MC-Rx

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Drug Information Updates

Genentech Receives Approval for Phesgo **06/29/2020**

Phesgo™ (pertuzumab/trastuzumab/hyaluronidase-zzxf) injection was approved to treat human epidermal growth factor receptor 2 positive (*HER2+*) breast cancer. A fixed-dose combination of two monoclonal antibodies that each obstruct separate parts of HER2 receptors, it is the first subcutaneous (SC) formulation for either of its active components. Additionally, it contains a proprietary hyaluronidase that is formulated to allow rapid SC administration. Although Phesgo still must be administered by a healthcare professional, treatments will need only a few minutes compared to one hour or longer for the intravenously (IV) infused dosage forms of the two drugs. Boxed warnings caution that using Phesgo may result in serious adverse effects on the heart and/or lungs.

Formulary Status: Phesgo is not covered under the pharmacy benefit as it is administered in a healthcare setting

New Bavencio Indication **06/30/2020**

Bavencio® (avelumab – EMD Serono/Pfizer) injection was approved to maintain disease-free status for patients whose locally advanced or metastatic urothelial carcinoma has not progressed during chemotherapy (chemo) with a platinum compound. The new maintenance indication is based on results of a phase III clinical trial showing that overall survival (OS) for patients using Bavencio along with best supportive care averaged about seven months longer than for patients receiving only best supportive care. Its recommended dosing is 800mg given as a 60-minute IV infusion once every two weeks.

Formulary Status: Bavencio is not covered under the pharmacy benefit as it is administered in a healthcare setting

Mycapssa Approved for Treatment of Acromegly **06/30/2020**

Mycapssa® (octreotide) capsules by Chiasma was approved for the maintenance of patients who have acromegaly that has been treated successfully with another octreotide product or with Somatuline® Depot (lanreotide - Ipsen). Acromegaly, most frequently caused by nonmalignant pituitary tumors, produces characteristic broadening of the face, feet and hands. It also may be associated with bone, heart and lung conditions. If needed, Mycapssa's recommended initial dose of 20mg twice a day may be increased to a daily maximum of 80mg (two capsules twice a day). Chiasma, plans a fourth quarter 2020 launch at a wholesale acquisition cost (WAC) of $5,152 for a 28-day supply of capsules at the 40mg/day dose level.

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

Dojolvi Approved for Fatty Acid Oxidation Disorders **06/30/2020**

Ultragenyx received approval for Dojolvi™ (triheptanoin) as a source of calories and fatty acids for the treatment of pediatric and adult patients who have molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD). Patients with this group of genetic disorders are unable to convert long-chain fatty acids into energy. Dosing is based on patients' metabolic requirements as determined by their daily caloric intakes (DCI). The recommended target daily dose is up to 35% of a patient's total prescribed DCI divided into at least four doses; diluted with foods, liquids or formula and administered by a feeding tube.

Formulary Status: Dojolvi is not covered under the pharmacy benefit as it is administered in a healthcare setting

Rukobia Approved for HIV-1 Infections **07/02/2020**

ViiV Healthcare received approval for a new HIV-1 drug, Rukobia™ (fostemsavir) for use in combination with other antiretrovirals, for the treatment of HIV-1 infections in heavily treatment-experienced adults with multidrug-resistant HIV-1 infections failing their current antiretroviral regimen due to resistance, intolerance or safety considerations. Rukobia is a novel oral antiretroviral known as a glycoprotein 120 (gp120) attachment inhibitor, and works by binding to the viral envelope protein, preventing viral attachment and entry into T-cells. The drug will be available in 600mg extended-release tablets with a dose of 600mg orally twice per day. Rukobia is expected to be launched late in July.

Formulary Status: Rukobia will be a tier 2 preferred brand specialty drug on the National Formulary

Byfavo Approved for Short Term Sedation **07/02/2020**

Cosmo Pharmaceuticals received approval for Byfavo™ (remimazolam) injection, a benzodiazepine with a very short action that will be used as moderate sedation for patients who have procedures, such as colonoscopies, that last one-half hour or less. To initiate sedation, the recommended adult doses are 5mg given intravenously (IV) over one minute or 2.5mg to 5mg if the patient is receiving other IV fluids. Launch for Byfavo depends on the date that it is scheduled as a controlled substance by the DEA.

Formulary Status: Byfavo is not covered under the pharmacy benefit as it is administered in a healthcare setting

Inqovi Approved for MDS & CMML **07/07/2020**

Astex Pharmaceuticals, a subsidiary of Otsuka Pharmaceutical Company, received approval for Inqovi® tablets, a fixed-dose combination of 35mg of decitabine, an antimetabolite, with 100mg of cedazuridine, a new cytidine deaminase inhibitor. Inqovi is indicated to treat adult patients who have specific subtypes of intermediate- and high-risk myelodysplastic syndromes (MDS), including chronic myelomonocytic leukemia (CMML). One tablet will be taken daily on an empty stomach for the first five days of 28-day treatment cycles. Inqovi will be available in the first half of August.

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

Hulio, a Biosimilar to Humira Approved **07/06/2020**

Hulio® (adalimumab-fkjp) was approved as a biosimilar to Humira® (adalimumab - AbbVie). Hulio is a TNF blocker that inhibits inflammation, and is indicated for treating adults who have ankylosing spondylitis, Crohn's disease, plaque psoriasis, psoriatic arthritis, rheumatoid arthritis (RA) and ulcerative colitis (UC). It also is approved for treating children four years old and older who have polyarticular juvenile idiopathic arthritis (pJIA). A prefilled, 40mg pen device will be available, as will prefilled syringes in both 20mg and 40mg strengths. Hulio will not be not interchangeable with Humira or with the other Humira biosimilars that already are FDA approved, and under the terms of an agreement with AbbVie, *Hulio will not be available in the U.S. until July 31, 2023*.

Formulary Status: Like all Humira biosimilars, Hulio will not be reviewed until early 2023

Qwo Receives Approval for Reduction of Cellulite in Women **07/06/2020**

Qwo™ (collagenase clostridium histolyticum-aaes – Endo International) was approved to reduce moderate-to-severe cellulite in the buttocks of women. It will be injected SC by trained health professionals using as many as 12 separate 0.3mL doses per affected side. Therapy will be spread over three separate injection cycles per side at 21-day intervals. Four-fifths of the women involved in testing for Qwo experienced temporary bruising, nearly one-half had pain and about one-third developed nodules, all at the injection sites. It presently is not approved for any other conditions, and Qwo cannot be interchanged with any other collagenase products. A launch is planned for the spring of 2021 through the offices of cosmetic surgeons, dermatologists and other aesthetic medical providers.

Formulary Status: Qwo is not covered under the pharmacy benefit as it is administered in a healthcare setting

Upneeq Approved for Drooping Eyelids **07/08/2020**

Osmotica Pharmaceutical's Upneeq™ was approved for the treatment of acquired blepharoptosis, or abnormal eyelid drooping, in adults. Upneeq, available as oxymetazoline 0.1% eye drops in a preservative-free solution is a reformulation of the vasoconstrictor oxymetazoline, a common active ingredient within over the counter nasal sprays. The drug works by constricting the Müller's muscle of the eye, raising the upper eyelid. The recommended dose is one drop topically into each affected eye once per day. Patients who suffer from blepharoptosis can have one or both eyelids affected which can impair peripheral vision and cause a "sleepy" appearance. Osmotica is launching the drug in August through a new subsidiary called RVL Pharmaceuticals, which will market and dispense exclusively through their fully owned and operated pharmacy. The company is using a cash-only model, in a direct-to-consumer pricing and dispensing strategy, at a cost of $3 to $4 per day, with discounts for a three-month supply. The product will be available as 0.3mL single-use containers in 15 or 30 count cartons.

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

New Pediatric Indications Approved for Dysport and Botox **06/19/2020**

Dysport: Ipsen Pharmaceuticals received approval for Dysport® (abobotulinumtoxinA) to treat both upper limb and lower limb spasticity from all causes, including cerebral palsy, for children at least two years old. For spasticity in the arms, its recommended pediatric dose for each arm is eight Units to 16 Units/kg or a maximum of 640 Units; for each leg, the dose is 10 Units to 15 Units/kg up to a maximum of 1,000 Units. Each total dose is divided into smaller injections that are administered in several sites of each muscle. Treatments should be separated by at least three months.

Botox: Botox® (onabotulinumtoxinA - Allergan) was approved to treat children as young as two years old who have spasticity in their lower legs due to cerebral palsy. To treat cerebral-palsy related spasticity in the lower legs, the pediatric dose is four Units to eight Units/kg of the child's body weight given as one Unit to two Units/kg injected into two separate sites in each affected muscle at the back of the calf. No more than eight Units/kg or 300 Units should be used for any one treatment and doses should total no more than the lower of 10 Units/kg or 300 Units in any 90-day period.

Formulary Status: Both drugs are not-preferred brands under pharmacy benefit and covered under medical benefit

IMPENDING FDA REVIEWS SCHEDULED FOR THE NEXT 2 WEEKS:

07/08: Ryanodex® (dantrolene – Eagle Pharmaceuticals): A new indication for the treatment of exertional heat stroke; IV

07/10: Vyrologix™ (leronlimab - CytoDyne): A C-C chemokine receptor type 5 (CCR5) receptor antagonist/immunomodulator for the treatment of human immunodeficiency virus (HIV) infection; SC

07/13: Ycanth™ (cantharidin 0.7% topical solution – Verrica Pharmaceuticals): Blistering agent for treatment of Molluscum Contagiosum lesions; topical

07/16: Tremfya® (guselkumab – Janssen): New indication for the interleukin-23 (IL-23)-targeting monoclonal antibody to treat adults who have active psoriatic arthritis (PsA); SC

GENERAL INFORMATION:

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