GASTRO-HEP News

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US Food and Drug Administration Approves Dexlansoprazole for Adolescent Patients With Gastroesophageal Reflux Disease

On July 11, 2016, the US Food and Drug Administration (FDA) approved delayed-release capsules of dexlansoprazole (Dexilant, Takeda) and delayed-release orally disintegrated tablets of dexlansoprazole (Dexilant SoluTab, Takeda) for use in patients ages 12 to 17 years with gastroesophageal reflux disease (GERD). The capsule version of dexlansoprazole received approval for adult patients in 2009. The safety and effectiveness of the proton pump inhibitor have not been established in patients younger than 12 years of age.

In patients 12 years of age and older, capsules in 30-mg and 60-mg doses and tablets in 30-mg doses are indicated for the treatment of heartburn related to nonerosive, symptomatic GERD for 4 weeks and for maintenance healing of erosive esophagitis and relief of heartburn for up to 16 weeks (up to 6 months for adults). Additionally, 30-mg and 60-mg capsules can be used for healing erosive esophagitis for up to 8 weeks.

The most common adverse reactions in patients ages 12 to 17 years were abdominal pain, diarrhea, headache, nasopharyngitis, and oropharyngeal pain. Dexlansoprazole is not intended for use in patients with known hypersensitivity reactions to any ingredient of the proton pump inhibitor.

Sofosbuvir/Velpatasvir Receives FDA Approval for All Genotypes of Hepatitis C Virus Infection

On June 28, 2016, the combination of sofosbuvir/velpatasvir (Epclusa, Gilead Sciences) received approval from the FDA for treatment in adults with chronic hepatitis C virus (HCV) genotypes 1 through 6 infection, including patients with cirrhosis. For patients with decompensated cirrhosis, sofosbuvir/velpatasvir is approved for combined use with ribavirin; however, it is not indicated for use in patients for whom ribavirin is contraindicated. This is the first drug to treat all 6 major genotypes of HCV.

Three phase 3 clinical trials evaluated the efficacy and safety of the fixed-dose combination tablet for 12 weeks in 1558 patients with no or mild cirrhosis. The majority of patients receiving sofosbuvir/velpatasvir (95%-99%) showed no signs of infection in the blood at 12 weeks posttreatment. In a clinical trial of 267 patients with moderate to severe cirrhosis, 94% had no detection of the virus in the blood at 12 weeks posttreatment.

Side effects of sofosbuvir/velpatasvir include fatigue, headache, and the potential to slow heart rate. When sofosbuvir (Sovaldi, Gilead Sciences) and amiodarone are combined with another direct-acting antiviral medication, pacemaker intervention has been necessary. The combination of sofosbuvir/velpatasvir with amiodarone is not advised.

Task Force Updates Recommendations on Colorectal Cancer Screening

The US Preventive Services Task Force (USPSTF) recommends colorectal cancer screening in average-risk, asymptomatic patients ages 50 to 75 years using any available screening method. Screening in patients 76 years and older should be performed on a case-by-case basis that considers the patient's screening history and overall health. Adults in the latter age group who have not previously undergone screening are more likely to benefit than those who have been screened before.

The colorectal cancer screening recommendations, published online on June 15, 2016 in *JAMA* following a draft version that was available for comments from October 6 to November 2, 2015, were last updated in 2008. The USPSTF reviewed 7 screening methods (colonoscopy, computed tomography colonography, flexible sigmoidoscopy, fecal immunochemical testing, guaiac-based fecal occult blood testing, methylated *SEPT9* DNA testing, and multitargeted stool DNA testing) for their effectiveness in reducing disease-related or all-cause mortality and detecting adenomatous polyps and colorectal cancer. Additionally, the task force determined ideal starting and stopping ages and screening intervals using a comparative model study. The tests have different levels of evidence to support their effectiveness, as well as unique advantages and limitations. No test is considered more effective than others, nor are the tests ranked.

The updated recommendations emphasize the benefits of colorectal cancer screening rather than specific screening approaches, as was the focus of the 2008 recommendations. The USPSTF recommends that patients select the test that works best for them in consultation with their clinician. The task force also stresses that more adults should take advantage of this preventive intervention, as screening significantly reduces disease-related mortality in patients ages 50 to 75 years.