Approvals & Updates

February 2020

New Drug Approvals

Ayvakit (avapritinib)

Indication: Unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGRFA) exon 18 mutation

Mechanism of Action: Kinase inhibitor

Dosage Form: Oral tablets

Ayvakit is FDA-approved for the treatment of adults with unresectable or metastatic GIST with a PDGFRA exon 18 mutation, including PDGFRA D842V mutations. The recommended dosage is 300 mg orally once daily on an empty stomach, at least 1 hour before and 2 hours after a meal. Ayvakit carries labeled warnings for the risk of intracranial hemorrhage, central nervous system adverse reactions, and embryo-fetal toxicity. Patients taking Ayvakit should avoid coadministration of strong and moderate CYP3A inhibitors and inducers. If coadministration of Ayvakit with moderate CYP3A inhibitors cannot be avoided, reduce the dose of Ayvakit. Most common adverse reactions (≥20%) reported with Ayvakit include edema, nausea, fatigue/asthenia, cognitive impartment, vomiting, decreased appetite, diarrhea, hair color changes, increased lacrimation, abdominal pain, constipation, rash and dizziness.

New Drug Approvals, Continued

Palforzia (peanut [Arachis hypogaea] allergen powder-dnfp)
Indication: Allergic reactions, including anaphylaxis, with accidental exposure to peanut
Mechanism of Action: Oral immunotherapy
Dosage Form: Oral capsules and sachets

Palforzia is FDA-approved for use in patients with a confirmed diagnosis of peanut allergy to mitigate allergic reaction, including anaphylaxis, to accidental peanut exposure. Palforzia is to be used in conjunction with a peanut-avoidant diet and is not indicated for emergency treatment of allergic reaction including anaphylaxis. Palforzia is for oral administration only; however, capsules must not be swallowed directly. Capsules must be opened and the entire dose of Palforzia powder must be emptied onto refrigerated or room temperature semisolid food. The dose must be mixed well into the food and patients must consume the entire volume of food by mouth. Initiation of Palforzia therapy is intended for patients aged 4 through 17 years of age, though treatment may be continued in adult patients. Palforzia carries a Boxed Warning related to the risk of anaphylaxis, which may be life-threatening and can occur at any time during therapy. Due to the potential for anaphylactic reaction, injectable epinephrine should be co-prescribed and dose modifications of Palforzia may be necessary after an anaphylactic reaction. Patients with uncontrolled asthma or those with a history of eosinophilic gastrointestinal disease should not take Palforzia. Patients should be observed during and after initial administration of Palforzia and upon each dosage increase, for a period of at least 60 minutes. Palforzia is available only through the PALFORZIA REMS restricted access program. Patients taking Palforzia should be monitored for signs and symptoms of anaphylaxis, gastrointestinal reactions, and eosinophilic esophagitis. Asthma patients must have their asthma under control prior to starting Palforzia, and treatment may be temporarily withheld during an acute asthma exacerbation. Most common adverse reactions (≥5%) reported with Palforzia include abdominal pain, vomiting, nausea, oral pruritus, oral paresthesia, throat irritation, cough, rhinorrhea, sneezing, throat tightness, wheezing, dyspnea, pruritus, urticaria, anaphylactic reaction, and ear pruritus.

Tazverik (tazemetostat)
Indication: Metastatic or locally advanced epithelioid sarcoma
Mechanism of Action: Methyltransferase inhibitor
Dosage Form: Oral tablets

Tazverik is FDA-approved for the treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection. Tazverik is given as 800 mg tablets orally twice daily with or without food. Tazverik carries labeled warnings for embryo-fetal toxicity and increased risk of secondary malignancies including T-cell lymphoblastic lymphoma, myelodysplastic syndrome, and acute myeloid leukemia. Patients taking Tazverik should avoid coadministration of strong and moderate CYP3A inhibitors and inducers. If coadministration of moderate CYP3A inhibitors cannot be avoided, reduce the dose of Tazverik. Most common adverse reactions (≥20%) reported with Tazverik include pain, fatigue, nausea, decreased appetite, vomiting, and constipation.

New Drug Approvals, Continued

Tepezza (teprotumumab-trbw)

Indication: Thyroid eye disease

Mechanism of Action: Insulin-like growth factor-1 receptor inhibitor

Dosage Form: Injection for intravenous infusion

Tepezza is FDA-approved for the treatment of thyroid eye disease. Tepezza is supplies as a 500 mg lyophilized powder in a single-dose vial for reconstitution. It is administered by intravenous injection at an initial dose of 10 mg/kg for the first infusion, followed by 20 mg/kg every 3 weeks for 7 additional infusions. Patients receiving IV infusions of Tepezza should be monitored for infusion reactions, exacerbation of preexisting inflammatory bowel disease, and hyperglycemia. Most common adverse reactions (>5%) reported with Tepezza include muscle spasm, nausea, alopecia, diarrhea, fatigue, hyperglycemia, hearing impairment, dry skin, dysgeusia and headache.

Note: This is not a comprehensive list. New drug approvals are reviewed for agents most relevant to the long-term care population.

Safety Updates

Possible increased risk of cancer with weight-loss medication Belviq (lorcaserin)

The FDA recently published a drug safety communication describing the possible increased risk of cancer with the weight loss medication lorcaserin (Belviq and Belviq XR). Currently, the cause of the cancer is uncertain and loraserin's role is unclear. The FDA continues to monitor the results of a clinical trial assessing the safety of lorcaserin and will provide further recommendations in the future.

Risk of serious bowel problems in patients with untreated constipation caused by clozapine

The FDA recently strengthened warnings related to the risk of serious bowel problems in patients with untreated constipation caused by clozapine. Bowel function should be evaluated before initiating clozapine, and the drug should be avoided in patients receiving other anticholinergic medicines that can cause gastrointestinal hypomotility. Patients who receive clozapine should stay hydrated to prevent constipation and should report symptoms such as nausea, abdominal distension or pain, and vomiting. A warning describing these adverse effects will be added to the label of all clozapine products.

Current Drug Shortages

The following shortages have been recently identified by the FDA:

- Ketorolac tromethamine injection
- Heparin sodium and sodium chloride 0.9% injection

For additional information on drug shortages, please contact the Center for Drug Information & Evidence-Based Practice.

Recently Approved Drug Combinations, Dosage Forms, and Biosimilars

Brand (Generic)	Indication	Mechanism of Action	Dosage Form	Comments
Monoferric (ferric derisomaltose)	Iron-deficiency anemia	Iron complex	Solution for injection	First iron IV formulation in the US for administering 1000 mg as a single dose
Trijardy XR (empagliflozin, linagliptin, and metformin extended-release)	Type 2 diabetes	Sodium-glucose co-transporter 2 (SGLT2) inhibitor, dipeptidyl peptidase-4 (DPP-4) inhibitor, biguanide	Oral tablets	New combination
Valtoco (diazepam)	Seizures	Benzo-diazepine	Nasal spray	New dosage form

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Drug Information Consultation Service

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