PULSE

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Pharmacy Benefit Dimensions®

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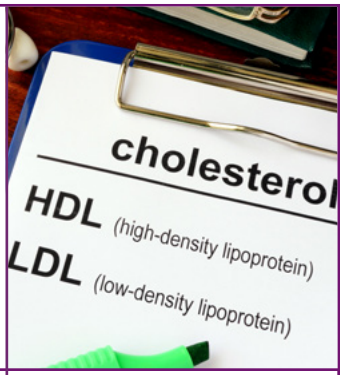
Clinical Updates



FDA approves new cholesterol medication

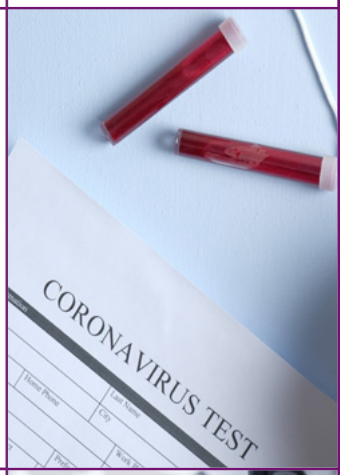
On February 21, 2020, the U.S. Food and Drug Administration (FDA) approved Nexletol™ (bempedoic acid) oral tablets as an additional cholesterol lowering therapy used in conjunction with diet and statin therapy for adult patients with a family history of high cholesterol or those that have heart disease. Nexletol™ belongs to a new class of medications that works by blocking an enzyme involved in the production of cholesterol in the liver. Clinical trials of the drug showed a significant reduction in LDL cholesterol levels in patients that were also on a statin, when compared to patients on a statin and placebo. The medication is the first once-daily oral non-statin treatment option for lowering LDL cholesterol approved by the FDA in almost 20 years. The manufacturer announced the medicine will be available in the U.S. on March 30, 2020.

Safety First

Taro Pharmaceuticals recalls seizure medication

On February 21, 2020, Taro Pharmaceuticals U.S.A, Inc. announced a voluntary recall of two lots of phenytoin oral suspension, a medication commonly used to treat seizure disorders. The recall was issued due to the possibility that the medication may not mix correctly when shaken, as directed, prior to administration. Inadequate mixture of the medication could result in dangerous under or overdosing. In the most at risk population, infants and pediatric patients, there is a higher likelihood that imprecise dosing may result in serious adverse reactions such as intoxication or breakthrough seizures. Taro is notifying its distributors and customers and is arranging for the return of all recalled products. To date, Taro has not received any reports of adverse events related to these batches.

From the Industry



FDA discloses actions in response to Coronavirus

On February 14, 2020, the FDA released a response to the Coronavirus (COVID-19) outbreak, describing their collaborative efforts with the U.S. Department of Health and Human Services and other public health partners. The press release outlines their comprehensive efforts in diagnosing, treating, and preventing the disease, monitoring the medical product supply chain, and managing the safety and quality of FDA-regulated products.

As a result, on February 27, 2020, the FDA issued a supply chain update informing the public that they have been in contact with manufacturers of drugs, medical devices, and other products that may potentially experience production issues due to Coronavirus. The FDA has identified about 20 drugs whose supply chain may be impacted due to effects of the virus and remain in contact with their manufacturers. The FDA reiterated that the outbreak represents an evolving and dynamic issue and that they will continue to communicate their response efforts to the public.

Recent FDA Approvals

Novel Drug Approval: Vyepti™ (eptinezumab-jjmr)
Intravenous solution for the prevention of migraine in adult patients [2/21/2020 – LUNDBECK PHARMACEUTICALS]

Novel Drug Approval: Barhemsys® (amisulpride)
Intravenous injection used for the prevention of nausea and vomiting both pre and post-surgery [2/26/2020 – ACACIA PHARMA LTD]

Novel Drug Approval: Nurtec™ ODT (rimegepant)
Orally disintegrating tablet for the acute treatment of migraine in adult patients [2/27/2020 – Priority Review – BIOHAVEN PHARMA HOLDING CO LTD]

New Generics Entering the Marketplace

Aczone® Gel (Dapsone Gel)
Indication: Acne
Dosage Form/Strength: 7.5% Gel
Average Wholesale Price (AWP): Generic = $675 | Brand = $825

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