born during or entering their first RSV season
- Direct, rapid and durable protection through 5 months, a typical RSV season
- IM 105 mg dose regardless of weight
- 105 mg/0.7 mL
- Phase 2b/3 CLEVER trial evaluating a single dose administered to preterm and full-term infants (1 year of age)
- Meet both primary endpoints reduced infections by 61% and hospitalizations by 84%

Zopapogene imadenovec-drab (Papzimeos) Injection

Recurrent Respiratory Papillomatosis

August 14, 2025 Precigen

- Non-replicating adenoviral vector-based immunotherapy for the treatment of adults with recurrent respiratory papillomatosis
- Rare, chronic disease characterized by the growth of benign, wart-like tumors (papillomas) in the respiratory tract, most commonly on the vocal cords
- Caused by HPV types 6 and 11, usually vertically transmitted from mother to infant at birth or STD
- SQ 5×10^{11} particle units (1 mL) per dose for a total of 4 doses over a 12-week treatment period
- Surgical debulking is recommend prior to zopapogene administration
- Increase risk of blood clots during therapy

Depemokimab-ulaa (Exdensur) Injection

Asthma

December 16, 2025 GlaxoSmithKline

- long-acting interleukin-5 antagonist for severe asthma with an eosinophilic phenotype
- add-on maintenance treatment in 12 years and up
- SQ 100 mg once every 6 months, missed dose as soon as possible then 6 months from that injection
- Half-life is about 48 days
- Room temperature for 30 minutes prior to injection and use within 8 hours once removed from carton
- Do not shake or warm with other methods rather than room temperature
- colorless to yellow to brown, clear to opalescent in color, do not use if cloudy
- Inject into the upper arm, thigh, or abdomen

Depemokimab-ulaa (Exdensur) Injection

- Comes as both prefilled pen and prefilled syringe
- **Pen:** After removing cap, hold yellow needle guard flat against skin at a 90-degree angle; press firmly to start the injection; a click may be heard at start of injection. Continue pressing firmly until second click is heard; injection may take up to 20 seconds to fully administer. If second click not heard, patient can verify administration of dose if the black stopper has stopped moving and the yellow indicator fills the inspection window.
- **Syringe:** Gently pinch skin and insert needle at a 45-degree angle; slowly push plunger until it stops and syringe is empty. Release pressure on plunger head to activate needle guard; remove syringe and release skin.
- Store pen/syringe at 36°F to 46°F in original carton—do not freeze or heat
- Neutralizing antibodies can occur in about 6-10% of patients

Depemokimab-ulaa (Exdensur) Injection

- Monitor asthma symptoms, FEV1, exacerbations
- ADRs: Injection site reactions, increase risk of infections, URI
- Depemokimab can cross the placenta, risk versus benefit, company has a registry for pregnant patients on drug
- SWIFT-1 and SWIFT-2 phase III trials
- Demonstrated sustained exacerbation reduction with two doses per year versus placebo, both plus standard of care (inhaler regimens)
- Results in a significant 58% and 48% reduction in the rate of annualized asthma exacerbations over 52 weeks from SWIFT-1 and SWIFT-2
- SWIFT-1 RR=0.42 (0.30, 0.59) $p<0.001$
- SWIFT-2 RR=0.52 (0.36, 0.73) $p<0.001$

Gastrointestinal

Diazoxide choline (Vykat XR) Extended-Release Tablets - formerly DCCR

Prader-Willi Syndrome

March 26, 2025 Soleno Therapeutics

- Extended-release formulation of the crystalline salt of diazoxide for treatment of hyperphagia in patients with Prader-Willi syndrome
- rare genetic disorder caused by a chromosome 15 abnormality, resulting in chronic hunger, obesity, poor muscle tone, and intellectual disability
- Approved for 4 years to adults
- Warning of hyperglycemia and DKA, risk of edema
- Weight-based dosing
- 25 mg, 75 mg, 150 mg ER tablet strengths

Infectious Disease

COVID-19 Vaccine, Adjuvanted (Nuvaxovid) Injectable Suspension - formerly Novavax COVID-19 Vaccine

COVID-19

May 16, 2025 Novavax

- Protein-based, non-MRNA vaccine for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
- Adults 65 years and older and individuals 12 through 64 years who have at least one underlying condition that puts them at high risk for severe outcomes from COVID-19
- 0.5mL IM

COVID-19 Vaccine, mRNA (mNEXSPIKE) Injection

COVID-19

May 30, 2025 Moderna

- Vaccine indicated for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
- Adults 65 years and older and individuals 12 through 64 years who have at least one underlying condition that puts them at high risk for severe outcomes from COVID-19
- 0.2 mL as a single IM dose
- For patients previously vaccinated with any COVID-19 vaccine, administer dose ≥3 months after the last dose of COVID-19 vaccine

Lenacapavir (Yeztugo) Tablets and Injection

Pre-Exposure Prophylaxis of HIV

June 18, 2025 Gilead Sciences

- Human immunodeficiency virus type 1 (HIV-1) capsid inhibitor for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1
- Warning: 2 lenacapavir products are available. Sunlenca, indicated for HIV-1 infection *treatment*, and Yeztugo, indicated for HIV-1 infection *preexposure prophylaxis*
- Both products are available as a 463.5 mg per 1.5 mL SQ injection and a 300 mg oral tablet
- Day 1: 600mg (2 tablets) oral and 927mg SQ (3 mL) , Day 2: 600mg oral
- Maintenance: SQ 927 mg every 6 months from the date of last injection ±2 weeks
- Specific recommendations if maintenance does is missed more than 2 weeks, see package inserts
- DDI- significant interactions with strong CYP3A inducers
- ADRs: injection site reactions with LAI

Clotrimazole (Clotic) Otic Solution

Otitis Externa

September 26, 2025 Laboratorios Salvat

- Azole antifungal ear drop for treatment of fungal otitis externa (otomycosis) due to Aspergillus species and Candida species in adults
- preservative-free formulation is administered as ear drops using single-dose vials
- 1% solution, every 12 hour administration for 14 days
- After opening a foil patch, remove a vial, hold one to two minutes in hands (to warm) and use it right away
- Place in ear while laying down for 1 minute after drops placed in ear
- Keep unused vials in the foil pouch
- Throw away any unused vials 30 days after opening foil pouch
- ADRs: headache, ringing in ears, pain in ears, rupture eardrum

Fosfomycin (Contepo) for Injection

Urinary Tract Infection

October 22, 2025 Meitheal Pharmaceuticals

- Epoxide antibacterial for *complicated* urinary tract infections
- 18 years of age and older with complicated UTI, including acute pyelonephritis, caused by susceptible isolates of *Escherichia coli* and *Klebsiella pneumoniae*
- Disrupting bacterial cell wall synthesis through covalently binding and inhibiting phosphoenolpyruvate transferase (MurA), thereby blocking the synthesis of peptidoglycan
- 6 grams administered every 8 hours by intravenous infusion over 1 hour in patients 18 years of age or older with an estimated creatinine clearance greater than 50 mL/min
- Duration of therapy is up to 14 days

Gepotidacin (Blujepa) Tablets

Urinary Tract Infection, Gonococcal Infection, Uncomplicated

March 25, 2025 GSK

- Triazaacenaphthylene bacterial type II topoisomerase for treatment of *uncomplicated* urinary tract infections and *uncomplicated* urogenital gonorrhea
- First-in-class oral antibiotic with a novel mechanism of action
- Treatment of female adults (≥40 kg) and pediatrics (≥12 years, ≥40 kg) with uncomplicated UTI caused by the following: *Escherichia coli*, *Klebsiella pneumoniae*, *Citrobacter freundii* complex, *Staphylococcus saprophyticus* and *Enterococcus faecalis*
- UTI: 1.5 gm twice daily for 5 days after a meal
- Gonorrhea: 3 gm as a single dose, followed by a second 3 gm dose 12 hours later with food
- Only comes in 750mg tablet

Gepotidacin (Blujepa) Tablets

- ADRs: GI disturbances, QT prolongation
- DDI: Significant interactions with CYP3A4 strong inducers
- Phase III EAGLE-2 demonstrated non-inferiority in therapeutic success which occurred in 50.6% compared to 47.0% for nitrofurantoin
- EAGLE-3 demonstrated statistically significant superiority versus nitrofurantoin

Zoliflodacin (Nuzolvence) Granules for Oral Suspension

Gonococcal Infection, Uncomplicated

December 12, 2025 Innoviva Specialty Therapeutics

- First-in-class, spiropyrimidinetrione bacterial type II topoisomerase inhibitor for *uncomplicated* urogenital gonorrhea
- 3 gram oral suspension given as a single dose
- Adults and children over 12 years of age weighing at least 35 kg
- Administration with regards to food is dependent on body weight
  - For body weight 35 kg to <50 kg, administer on an empty stomach, 1 hour before or 2 hours after food
  - For body weight ≥50 kg, administer with food (significant increase is Cmax and AUC for drug with food)
- Granules must be mixed with 60 mL of water prior to administration (only water!!) Put provided lid back on and shake vigorously for at least 60 seconds. All granules should be dissolved.
- Do not administer in the dry form, mix with liquids other than water, or sprinkle on food
- Once mixed, give in mixing container immediately, than add an additional 60 mL of water and shake and have patient drink this 60 mL to ensure the full dose is given
- Dose MUST be given within 15 minutes of mixing granules, otherwise a new dose needs to be prepared and given

Zoliflodacin (Nuzolvence) Granules for Oral Suspension

- Not on NIOSH List (2024), but has developmental toxicity and should be handled following NIOSH and USP 800 recommendations
- Store at room temperature
- DI: Significant interactions with concomitant use of moderate or strong CYP3A4 inducers
- ADRs: Neutropenia (10%), alopecia, palpitations, night sweats, rash, headache,
- Avoid in pregnancy (negative test), males should use condoms for up to 3 months after administration to reduce risk of adverse pregnancy outcomes, potential for testicular toxicity
- Available second half of 2026

Zoliflodacin (Nuzolvence) Granules for Oral Suspension

- Reserve for patients at risk for bacterial resistant gonorrhea
- Phase 3, multinational, randomized, controlled, open-label, zoliflodacin demonstrated non-inferiority compared to ceftriaxone plus azithromycin in uncomplicated urogenital gonorrhea
- 930 adolescent and adult patients to evaluate the efficacy and safety of a single 3 gm dose versus 500mg IM of ceftriaxone plus 1 gm oral azithromycin for uncomplicated gonorrhea
- 16 trial sites in regions with a high prevalence of gonorrhea across five countries, including Belgium, the Netherlands, South Africa, Thailand, and the U.S.

Endocrine

Hydrocortisone (Khindivi) Oral Solution

Adrenocortical Insufficiency

May 28, 2025 Eton Pharmaceuticals

- Oral solution of hydrocortisone as replacement therapy in pediatrics 5 years of age and older with adrenocortical insufficiency
- Individualized dosing based adrenal response
- 2 per day or 3 per day dosing strategies
- Higher doses are typically administered in the morning and midday with lower doses in the evening to replicate diurnal variation; early evening doses (18:00) may be necessary in some children
- Dispense with calibrated syringe or cup
- Store at 36°F to 77°F
- Protect from heat and light
- Use within 120 days of initial opening, discard any unused portion
- 1 mg/mL (473 mL), berry flavored

Insulin aspart-xjhz (Kirsty) Injection

Diabetes Mellitus

July 15, 2025

Biocon Biologics

- Rapid acting human insulin analog interchangeable biosimilar to NovoLog (insulin aspart) to improve glycemic control in adults and pediatrics with diabetes mellitus
- 100 units/mL (10 mL vial and 3 mL pen)
- First interchangeable with NovoLog

Paltusotine (Palsonify) Tablets

Acromegaly

September 25, 2025 Crinetics Pharmaceuticals

- Somatostatin receptor agonist for treatment of adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option
- 40 mg once daily
- May temporarily reduce to 20 mg once daily if needed based on tolerability, then resume 40 mg once daily once adverse effects have resolved
- After 2 to 4 weeks on 40 mg once daily, may increase to 60 mg once daily based on insulin-like growth factor 1 levels
- 20 mg, 30 mg tablets
- ADRs: GI, hyperglycemia, bradycardia
- Significant DDI

Denosumab-bnht (Conexxence) Injection

Osteoporosis

March 25, 2025

Fresenius Kabi USA

- RANK ligand (RANKL) inhibitor biosimilar to Prolia used to treat osteoporosis

Denosumab-nxxp (Bildyos) Injection

Osteoporosis

August 29, 2025

Shanghai Henlius Biotech and Organon

- RANK ligand (RANKL) inhibitor biosimilar to Prolia used to treat osteoporosis

Denosumab-kyqq (Bosaya) Injection

Osteoporosis

September 16, 2025 Biocon Biologics

- RANK ligand (RANKL) inhibitor biosimilar to Prolia used to treat osteoporosis

.

Denosumab-qbde (Enoby) Injection

Osteoporosis

September 26, 2025

Gedeon Richter and Hikma Pharmaceuticals

- RANK ligand (RANKL) inhibitor biosimilar to Prolia used to treat osteoporosis
- 4th biosimilar on market for Prolia

Denosumab-desu (Osvyrti) Injection

Osteoporosis

October 29, 2025

Accord BioPharma

- RANK ligand (RANKL) inhibitor biosimilar to Prolia for treatment of osteoporosis
- 5th biosimilar on market for Prolia

Denosumab-mobz (Boncresa) Injection

Osteoporosis

December 19, 2025 Amneal Pharmaceuticals

- RANK ligand (RANKL) inhibitor biosimilar to Prolia for treatment of osteoporosis
- Must be administered by a healthcare professional
- Monitor calcium levels
- As of December 2025, 6 biosimilars FDA approved

Sildenafil (Vybrique) Oral Film

Erectile Dysfunction

December 16, 2025 IBSA Pharma Inc

- oral film formulation of the approved phosphodiesterase-5 (PDE5) inhibitor sildenafil indicated for erectile dysfunction
- Film dissolves on tongue without water (do not cut or chew)
- Can be taken with or without food, empty stomach may be preferred
- Remove from pouch with dry hands
- 30 minutes to four hours before sexual activity (1 hour is preferred), no more than once daily
- 12-week clinical study showing that it was effective in adult men with ED.
- 475 adult men with ED given doses of 25, 50, 75, or 100 milligrams or a placebo
- *By week 4,* patients showed better improvements in sexual function than those on placebo
- Blood tests showed absorbed into the bloodstream fairly quickly, reaching its highest levels between 30 and 300 minutes, with an average of about 80 minutes on an empty stomach

Elinzanetant (Lynkuet) Capsules

Hot Flashes, Menopause

October 24, 2025 Bayer

- Neurokinin 1 (NK1) and neurokinin 3 (NK3) receptor antagonist for treatment of moderate to severe vasomotor symptoms due to menopause
- first and only dual neurokinin (NK) targeted therapy,[1] neurokinin 1 (NK1) and neurokinin 3 (NK3) receptor antagonist
- 120 mg once daily at bedtime (60mg capsules—2 capsule dosing)
- Administer at about the same time each day with water
- With or without food
- Swallow capsules whole and do not cut, crush, or chew
- Avoid in moderate or severe liver dysfunction, monitor liver
- Clinical studies OASIS 1, OASIS 2 and OASIS 3

Renal

Nitisinone (Harliku) Tablets

Alkaptonuria

June 19, 2025

Cycle Pharmaceuticals

- Hydroxyphenyl-pyruvate dioxygenase inhibitor for the reduction of urine homogentisic acid in adults with alkaptonuria
- rare, inherited metabolic disorder, "black urine disease," caused by a mutation in the *HGD* gene that prevents the body from properly breaking down amino acids tyrosine and phenylalanine
- 1 to 10 mg once daily, adjust dose if needed based on urine homogentisic acid and plasma tyrosine levels
- 2 mg (Harliku is the only one FDA approved for alkaptonuria)
- Other medications available with same generic drug Nityr 2 mg, 5 mg, 10 mg and Orfadin oral suspension 4 mg/mL

Atrasentan (Vanrafia) Tablets

Immunoglobulin A Nephropathy

April 2, 2025 Novartis Pharmaceuticals

- Endothelin A receptor antagonist used for proteinuria reduction in primary immunoglobulin (IgA) nephropathy
- Rapidly progressing disease defined urine protein-to-creatinine ratio ≥1.5 g/g
- once-daily added onto supportive care, including a renin-angiotensin system (RAS) inhibitor with or without a sodium-glucose co-transporter-2 (SGLT2) inhibitor
- 0.75 mg once daily
- ADRs: anemia, decreased hemoglobin, peripheral edema, liver enzyme increasess
- DDI: strong CYP3A4 inducers

Sibeprenlimab-szsi (Voyxact) Injection

Immunoglobulin A Nephropathy

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- A Proliferation Inducing Ligand (APRIL) blocker indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy at risk for disease progression
- FDA accelerated approval
- First and only therapy to block A-PRoliferation-Inducing-Ligand (APRIL)
- Self-administered, 400mg SQ given every four weeks
- Prefilled syringe 400 mg/2 mL
- Abdomen, back of upper arm (HC provider admin), or front of upper thigh; rotate injection sites
- Allow syringe to reach room temperature for 15 to 30 minutes prior to administration
- Do not shake or roll syringe
- Do not freeze
- Keep in the original box to protect from light
- Once drug is at room temperature, do NOT put back into refrigerator
- Discard syringes that have been at room temperature for ≥7 days

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- Do not inject into moles, scars, bruises, or areas where the skin is tender, damaged, red, scaly, or hard
- Patient may self-inject after proper training or the patient's caregiver may administer (upper outer arm)
- eGFR > 30 mL/min (not studied below this level)
- ADRs: passing out or fainting with injection, injection site reactions, increase risk of infections, neutralizing antibodies
- Review vaccine history and start any needed vaccines before treatment
- Injection contains polysorbate 80 (potential for allergies)
- Avoid in pregnancy, crosses placenta
- VISIONARY Phase 3 interim analysis, where it achieved a significant placebo-adjusted treatment effect of 51% ($P<0.0001$) reduction in proteinuria at nine months (n=320) of treatment (50% sibeprenlimab vs 2% placebo)
- In the study, patients with IgAN had to be receiving standard-of-care therapy, defined as maximally tolerated ACE inhibitor and/or ARB with or without SGLT2 inhibitor
- Other drugs for IgAN, but none directly targeting mechanism

References

Notable drug approvals, MPR website, https://www.empr.com/?s=new+drugs&published=12months

FDA access database
FDA safety alerts
Drugs.com
Lexicomp database
Manufacturer websites
PubMed

Need More Information?

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