New Drug Approvals

Amjevita (adalimumab-atto)

**Indication:** Rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn’s disease, ulcerative colitis, and plaque psoriasis

**Mechanism of Action:** Tumor necrosis factor (TNF) blocker

**Dosage Form(s):** Injection (for subcutaneous use)

**Comments:** Amjevita is biosimilar to Humira (adalimumab) and is FDA-approved to treat a variety of inflammatory conditions. It is available as a single-use autoinjector and pre-filled syringe, with dosing of Amjevita dependent upon the indication for use. While there are no contraindications to its use, Amjevita carries a Boxed Warning describing an increased risk of serious infections, including tuberculosis (TB), sepsis, and invasive fungal infection. Patients should be screened for TB prior to initiating treatment, and Amjevita should be discontinued in any patients who develop a serious infection. The Boxed Warning also describes an increased risk for malignancy in patients treated with Amjevita. In addition to these risks, patients receiving Amjevita should be monitored for anaphylaxis, demyelinating disease, heart failure, lupus-like syndrome, and reactivation of hepatitis B. The most common adverse reactions reported with Amjevita include infections, injection site reactions, headache, and rash.

Cuvitru [immune globulin (human)]

**Indication:** Primary humoral immunodeficiency

**Mechanism of Action:** Immunoglobulin

**Dosage Form(s):** Injection (for subcutaneous use)

**Comments:** Cuvitru is a subcutaneous immunoglobulin FDA-approved for the treatment of primary humoral immunodeficiency in adults and children two years of age and older. It is the only subcutaneous immunoglobulin available as a 20% solution. Dosing of Cuvitru is individualized based on patient pharmacokinetic parameters and clinical response. Cuvitru carries a Boxed Warning describing an increased risk for thrombosis. Patients with a history of anaphylaxis or severe reaction to subcutaneous immunoglobulin should not receive Cuvitru – neither should IgA deficient patients with antibodies against IgA. In addition to thrombosis, patients receiving Cuvitru should be monitored for aseptic meningitis syndrome, hemolysis, pulmonary reactions, and renal insufficiency. The most common adverse reactions reported with Cuvitru include diarrhea, fatigue, headache, injection site reactions, nausea, and vomiting.

Exondys 51 (eteplirsen)

**Indication:** Duchenne muscular dystrophy (DMD)

**Mechanism of Action:** Antisense oligonucleotide

**Dosage Form(s):** Injection (for intravenous use)

**Comments:** Exondys 51 is FDA-approved for the treatment of DMD in patients with a confirmed mutation of the DMD gene in which the gene is amenable to exon 51 skipping. Exondys 51 received approval upon an accelerated review, and future studies assessing its clinical benefit are pending. Exondys 51 is administered as an intravenous infusion at a dose of 30 mg/kg weekly given over 35-60 minutes. The most common adverse reactions reported with Exondys 51 include balance disorder, contact dermatitis, and vomiting.
New Drug Approvals
(continued)

Yosprala (aspirin and omeprazole)

Indication: Secondary prevention of cardiovascular and cerebrovascular events in patients at risk of developing ulcers associated with aspirin therapy

Mechanism of Action: Anti-platelet agent (aspirin) and proton pump inhibitor (omeprazole)

Dosage Form(s): Oral tablets (delayed-release)

Comments: Yosprala is an aspirin-omeprazole combination product FDA-approved for the secondary prevention of cardiovascular and cerebrovascular events in patients who are also at risk of developing ulcers caused by aspirin. It is available in two strengths: aspirin 81 mg/omeprazole 40 mg and aspirin 325 mg/omeprazole 40 mg. The aspirin component is a delayed-release formulation while the omeprazole component is immediate-release. Yosprala should be taken once per day, and the tablet should not be split or crushed. The same contraindications, warnings, and precautions of the individual components are true of Yosprala. It should be avoided in patients with severe renal failure or any degree of hepatic impairment. The most common adverse reactions reported with Yosprala include diarrhea, gastric polyps, gastritis, nausea, and non-cardiac chest pain.

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

Creighton University’s Center for Drug Information & Evidence-Based Practice, in collaboration with PharMerica, is offering drug information services to all PharMerica-affiliated healthcare professionals.

Drug Information Consultation Service
Monday through Friday
830 am – 430 pm Central
Submit your questions online at http://creighton.edu/pharmerica or call us at 1-800-561-3728
Voicemail service is available afterhours

Current Shortages

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.

- Ketoprofen capsules