Approvals & Updates

May 2023

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New Drug Approvals

Qalsody (tofersen)

Indication: Amyotrophic lateral sclerosis in adults who have a SOD1 gene mutation

Mechanism of Action: Antisense oligonucleotide

Dosage Form(s): Intrathecal injection

Comments: Qalsody is FDA-approved for treating adults who have a mutation in the superoxide dismutase 1 (SOD1) gene with amyotrophic lateral sclerosis (ALS). The recommended dose of Qalsody is 10mg (15mL) administered intrathecally as a bolus injection over 1 to 3 minutes. Qalsody treatment is first initiated as 3 loading doses that are administered every 14 days. Then treatment is maintained by administration of a maintenance dose once every 28 days thereafter. Specific preparation instructions for Qalsody include allowing the vial to warm to room temperature, administration within 4 hours after removal from the vial, and removing approximately 10mL of cerebrospinal fluid prior to administration. Qalsody has labeled warnings and precautions for myelitis and/ or radiculitis, papilledema and elevated intracranial pressure, and aseptic meningitis. The most common adverse reactions (≥10%) reported with Qalsody are pain, fatigue, arthralgia, increased cerebrospinal fluid white blood cells, and myalgia.

New Safety Alerts

FDA updates prescribing information for all opioid pain medications to provide guidance for safe use

The FDA recently published updates that provide additional guidance to the prescribing information for all immediate-release (IR) and extended release/long acting (ER/LA) opioid pain medications. The FDA is requiring changes to several sections of the opioid prescribing information and patient medication guides, including to the indications and usage, dosage/administration, warnings/precautions, and boxed warning. Updates include stating that the risk of overdoses increases as the dose of opioid increases. IR opioids must state that these products should not be used for extended periods of time and that many acute pain conditions require no more than a few days of opioid treatment. If the patient's pain is severe enough that opioids must be used and alternative treatment options are unavailable, then the lowest effective dose and shortest duration of an IR opioid can be used. Additionally, the FDA updated the approved uses for ER/LA opioid medications to be reserved for the severe and persistent types of pain that require extended treatment durations and recommend that they be used in conjunction with a daily opioid pain medication. The FDA has also added a new warning about opioid-induced hyperalgesia (OIH), a condition where opioids cause an increase in pain and provided information on the differentiation between OIH from opioid tolerance and withdrawal. Additionally, the boxed warning will also be updated and reordered to emphasis the importance of life-threatening respiratory depression and the risk of using opioids in combination with benzodiazepines and other central nervous system depressants. The FDA has also recommended that healthcare professionals discuss the availability of naloxone and to consider prescribing it to patients who display an increased risk of overdose.

Current Drug Shortages

The following shortages have been recently identified by the FDA:

- Fludarabine phosphate injection

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

Recently Approved Drug Combinations, Dosage Forms/Strengths, Indications, and Biosimilars

Brand (Generic)	Indication	Mechanism of Action	Dosage Form	Comments
Abilify Asimutifii (aripiprazole)	Schizophrenia and bipolar I disorder	Atypical antipsychotic	Extended-release injectable suspension	New formulation
RizaFilm (rizatriptan)	Acute treatment of migraine	Serotonin (5-HT) 1B/1D receptor agonist	Oral film	New dosage form
Uzedy (risperidone)	Schizophrenia	Atypical antipsychotic	Extended-release injectable suspension	New formulation
Vowst (fecal microbiota spores, live-brpk)	Prevention of recurrence of Clostridioides difficile infection (CDI)	Modulating the disrupted microbiome	Oral capsule	New microbiome therapeutic

Creighton University Center for Drug Information & Evidence-Based Practice

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