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PharmNotes

Monthly Communications

April 2026

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ACCREDITED
Pharmacy Benefit Management
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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 April.

New FDA-Approved Drug Products

New Molecular Entity

Foundayo (orforglipron) tablets, for oral use

FDA-Approved Indication

In combination with a reduced-calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition.

Dosage & Administration

Take once daily by mouth, with or without food. The starting dose is 0.8 mg once daily, with dose increases every ≥30 days based on response and tolerability (2.5 mg, 5.5 mg, then 9 mg, 14.5 mg, and up to a maximum of 17.2 mg once daily).

Dosage Forms & Strengths

Tablets: 0.8 mg, 2.5 mg, 5.5 mg, 9 mg, 14.5 mg, and 17.2 mg.

Contraindications

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

Common Adverse Reactions

Nausea, constipation, diarrhea, vomiting, dyspepsia, abdominal pain, headache, abdominal distension, fatigue, eructation, gastroesophageal reflux disease, flatulence, and hair loss.

Warnings & Precautions

- ***BBW**: Risk of Thyroid C-Cell Tumors*
- Acute Pancreatitis
- Severe Gastrointestinal Reactions
- Acute Kidney Injury (Volume Depletion)
- Hypoglycemia
- Hypersensitivity Reactions
- Diabetic Retinopathy in Patients with Type 2 Diabetes
- Acute Gallbladder Disease
- Pulmonary Aspiration During General Anesthesia and Deep Sedation

Drug Interactions

- Strong CYP3A4 Inhibitors
- CYP3A4 Inducers
- Simvastatin
- Foundayo delays gastric emptying and has the potential to impact the absorption of concomitantly administered oral medications.

Use in Specific Populations

- Pregnancy: May cause fetal harm.
- Females of Reproductive Potential: Double contraceptive method recommended.
- Hepatic Impairment: Not recommended

Clinical Studies

The efficacy of Foundayo (orforglipron) was demonstrated in two Phase 3, randomized, double-blind, placebo-controlled trials in adults receiving lifestyle interventions (reduced-calorie diet and ≥150 minutes/week of physical activity). Over 72 weeks, doses of 5.5 mg, 9 mg, and 17.2 mg once daily significantly reduced body weight compared to placebo. Trial 1 included adults with obesity or overweight without diabetes, while Trial 2 included those with type 2 diabetes. Weight reduction was consistent across subgroups, with discontinuation rates similar to or lower than placebo.

Place in Therapy

Foundayo is an oral GLP1 option for chronic weight management in adults with obesity or overweight, effective in both diabetic and non-diabetic patients, and useful for those who prefer or need alternatives to injectable therapies like semaglutide or tirzepatide.

New FDA-Approved Drug Products

New Molecular Entity

Idvynso (doravirine and islatravir) tablets, for oral use

FDA-Approved Indication

As a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of virologic treatment failure and no known substitutions associated with resistance to doravirine.

Dosage & Administration

One tablet taken orally once daily.

Dosage Forms & Strengths

Tablets: 100 mg doravirine and 0.25 mg islatravir.

Contraindications

- When co-administered with drugs that are strong cytochrome P450 (CYP)3A enzyme inducers as significant decreases in doravirine plasma concentrations may occur.
- When co-administered with lamivudine (3TC) or emtricitabine (FTC), which are deoxycytidine kinase (dCK) substrates, as a decrease in islatravir-triphosphate (ISL-TP).

Common Adverse Reactions

Diarrhea, dizziness, fatigue, abdominal distension, headache, and weight increased.

Warnings & Precautions

Severe skin reactions, including Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN), and Drug Rash with Eosinophilia and Systemic Symptoms (DRESS).

Drug Interactions

- Co-administration with other antiretroviral medications for treatment of HIV-1 infection is not recommended.

Clinical Studies

The approval came from two randomized, active-controlled, non-inferiority, Phase 3 clinical trials (Trial 051 and Trial 052) involving virologically suppressed adults with HIV-1 who were switched from a stable baseline antiretroviral regimen. Idvynso demonstrated non-inferiority to comparator treatment in terms of virological suppression. In both studies, Idvynso effectively maintained virologic suppression.

Place in Therapy

Idvynso represents a complete, two-drug oral regimen for the maintenance treatment of HIV-1 infection in virologically suppressed adults, offering a simplified alternative to traditional three-drug antiretroviral therapies. It may be particularly beneficial for patients seeking regimen simplification, reduced pill burden, or avoidance of certain nucleoside analogs.

New FDA-Approved Drug Products

New Biosimilar Product

Drug Name	Reference Product	Designations	Additional Information
Langlara (insulin glargine-aldy)	Lantus	Biosimilar	Langlara is the third FDA-approved biosimilar to Lantus.

Other Notable New Approvals

Otarmeni (lunsotogene parvec-cwha) Suspension for Intracochlear Infusion Gene/Cell Therapy

- An adeno-associated virus vector-based gene therapy indicated for the treatment of pediatric and adult patients with severe-to-profound and profound sensorineural hearing loss (any frequency >90 dB HL) associated with molecularly confirmed biallelic variants in the OTOF gene, preserved outer hair cell function, and no prior cochlear implant in the same ear.

Saphnelo (anifrolumab-fnia) injection, for subcutaneous use

- A type I interferon (IFN) receptor antagonist indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy. Saphnelo was previously only available as an intravenous infusion for the same indication.

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*
Nintedanib Esylate Capsules 100 mg (base) and 150 mg (base)	Apotex Inc.; Cipla USA Inc.; Dexcel Pharma Technologies Ltd.; Dr. Reddy's Laboratories Limited; Sandoz Inc.	Ofev	Idiopathic Pulmonary Fibrosis; Interstitial Lung Disease	April 2026
Dapagliflozin Tablets 5 mg and 10 mg	Aizant Drug Research Solutions Pvt. Ltd.; Ajanta Pharma Limited; Alembic Pharmaceuticals, Inc.; Alkem Laboratories Ltd.; Aurobindo Pharma Limited; Biocon Pharma Inc.; Cipla USA Inc.; Inventia Healthcare Limited; Lupin Pharmaceuticals, Inc.; Macleods Pharma USA, Inc.; Micro Labs Limited; MSN Laboratories Private Limited; Sandoz Inc.; Teva Pharmaceuticals USA, Inc.; Zydus Pharmaceuticals USA Inc.	Farxiga	Type 2 Diabetes	April 2026
Dapagliflozin and Metformin Hydrochloride Extended Release Tablets 2.5 mg/1000 mg, 5 mg/500 mg, 5	Alkem Laboratories Ltd.; Aurobindo Pharma Limited; Cipla USA Inc.; Lupin	Xigduo XR	Type 2 Diabetes	April 2026

mg/1000 mg, 10 mg/500 mg, 10 mg/1000 mg	Pharmaceuticals, Inc.; Macleods Pharmaceuticals Ltd.; Micro Labs Limited; MSN Laboratories Private Limited; Sun Pharmaceutical Industries, Inc.; Teva Pharmaceuticals USA, Inc.			
Canagliflozin Tablets 100 mg and 300 mg	Apotex Inc.; Aurobindo Pharma Limited	Invokana	Type 2 Diabetes	2027 or later
Ipratropium Bromide	Amphastar	Atrovent HFA	COPD	April 2026

**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
Filspari (sparsentan) From: Travere Therapeutics, Inc.	To slow kidney function decline in adults with primary immunoglobulin a nephropathy who are at risk for disease progression	To reduce proteinuria in adult and pediatric patients aged 8 years and older with focal segmental glomerulosclerosis without nephrotic syndrome
Tzield (teplizumab-mzwv) From: Sanofi	To delay the onset of stage 3 type 1 diabetes in adults and pediatric patients aged 8 years and older with stage 2 T1D	To delay the onset of stage 3 type 1 diabetes in adult and pediatric patients 1 year of age and older with stage 2 T1D
Dupixent (dupilumab) From: Regeneron Pharmaceuticals	[1] For the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe ad whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable; [2] As an add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma; [3] As an add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps; [4] For the treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis; [5] For the treatment of adult patients with prurigo nodularis; [6] As an add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease and an eosinophilic phenotype; [7] For the treatment of adult and pediatric patients aged 12 years and older with chronic spontaneous urticaria who remain symptomatic despite H1 antihistamine treatment; [8] For the treatment of adult patients with bullous pemphigoid; [9] For the treatment of adult and pediatric patients aged 6	For the treatment of adult and pediatric patients aged 2 years and older with chronic spontaneous urticaria who remain symptomatic despite H1 antihistamine treatment

	years and older with allergic fungal rhinosinusitis who have a history of sino-nasal surgery	
Stelara (ustekinumab) From: Janssen	For the treatment of adult patients with: [1] Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy; [2] Active psoriatic arthritis; [3] Moderately to severely active Crohn's disease; [4] Moderately to severely active ulcerative colitis. Pediatric patients 6 years and older with: [5] Moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy; [6] Active psoriatic arthritis	Moderately to severely active Crohn's disease in adult and pediatric patients 2 years of age and older
Cosentyx (secukinumab) From: Novartis	[1] Moderate to severe plaque psoriasis in patients 6 years and older who are candidates for systemic therapy or phototherapy; [2] Active psoriatic arthritis in patients 2 years of age and older; [3] Adults with active ankylosing spondylitis; [4] Adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation; [5] Active enthesitis-related arthritis in pediatric patients 4 years of age and older; [6] Adults with moderate to severe hidradenitis suppurativa	Active ankylosing spondylitis in adults and pediatric patients 12 years of age and older
Breztri Aerosphere (budesonide/ glycopyrrolate/ formoterol fumarate) From: AstraZeneca	For the maintenance treatment of patients with chronic obstructive pulmonary disease	For the maintenance treatment of asthma in adult and pediatric patients 12 years of age and older
Auvelity (dextromethorphan hydrobromide and bupropion hydrochloride) From: Axsome Therapeutics, INC.	For the treatment of major depressive disorder in adults	For the treatment of agitation associated with dementia due to Alzheimer's disease

Pipeline

PDUFA Date: Possibly late 2026 – Early 2027

CagriSema

Overview

CagriSema (cagrilintide + semaglutide) is an investigational, once-weekly, subcutaneous fixed-dose combination being developed for the treatment of obesity and type 2 diabetes. It combines a GLP-1 receptor agonist (semaglutide) with an amylin receptor agonist (cagrilintide), targeting complementary pathways involved in appetite regulation, satiety, and glycemic control. This dual-mechanism approach aims to enhance weight loss efficacy beyond what is achieved with GLP-1 receptor agonists alone.

Clinical Studies

The clinical development program for CagriSema includes multiple Phase 3 trials (REDEFINE program) evaluating its efficacy in patients with obesity, with and without type 2 diabetes. In the pivotal REDEFINE 1 trial (68 weeks) involving patients with overweight or obesity without diabetes, CagriSema demonstrated a mean weight loss of about 22%, compared to 11% with cagrilintide alone, about 15% with semaglutide alone, and 3.0% with placebo. In REDEFINE 2, which included patients with obesity and type 2 diabetes, treatment resulted in a 15.7% reduction in body weight vs 3.1% with placebo, meeting the primary endpoint. A head-to-head Phase 3 trial (REDEFINE 4) comparing CagriSema with tirzepatide (Zepbound) showed substantial weight loss (≈23.0%); however, it did not meet noninferiority criteria, as tirzepatide achieved greater weight reduction (~25.5%). Despite this, CagriSema consistently demonstrated superior efficacy compared to semaglutide monotherapy across trials. Overall, CagriSema produces robust and clinically meaningful weight loss (~15–23%).

Place in Therapy

CagriSema is expected to be positioned as a high-efficacy option for chronic weight management in adults with obesity or overweight with comorbidities, particularly in patients who require greater weight reduction than what is achieved with GLP-1 monotherapy. Current standard therapies include GLP-1 receptor agonists (e.g., semaglutide), dual GIP/GLP-1 agonists (tirzepatide), and other anti-obesity medications. Due to its dual mechanism (GLP-1 + amylin agonism), CagriSema offers a novel approach that enhances satiety and reduces caloric intake more effectively than single-agent therapies. However, based on available data, it may be less effective than tirzepatide, which is currently considered the most efficacious agent in this class. Given its strong efficacy but lack of clear superiority over existing best-in-class agents, CagriSema will likely be positioned as an alternative to GLP-1 monotherapy (e.g., Wegovy), or a second-line or competitive option vs tirzepatide, depending on patient response, tolerability, and access

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.

Generic Name	Brand Name	Brand Manufacturer
Tofacitinib Citrate	Xeljanz (tablet)	Pfizer
Linagliptin; Metformin Hydrochloride	Jentadueto XR	Boehringer Ingelheim; Eli Lilly