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Clinical Update

FDA Approves New Oral Treatment for Myelodysplastic Syndromes (MDS)

On July 7, 2020, The U.S. Food and Drug Administration (FDA) announced the approval of Inqovi® (decitabine and cedazuridine) oral tablets to treat adult patients with myelodysplastic syndromes (MDS) and chronic myelomonocytic leukemia (CMML), which signifies an advancement in MDS treatment options. MDS are a collection of conditions that are classified as a type of blood cancer. MDS occur when blood cells in the bone marrow become abnormal, resulting in low healthy blood cell counts. Currently, a variety of treatments are used to help manage the condition, including stem cell transplants, chemotherapy (e.g. intravenous decitabine) and blood transfusions. Clinical trials evaluating the medication showed that similar blood levels were achieved with oral Inqovi® (decitabine and cedazuridine) taken once daily for 5 consecutive days compared to intravenous (IV) decitabine administered as a 1-hour infusion. Both drugs also displayed similar safety profiles, with common adverse events including fatigue, constipation and nausea. The approval of Inqovi® represents an alternative treatment option for patients who previously needed to visit a health care facility to receive IV therapy.

Safety First

FDA Adds Safety-Related Labeling Change to Rheumatoid Arthritis Drug

On July 8, 2020, the FDA published a Drug Safety-related Labeling Change (SrLC) to several sections of the prescribing information of Olumiant® (baricitinib), a medication approved to treat Rheumatoid Arthritis (RA). As a result of the SrLC, an exaggerated immune response (hypersensitivity) is now listed under the Warnings and Precautions section of the label due to reports of angioedema (rapid swelling beneath the skin), itching and rash in patients taking the medicine. However, these reactions were self-reported in a population of unknown size and it is therefore difficult to accurately estimate their frequency or establish a cause-and-effect relationship as outlined in the label. Additionally, the Patient Counseling Information/Patient Information/Medication Guide (PCI/PI/MG) section now advises patients who experience allergic symptoms while taking Olumiant® to stop taking the medicine and contact their health care provider right away.

From the Industry

Tremfya® Receives FDA Approval for Treatment of Psoriatic Arthritis (PsA)

On July 14, 2020, Johnson and Johnson announced that the FDA has approved Tremfya® (guselkumab) for treatment of adult patients with active psoriatic arthritis (PsA), making it the first medicine in its class to be approved for the condition. PsA is a chronic, inflammatory disease of the joints and commonly results in swelling, pain, and stiffness of the joints and surrounding areas. Tremfya® is part of a class of medications known as selective interleukin (IL)-23 inhibitors, which help to limit the inflammation that causes symptoms. In clinical trials, Tremfya® was found to significantly improve signs and symptoms in joints, skin, and soft tissue in adult patients with PsA. Psoriasis is estimated to affect more than 8 million Americans and studies show that 10-30% of these patients will develop PsA.

FDA Approvals

Recent FDA Approvals

Novel Drug Approval: Byfavo™ (remimazolam)
Intravenous injection for induction and maintenance of sedation in adult patients undergoing procedures that last 30 minutes or less [7/2/2020 – COSMO]

Novel Drug Approval: Rukobia® (fostemsavir)
In combination with other antiretrovirals, Rukobia® extended-release oral tablet is indicated for for the treatment of adult patients infected with HIV who are failing other treatment regimens due to resistance, intolerance, or safety concerns [7/2/2020 – Priority Review – VIIV HLTHCARE]

Novel Drug Approval: Inqovi® (cedazuridine/decitabine)
Oral tablet for the treatment of adult patients with myelodysplastic syndromes (MDS) [7/7/2020 – Orphan Drug; Priority Review – OTSUKA]

Special Announcements

PBD Adding Coverage for COVID-19 Diagnostic Testing

As a result of updated guidance from the Department of Health (DOH), Centers for Medicare and Medicaid Services (CMS) and other federal and state recommendations, PBD will be adding coverage for COVID-19 diagnostic testing through certain registered and approved CLIA-waived pharmacies. This will include coverage for both nasal swab tests for active infection as well as collection of samples for antibody testing to submit to labs for final analysis. Tests are generally recommended to be requested by the member's primary care provider but, can be requisitioned and administered through CLIA-waived pharmacies directly after being screened by a pharmacist.

Members will have to verify if testing capability is available at their local pharmacies since not all pharmacies are CLIA-waived, approved, and registered to administer these tests. The approximate costs will range from $20-$50 per test depending on the test type, which is lower than initial estimates suggested, and will be processed as pharmacy claims. However, these services will be covered at $0 to the member, following federal guidelines mandating COVID-19 testing have no member cost share.

HHS Extends COVID-19 Public Health Emergency

U.S. Department of Health and Human Services (HHS) Secretary Alex Azar tweeted that he officially extended the COVID-19 public health emergency for another 90 days. The public health emergency is now scheduled to expire on October 23, 2020. Several payment policies and regulatory adjustments are attached to the public health emergency, including Medicare inpatient 20% add-on payment for COVID-19 patients, increased federal Medicaid matching rates, requirements that insurers cover COVID-19 testing without cost-sharing, and waivers of telehealth restrictions.

PBD's system adjustments will be extended until October 23, 2020 to align with this new guidance.

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