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PharmNotes

Monthly Communications

January 2026

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Pharmacy Benefit
Management
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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.

Safety Alert	Date	Additional Information
FDA Requests Removal of Suicidal Behavior and Ideation Warning from Glucagon-Like Peptide-1 Receptor Agonist (GLP-1 RA) Medications	01/13/2026	FDA is requesting that drug application holders remove information regarding the risk of suicidal ideation and behavior (SI/B) from the labeling of glucagon-like peptide-1 receptor agonist (GLP-1 RA) medications that currently include such language. The affected products are Saxenda (liraglutide), Wegovy (semaglutide), and Zepbound (tirzepatide). This action follows a comprehensive FDA review that found no increased risk of SI/B associated with the use of GLP-1 RA medications. Saxenda, Wegovy, and Zepbound are each approved for weight reduction in persons with obesity or overweight. At the time of the original FDA approvals, the labeling for each of these products included information in the Warnings and Precautions section about the potential risk of SI/B. Similar information about SI/B is also included in the labeling of other types of weight loss medicines and is based on reports of such events observed with a variety of older medicines used or studied for weight loss.

New FDA-Approved Drug Products

Orphan Drug | Specialty

New Molecular Entity

Zycubo (copper histidinate) for injection, for subcutaneous use

FDA-Approved Indication

For the treatment of Menkes disease in pediatric patients.

Dosage & Administration

Less than 1 year of age is 1.45 mg twice daily (8-12 hours between injections). 1 year of age to less than 17 years of age is 1.45 mg once daily.

Dosage Forms & Strengths

For Injection: 2.9 mg of copper histidinate (equivalent to 0.5 mg elemental copper) as a lyophilized powder or cake in a single-dose vial for reconstitution.

Contraindications

- None

Common Adverse Reactions

Pneumonia, viral infection, respiratory failure, seizure, bacterial infection, hemorrhage, hypotension, vomiting, tachycardia, pyrexia, volume depletion, fracture, dyspnea, transaminases elevation, diarrhea, fungal infection, anemia, and local administration reaction.

Warnings & Precautions

- Copper Accumulation and Risk of Toxicity

Clinical Studies

The approval came from two open-label, single arm trials in 83 pediatric patients treated for up to three years. Overall survival was compared to untreated patients from external control groups. Results showed that the risk of death was reduced by 78% in children who began treatment within four weeks of birth compared with untreated patients. Some of the early-treated patients survived beyond six years, and some survived more than 12 years. On the other hand, no patients in the untreated control group survived beyond six years.

Place in Therapy

Zycubo is a copper replacement therapy that is administered by the subcutaneous route, thus bypassing the impaired intestinal absorption seen in patients with this disease. It is the first and only treatment approved for Menkes disease, a rare and fatal genetic condition characterized by impaired copper absorption.

New FDA-Approved Drug Products

New Formulations, Combinations, and Line Extensions

Yuvezzi (carbachol and brimonidine tartrate ophthalmic solution)

FDA-Approved Indication

For the treatment of presbyopia in adults.

Dosage & Administration

Instill one drop in each eye once daily.

Dosage Forms & Strengths

Ophthalmic solution: carbachol 2.75% and brimonidine tartrate 0.1% in a single-dose vial.

Contraindications

- Hypersensitivity.

Common Adverse Reactions

Eye pain upon instillation, visual impairment, eye irritation upon instillation, and headache.

Warnings & Precautions

- Blurred Vision
- Risk of Retinal Detachment
- Potentiation of Vascular Insufficiency
- Iritis

Drug Interactions

- Antihypertensives/cardiac glycosides
- CNS depressants
- Tricyclic antidepressants
- Monoamine oxidase inhibitors

Clinical Studies

The approval came from two Phase 3, randomized, double-masked, controlled studies, BRIO I and BRIO II, in participants 45 to 80 years old with presbyopia. Study results showed that there was statistically significant near vision improvement over 8 hours without the loss of one line or more in binocular uncorrected distance visual acuity (BUDVA).

Place in Therapy

Standard management of presbyopia, which is the inability to see up close, includes optical correction with reading glasses, multifocal spectacles, or contact lenses. Several pharmacological products are available for the treatment of presbyopia, such as Vuity and Qlosi.

New FDA-Approved Drug Products

New Biosimilar Product

Drug Name	Reference Product	Designations	Additional Information
Filkri (filgrastim-laha)	Neupogen	Biosimilar	Filkri joins other Neupogen biosimilars such as Nivestym, Nypozi, Releuko, and Zarxio.

Other Notable New Approvals

Quiofic (folic acid)

- Oral solution for the treatment of megaloblastic anemias due to a folic acid deficiency in adult and pediatric patients.

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*
Mirabegron Granules for Extended Release Oral Suspension 8 mg/mL	Alkem Laboratories Limited	Myrbetriq Granules	Overactive Bladder; Neurogenic Detrusor Overactivity	Unknown
Tapentadol Hydrochloride Oral Solution 20 mg (base)/mL	Teva Pharmaceuticals USA, Inc.	Nucynta (oral solution)	Acute pain	Early – Mid 2026
Tapentadol Hydrochloride Tablets 50 mg (base), 75 mg (base) and 100 mg (base)	Humanwell Pharmaceutical US, Inc.	Nucynta (tablets)	Acute pain	Early – Mid 2026

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

New FDA-Approved Indications for Existing Drugs

No notable drugs gained FDA-approval for the treatment of additional diseases or conditions during the month of January.

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
Rusfertide From: Takeda and Protagonist Therapeutics	Polycythemia Vera	NDA submitted	Moderate
Lorecivivint From: Biosplice Therapeutics, Inc.	Osteoarthritis (knee)	NDA submitted	High
Tegoprazan From: Braintree Laboratories, Inc.	Erosive esophagitis; Non-erosive reflux disease	NDA submitted	Low
Pimicotinib From: EMD Serono, Inc.	Tenosynovial giant cell tumor	NDA submitted	Moderate
Centanafadine From: Otsuka Pharmaceutical Co., Ltd.	Attention-deficit hyperactivity disorder (ADHD)	NDA accepted	Moderate
Gedatolisib From: Celcuity Inc.	Hormone receptor positive, human epidermal growth factor receptor 2 negative advanced breast cancer	NDA accepted	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.