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PharmNotes

Monthly Communications

June 2026

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Pharmacy Benefit Management
Expires: 12/01/2028

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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 June.

New FDA-Approved Drug Products

Specialty

New Molecular Entity

Utebzi (tebipenem pivoxil) tablets, for oral use

FDA-Approved Indication

For the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, caused by the following susceptible microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae* species complex, *Klebsiella oxytoca*, and *Enterococcus faecalis* in adult patients who have limited or no alternative oral treatment options.

Dosage & Administration

600 mg (two 300 mg tablets) taken orally every 6 hours for 7 to 10 days.

Dosage Forms & Strengths

Tablets: 300 mg of tebipenem pivoxil.

Contraindications

- In patients with hypersensitivity to Utebzi or other beta-lactam antibacterials.
- In patients with primary or secondary carnitine deficiency or inborn errors of metabolism that may result in clinically significant carnitine deficiency.

Common Adverse Reactions

Diarrhea, headache, nausea, abdominal pain, hepatic enzyme increased, and *Clostridioides difficile* infection.

Warnings & Precautions

- Hypersensitivity Reactions
- Seizures and Other Central Nervous System (CNS) Adverse Reactions
- Concomitant use with valproic acid or divalproex sodium may reduce the serum concentration of these drugs potentially increasing the risk of breakthrough seizures
- Secondary carnitine deficiency may occur with Utebzi
- *Clostridioides difficile* Infection (CDI)
- Interference with Newborn Screening Test

Drug Interactions

- Organic Anion Transporter 1 (OAT1) and 3 (OAT3) inhibitors

Clinical Studies

The approval came from the phase 3, randomized, double-blind PIVOT-PO trial that evaluated Utebzi versus intravenous imipenem-cilastatin in 1,690 hospitalized adults with complicated urinary tract infections (cUTIs), including acute pyelonephritis. Patients received tebipenem pivoxil 600 mg orally or imipenem-cilastatin 500 mg intravenously every 6 hours for 7–10 days. The primary endpoint was overall response at the test-of-cure visit, defined as a composite of clinical cure and microbiological eradication. Utebzi demonstrated non-inferiority to imipenem-cilastatin, achieving overall response rates of 58.5% and 60.2%, respectively (adjusted treatment difference: −1.3%).

Place in Therapy

Utebzi is the first oral carbapenem approved for the treatment of adults with complicated urinary tract infections, offering a potential alternative to intravenous antibiotic therapy, which often necessitates hospitalization. Clinical trial results demonstrated that Utebzi is an effective oral alternative to IV carbapenem therapy in patients with cUTIs, including acute pyelonephritis.

New FDA-Approved Drug Products

Specialty

New Molecular Entity

Lumvoa (veligrotug-vvze) injection, for intravenous use

FDA-Approved Indication

For the treatment of thyroid eye disease regardless of thyroid eye disease activity or duration.

Dosage & Administration

10 mg/kg every three weeks for a total of 5 infusions.

Dosage Forms & Strengths

Injection: 500 mg/10 mL (50 mg/mL) solution in a single-dose vial.

Contraindications

None

Common Adverse Reactions

Muscle spasms, headache, hearing impairment, hyperglycemia, fatigue, diarrhea, ear discomfort, infusion-related reaction, nausea, nasopharyngitis, blood creatine phosphokinase increased, dry skin, and hypertension.

Warnings & Precautions

- Infusion Reactions
- Inflammatory Bowel Disease (IBD)
- Hyperglycemia
- Hearing Impairment including Hearing Loss

Use in Specific Populations

- Females of Reproductive Potential: Appropriate forms of contraception should be implemented prior to initiation, during treatment and for 6 months following the last dose of Lumvoa.

Clinical Studies

The approval came from the pivotal phase 3 THRIVE and THRIVE-2 trials in patients with active and chronic thyroid eye disease (TED), respectively. The primary endpoint was proptosis response at week 15, defined as a ≥2 mm reduction in proptosis without worsening in the fellow eye. Lumvoa demonstrated statistically significant and clinically meaningful improvements in proptosis compared with placebo in both active TED (70% vs 5%) and chronic TED (57% vs 8%), with benefits observed as early as week 3 and maintained through week 52 in many responders. Additionally, Lumvoa significantly improved diplopia response and resolution in both trials.

Place in Therapy

Lumvoa expands the treatment options for thyroid eye disease alongside Tepezza (teprotumumab), with both therapies targeting the insulin-like growth factor-1 receptor (IGF-1R). While glucocorticoids, administered orally or intravenously and sometimes in combination with mycophenolate, remain the standard first-line treatment for moderate-to-severe TED, patients with an inadequate response may be candidates for IGF-1R–targeted therapies. Lumvoa is administered as five intravenous infusions every three weeks, offering a shorter treatment course than Tepezza, which requires eight infusions delivered at the same interval.

New FDA-Approved Drug Products

New Biosimilar Product

Drug Name	Reference Product	Additional Information
Ranluspec (ranibizumab-hkdz)	Lucentis	Ranluspec is the fourth FDA-approved biosimilar to Lucentis.

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*
Fostamatinib Disodium Tablets 100 mg (base) and 150 mg (base)	Annora Pharma Private Limited	Tavalisse	Immune Thrombocytopenia	2032
Baloxavir Marboxil Tablets 40 mg and 80 mg	Norwich Pharmaceuticals, Inc.	Xofluza	Influenza and Influenza Prophylaxis	2036
Solriamfetol Hydrochloride Tablets 75 mg (base) and 150 mg (base)	Alkem Laboratories Ltd.; Hikma Pharmaceuticals USA Inc.	Sunosi	Excessive Daytime Sleepiness Associated with Narcolepsy /Obstructive Sleep Apnea	2040
Rifapentine Tablets 150 mg	Macleods Pharmaceuticals Limited	Priftin	Tuberculosis	Unknown

**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
Hympavzi (marstacimab-hncq) From: Pfizer Inc.	For routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with: hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors, or hemophilia B (congenital factor IX deficiency) without factor IX inhibitors	For routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 6 years of age and older with: hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors, or hemophilia B (congenital factor IX deficiency) without factor IX inhibitors
Tzield (teplizumab-mzwv) From: Sanofi	To delay the onset of Stage 3 type 1 diabetes (T1D) in adult and pediatric patients 1 year of age and older with Stage 2 T1D	Delay the decline in endogenous insulin production in pediatric patients aged 8 to 17 years recently diagnosed with Stage 3 T1D
Tryngolza (olezarsen) From: Ionis Pharmaceuticals, Inc.	As an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome	To reduce TG and the risk of acute pancreatitis in adults with severe hypertriglyceridemia
Welireg (belzutifan) From: Merck Sharp Dohme	[1] For treatment of adult patients with advanced renal cell carcinoma (RCC) with a clear cell component following a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI); [2] von Hippel-Lindau (VHL) disease; [3] Pheochromocytoma or paraganglioma (PPGL)	In combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph, for the adjuvant treatment of adult patients with renal cell carcinoma with a clear cell component at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions
Truqap (capivasertib) From: AstraZeneca	In combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations as detected by an FDA-approved test following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy	In combination with abiraterone and prednisone for the treatment of adult patients with metastatic androgen pathway modulation-naïve or - sensitive prostate cancer that is PTEN-deficient as detected by an FDA-authorized test
Capvaxive (pneumococcal 21-valent conjugate vaccine)	For active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 3, 6A, 7F, 8, 9N, 10A, 11A,	For active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 3, 6A, 7F, 8, 9N, 10A, 11A,

From: Merck Sharp Dohme	12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age or older who are at increased risk for pneumococcal disease	12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 2 through 17 years of age who are at increased risk for pneumococcal disease
Skyrizi (risankizumab-rzaa) From: AbbVie	[1] Moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy; [2] Active psoriatic arthritis in adults; [3] Moderately to severely active Crohn's disease in adults; [4] Moderately to severely active ulcerative colitis in adults	[1] For the treatment of moderate-to-severe plaque psoriasis in adults and pediatric patients 6 years of age and older who are candidates for systemic therapy or phototherapy; [2] For the treatment of active psoriatic arthritis in adults and pediatric patients 6 years of age and older
Ibrance (palbociclib) From: Pfizer Inc.	[1] For the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with: an aromatase inhibitor as initial endocrine-based therapy; or fulvestrant in patients with disease progression following endocrine therapy; [2] In combination with inavolisib and fulvestrant for the treatment of adult patients with endocrine-resistant, PIK3CA mutated, HR-positive, HER2-negative, locally advanced or metastatic breast cancer, as detected by an FDA-approved test, following recurrence on or after completing adjuvant endocrine therapy	In combination with trastuzumab, with or without pertuzumab, and endocrine therapy for the maintenance treatment of adult patients with HR-positive, HER2-positive locally advanced or metastatic breast cancer following induction treatment
Trodelvy (sacituzumab govitecan-hziy) From: Immunomedics Inc.	[1] Unresectable locally advanced or metastatic triple-negative breast cancer who have received two or more prior systemic therapies, at least one of them for metastatic disease; [2] Unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH–) breast cancer who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting	[1] As a single agent for the first-line treatment of adult patients with unresectable locally advanced or metastatic triple negative breast cancer (TNBC) who are not candidates for PD-1 or PD-L1 inhibitor-based therapy; [2] In combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph for the first-line treatment of adult patients with unresectable locally advanced or metastatic TNBC whose tumors express PD-L1 (CPS ≥ 10) as determined by an FDA-authorized test
Zoryve (roflumilast) From: Arcutis	[1] Zoryve cream, 0.3%, is indicated for the topical treatment of plaque psoriasis, including intertriginous areas, in adult and pediatric patients 6 years of age and older; [2] Zoryve cream, 0.15%, is indicated for the topical treatment of mild to moderate atopic dermatitis in	Zoryve cream, 0.3%, is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in adult and pediatric patients 2 years of age and older

	adult and pediatric patients 6 years of age and older; [3] Zoryve cream, 0.05%, is indicated for the topical treatment of mild to moderate atopic dermatitis in pediatric patients 2 to 5 years of age.	
Xeomin (incobotulinumtoxinA) From: Merz Therapeutics	[1] Upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy; [2] Chronic sialorrhea; [3] Cervical dystonia; [4] Blepharospasm; [5] Upper facial lines (glabellar lines, horizontal forehead lines, and lateral canthal lines)	For the treatment of upper limb spasticity in patients 2 years of age and older

Pipeline

PDUFA Date: Q3 2026

Oveporexton

Overview

Oveporexton is an investigational, oral, orexin receptor-2 (OX2R) selective agonist developed to directly address the underlying orexin deficiency that causes narcolepsy type 1 (NT1). By restoring OX2R signaling, the agent is designed to promote physiologic wakefulness and reduce abnormal REM-sleep–like phenomena, including cataplexy, hallucinations, and sleep paralysis, thereby targeting the broad spectrum of daytime and nighttime symptoms characteristic of NT1.

Clinical Studies

The NDA is supported by two global, multicenter, placebo-controlled Phase 3 studies known as FirstLight and RadiantLight. FirstLight icnluded 168 participants that were randomized to receive either twice-daily 2 mg, 1 mg, or placebo, while RadiantLight enrolled 105 participants that were randomized to receive twice-daily 2 mg or placebo. Both studies met all primary and secondary endpoints, demonstrating statistically significant improvements across core NT1 symptoms compared with placebo. More than 95% of study completers entered the ongoing long-term extension.

Across both trials, oveporexton improved daily functioning at week 12 ($p<0.001$) across all six domains of the Functional Impacts of Narcolepsy Instrument (FINI), with most patients reaching or exceeding normative thresholds. Cognitive performance improved on objective neuropsychological testing and patient-reported measures, with approximately 70% of treated patients reporting no significant cognitive difficulties versus ~15% on placebo. Exploratory nighttime-sleep endpoints showed reductions in hallucinations, sleep paralysis, and disturbed sleep, along with REM-sleep patterns shifting toward those observed in healthy controls.

Place in Therapy

If approved, oveporexton would be the first treatment to directly restore orexin signaling, the root cause of NT1, rather than simply boosting alertness or managing individual symptoms. Current options like sodium oxybate products, pitolisant, modafinil, and armodafinil help with parts of the condition but do not address the underlying orexin loss. Oveporexton's broad impact across wakefulness, cataplexy, cognition, daily functioning, and nighttime stability suggests it could shift NT1 management toward a more comprehensive, disease-targeted approach.