New Drug Approvals

Carnexiv (carbamazepine)

**Indication:** Partial seizures, generalized tonic-clonic seizures, mixed partial or generalized seizures  
**Mechanism of Action:** Antiepileptic; mechanism unknown  
**Dosage Form(s):** Injection (for intravenous use)  
**Comments:** Carnexiv is the first injectable formulation of carbamazepine and is FDA-approved as replacement therapy for oral carbamazepine formulations when oral administration is not feasible. The total daily dose of Carnexiv should equal 70% of the total daily dose of oral carbamazepine and be divided into four infusions separated by 6 hours. Carnexiv should not be used for more than 7 days. It should not be used in patients with bone marrow depression, and patients with renal impairment should be monitored closely as Carnexiv is typically not used in patients with moderate or severe renal impairment. Carnexiv carries a Boxed Warning describing an increased risk for serious dermatologic reactions, especially in patients with Asian ancestry. A Boxed Warning for aplastic anemia and agranulocytosis is also included on the drug’s label. Patients taking Carnexiv should be closely assessed for significant drug-drug interactions, as Carnexiv is a potent enzyme inducer and is also a substrate of CYP3A4. Patients should also be monitored for hyponatremia, hepatic toxicity, and suicidal behavior and ideation. The most common adverse reactions reported with Carnexiv include anemia, blurred vision, diplopia, dizziness, headache, infusion-related reactions, infusion-site pain, and somnolence.

Lartruvo (olaratumab)

**Indication:** Soft tissue sarcoma  
**Mechanism of Action:** Platelet-derived growth factor receptor alpha (PDGFR-alpha) blocking antibody  
**Dosage Form(s):** Injection (for intravenous use)  
**Comments:** Lartruvo is a PDGFR-alpha blocking antibody FDA-approved, in combination with doxorubicin, for the treatment of soft tissue sarcoma in adults with a histologic subtype for which an anthracycline regimen is appropriate and which is not treatable with radiation or surgery. Lartruvo is given as a 15 mg/kg infusion over 60 minutes on days 1 and 8 of each 21-day cycle. Patients receiving Lartruvo should be premedicated with diphenhydramine and dexamethasone on day 1 of cycle 1. Lartruvo was approved under accelerated approval, and continued approval is contingent on future evidence regarding its safety and effectiveness. Patients should be monitored for infusion-related reactions. The most common adverse reactions reported with Lartruvo (in combination with doxorubicin) include abdominal pain, alopecia, decreased appetite, diarrhea, fatigue, headache, mucositis, musculoskeletal pain, nausea, neuropathy, and vomiting. Laboratory abnormalities including lymphopenia, neutropenia, thrombocytopenia, hyperglycemia, elevated aPTT, hypokalemia, and hypophosphatemia have been reported with Lartruvo.
The FDA recently issued a safety communication describing an increased risk for hepatitis B virus (HBV) activation in patients with a current or previous infection with HBV who are being treated with direct-acting antivirals for HCV. A Boxed Warning describing this risk will be added to the drug labels of these direct-acting antivirals. Health care providers are encouraged to screen all patients for evidence of current or prior HBV infection before initiating treatment with direct-acting antivirals for HCV.

The following shortages have been recently identified by the FDA. For additional information on drug shortages, please contact the Center for Drug Information & Evidence-Based Practice.

- No new shortages identified