MC-Rx

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Drug Information Updates

Tremfya Adds Second Indication **07/13/2020**

Tremfya® (guselkumab - Janssen), an interleukin-23 (IL-23) inhibitor gained an additional indication as the first drug in its class for treating psoriatic arthritis (PsA). By blocking a key cytokine, it interferes with inflammation and the immune process. PsA affects approximately 1.5 million patients. Tremfya's recommended dose is 100mg, available as single-dose prefilled syringes and One-Press auto-injectors for subcutaneous (SC) use. The first injection is followed by a second four weeks later, then every eight weeks thereafter.

Formulary Status: Tremfya is a tier 3 non-preferred brand specialty drug on the National Formulary

New Indication for Qutenza **07/18/2020**

Qutenza® (capsaicin – Averitas Pharma) 8% patch was given a new indication to relieve peripheral neuropathy of the feet for adult patients who have diabetes. For the new use, up to four patches will be applied to the patient's feet in a well-ventilated treatment facility and by a trained healthcare provider using appropriate protection, such as nitrile gloves and a face shield. Patches may be cut to fit the size and shape of the painful areas, which must be pretreated with a topical anesthetic before the patches are applied. Left in place on the feet for no more than 30 minutes, Qutenza patches are believed to deactivate pain receptors. For most patients, side effects can be managed with ice packs and oral pain medications. Treatments, which should be at least three months apart, also may cause brief episodes of hypertension, so blood pressure will be monitored during therapy sessions.

Formulary Status: Qutenza Patches are not covered under the pharmacy benefit as they are only to be administered in a healthcare setting

Wynzora Wins Approval **07/20/2020**

MC2 Therapeutics received approval for Wynzora® (calcipotriene/betamethasone dipropionate) 0.005%/0.064% topical cream, the first cream in class and not interchangeable with any other product. Combining a vitamin D analogue and a corticosteroid, it is indicated to treat plaque psoriasis for patients at least 18 years old. Directions are to coat affected areas with the cream once a day until plaques clear up. No more than 100g should be used per week and Wynzora should not be used continually for more than eight weeks, but not applied to the armpits, face or genital area.

Formulary Status: Wynzora will be reviewed at the next P&T Committee meeting in September

Xywav Approved for Excessive Daytime Sleepiness **07/21/2020**

Xywav™ (calcium, magnesium, potassium and sodium oxybates) oral solution from Jazz Pharmaceuticals was approved to treat patients 7 and older with cataplexy (sudden loss of muscle tone, but not consciousness) and excessive daytime sleepiness (EDS). A successor to Xyrem®, Xywav has 92% less sodium (approximately 1,000mg and 1,500mg less per night) than Xyrem. For patients transitioning from Xyrem, the starting dose of Xywav is the same as the Xyrem dose. For patients new to treatment, doses begin at 4.5g/night – divided into one 2.25g dose at bedtime and a second one at two and one-half to four hours later. Xywav doses may be increased by 1.5g/night on a weekly basis until the target maintenance dose is reached. Both doses must be diluted with about one-fourth cup of water in separate designated containers and placed within easy reach of the patient, who should take each dose while in bed and lie down after dosing. Xywav will be distributed through the Xywav/Xyrem Risk Evaluation and Mitigation Strategy (REMS) that requires prescribers and dispensers to be trained and certified.

Formulary Status: Xywav will be reviewed at the next P&T Committee meeting in September

Breztri Aerosphere Approved **07/24/2020**

AstraZeneca's Breztri Aerosphere™ (budesonide/glycopyrrolate/formoterol), a combination metered-dose inhaler containing a corticosteroid, a long-acting muscarinic antagonist (LAMA) and a long-acting beta$_2$ agonist (LABA) was approved as maintenance therapy for patients with chronic obstructive pulmonary disease (COPD). Recommended dosing is two oral inhalations every morning and two more each evening. It will be supplied as 120 inhalations per inhaler.

Formulary Status: Breztri will be reviewed at the next P&T Committee meeting in September

US FOOD & DRUG ADMINISTRATION — IMPORTANT INFORMATION

NALOXONE SAFETY WATCH: In a Safety Communication, the FDA alerted prescribers, pharmacies and patients of a new requirement for opioid drugs. It is directing drug manufacturers that make opioids for pain relief and for use in treating opioid use disorder to add information on the labels about the use of **Naloxone**. As emergency treatment for opioid overdoses, **Naloxone** blocks breathing problems that can cause death from overdoses. Several doses may be needed to control an overdose, but **Naloxone** is not a substitute for emergency medical help. Even if it is used to reverse an overdose, 911 should be called and medical attention given to the patient. The FDA suggests that health professionals who prescribe opioids discuss **Naloxone** with patients and provide prescriptions for those who might be at risk for overdoses. Some states allow pharmacies to dispense it without a prescription. Patients and their caregivers should be trained in how and when to use **Naloxone**, and patients should carry it with them. Click Here to View the Notice.

HAND SANITIZERS: During June and July, the FDA has issued a series of warnings that some commercial **hand sanitizers** contain methanol and it has asked a number of manufacturers to recall their products. Methanol is intended for industrial use in products such as pesticides and solvents, has no medical uses, and should never be ingested. If it is absorbed through the skin, methanol can cause dangerous acid buildup in the blood. Immediate symptoms of methanol poisoning can include blurred vision, confusion, dizziness, drowsiness, headache and nausea.

Anyone who thinks they may have signs of methanol poisoning or who thinks they may have been exposed to methanol should talk with a doctor right away. Prolonged contact with or consumption of large amounts can lead to serious side effects, such as blindness, coma, seizures and death. The FDA has received reports of deaths, including some children who drank a **hand sanitizer** by accident, associated with some of the products being recalled. *It reminds the public that frequently washing hands with soap and water for at least 20 seconds is the best way to prevent the spread of disease.* If **hand sanitizers** are used, they should contain 60% or more of **ethanol** (also called ethyl alcohol). Many of the recalled products are labeled as ethanol, so people who have hand sanitizers should check the FDA's website for the brand name of the product. For more information, including a list of the affected products, Click Here to View the Notice & List.

IMPENDING FDA REVIEWS SCHEDULED FOR THE NEXT 2 WEEKS:

07/30: Adlarity® (donepezil transdermal system - Corium): A new once-weekly dosage form for the cholinesterase inhibitor to treat of dementia of the Alzheimer's type; topical

07/31: Epidiolex® (cannabidiol – GW Pharmaceuticals): A new indication for the highly purified solution for treatment of seizures associated with tuberous sclerosis complex (TSC); oral

08/02: Trelegy® Ellipta® (fluticasone furoate/umeclidinium/vilanterol – GlaxoSmithKline): A new indication for the combination corticosteroid/LAMA)/LABA for treating adults who have asthma; inhalation

08/02: Spravato® C-III (esketamine – Janssen): A new indication for the small-molecule NMDA receptor antagonist for the rapid reduction of depressive symptoms in adult patients who have major depressive disorder and active suicidal ideation with intent; intranasal

For more information, please either visit FDA.gov or contact your account manager.