MC-Rx

Powered by ProCare Rx

Drug Update

Volume 2020 #15

Prepared for 06/01/2020

Drug Information Updates

Kynmobi Approved for Parkinson's Disease **05/21/2020**

The FDA approved Sunovion's Kynmobi™ (apomorphine) to treat "off" episodes in patients who have Parkinson's disease (PD). PD is a progressive deterioration of nerve function due to reduced dopamine production that can cause balance problems, shaking and stiffness. Although drugs that restore dopamine levels are used to treat PD, the drug effect sometimes "wear off" between doses. Kynmobi, a single film, sublingually administered dopamine agonist, is designed to act quickly for relieving these "off" episodes. Doses should be limited to a maximum of 30mg and no more than five doses should be administered per day. Kynmobi sublingual film will launch in September in various strengths.

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

Rubraca Approved for Prostate Cancer **05/15/2020**

Clovis Oncology received FDA approval for Rubraca® (rucaparib) tablets for the treatment of adult patients with deleterious *BRCA* mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC). Patients should be treated first with an androgen receptor therapy and a taxane-based chemotherapy. The recommended dose is 600mg orally (two 300mg tablets) twice per day with or without food until disease progression or unacceptable toxicity. Patients who are being treated for mCRPC should also receive a gonadotropin-releasing hormone (GnRH) analog or have surgical removal of both testicles in order to lower testosterone production.

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

Lynparza Approved for Another New Indication **05/20/2020**

AstraZeneca's Lynparza® (olaparib) tablets received FDA approval for treatment of adult patients who have deleterious or suspected germline or somatic homologous recombination repair (HRR) gene mutated metastatic castration-resistant prostate cancer (mCRPC). A new indication for the approved drug, it should be used after the patient tries and fails Xtandi® - (enzalutamide - Pfizer/Astellas) or Zytiga® (abiraterone - Janssen). The recommend dose of Lynparza is 300mg taken orally twice daily with or without food.

Formulary Status: Lymparza is a tier 2 preferred brand specialty drug on the National Formulary

Tecentriq Receives New Indication **05/18/2020**

Genentech's Tecentriq® (atezolizumab) injection has been granted an additional FDA indication for treating NSCLC, being approved for first-line treatment of adults who have NSCLC tumors with 50% or more PD-L1 expression and no deformities in EGFR or ALK genes. Either alone or in multi-drug regimens, Tecentriq has previous indications for some other kinds of NSCLC and for some small cell lung cancers (SCLC), triple-negative breast cancers (TNBC) and urothelial cancers. For NSCLC, Genentech suggests a dose of 840mg once every two weeks, 1200mg once every three weeks or 1680mg once every four weeks, administered through an IV infusion.

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

Generic Launched for Samsca 30mg **05/21/2020**

Apotex launched Tolvaptan tablets, 30mg, on May 21, 2020. An AB-rated generic to Otsuka's Samsca® 30mg tablets, it is dispensed in blister packs each containing 10 tablets and is indicated to regulate hyponatremia (low blood sodium levels) for certain patients who have cirrhosis, heart failure or other conditions that deplete sodium and that have not been relieved by limiting fluid intake. Beginning at 15mg per day, doses may be increased to a maximum of 60mg/day if sodium levels do not recover. Tolvaptan should be discontinued when blood sodium stabilizes at normal levels and should not be taken for longer than 30 days at a time because liver damage may occur. Samsca's 15mg tablet formulation remains brand-only, as do all strengths of Jynarque® (tolvaptan – Otsuka) tablets, which are taken continually to decrease the worsening of kidney function for patients who have rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).

Formulary Status: Position of Tolvaptan is uncertain pending a price review at the next P&T Committee meeting in June

Phexxi Contraceptive Approved **05/22/2020**

Evofem Biosciences received FDA approval for Phexxi™ (L-lactic acid/citric acid/potassium bitartrate) vaginal gel. A unique form of contraception, Phexxi is a non-hormonal product that works by adjusting the pH (acid-alkaline balance) in the vagina to an acidic level that does not sustain sperm, as well as provides vaginal lubrication. One prefilled, single-dose applicator is inserted vaginally up to one hour before having sex. Release is scheduled for early September at a WAC estimated at $250 - $275 per box of 12.

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

VESIcare LS Approved for Pediatric Patients **05/27/2020**

Astellas' VESIcare LS® (solifenacin) oral suspension, a new dosage form was approved for the treatment of pediatric patients who have neurogenic detrusor over-activity (NDO), a form of bladder dysfunction caused by disease or injury in the nervous system. VESIcare LS helps increase the amount of urine the bladder can hold and decrease the amount of urine that leaks. Its effectiveness for children was established in two trials that included patients from 2 to 17 years old. VESIcare 5mg/5mL oral solution will be available in late 2020 with weight based recommended dosing and taken once daily followed by liquid, such as milk or water.

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

Artesunate Approved to Treat Severe Malaria **05/27/2020**

Artesunate for Injection, a component of the natural product artemisinin, was approved as the drug of choice to treat severe cases of malaria. An Orphan Drug previously available only through the CDC's investigational new drug (IND) program, it is estimated that about 15% of the approximately 2,000 U.S. patients who are diagnosed as having malaria each year will have the severe form of the disease. The recommended dose of Artesunate is 2.4mg/kg, where patients receive three doses given as one-to-two-minute bolus intravenous (IV) injections at 12-hour intervals on the first day followed by one dose daily until parasite levels are 1% or lower, but no longer than seven total days. Treatment with artesunate should be accompanied by therapy with another malaria drug, such as primaquine, that is approved for malaria caused by certain types of parasites. A complete, three-day course of treatment with an oral antimalarial drug, such as Coartem® (artemether/lumefantrine - Novartis), should be taken after artesunate treatment ends.

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

Dupixent Approved for Children **05/26/2020**

The FDA approved Dupixent® (dupilumab – Sanofi) for children aged 6 to 11 years of age who have moderate to severe atopic dermatitis and whose disease is not adequately controlled with topical prescription therapies. Dupixent, the first biologic approved for this patient population, will be given as subcutaneous (SC) injections, at different injection sites. The pediatric weight-based dose, for patients up to 11 years of age is 300mg once every 4 weeks for children weighing between 15kg (33 pounds) and 30kg (66 pounds) or 200mg once every two weeks for children weighing between 30kg and 60kg (132 pounds) following an initial loading dose. Dupixent is also approved to be used with other asthma medicines for maintenance treatment of moderate-to-severe eosinophilic or oral-steroid dependent asthma in patients 12 years and older, and as an add-on maintenance therapy for adult patients who have uncontrolled chronic rhino-sinusitis with nasal polyps (CRSwNP).

Formulary Status: Dupixent is a tier 2 preferred brand specialty drug on the National Formulary

Alunbrig Approved for ALK+ NSCLC **05/27/2020**

Takeda Oncology's Alunbrig™ (brigatinib), an oral tyrosine kinase inhibitor (TKI), received an additional approval as a first-line treatment for patients who have metastatic anaplastic lymphoma kinase-positive (ALK+) non-small cell lung cancer (NSCLC). NSCLC, the most common form of lung cancer, although only about 2-8% of NSCLC patients also have ALK mutations. Originally approved for patients who have progressed or who were intolerant to Xalkori® (crizotinib – Pfizer/EMD Serono), Alunbrig was superior to Xalkori in results from the phase III ALTA 1L trial (results available).

Formulary Status: Alunbriq is a tier 2 preferred brand specialty drug on the National Formulary

Pediatric Indication / New Formulation Approved for Sirturo **05/20/2020**

Janssen gained pediatric approval for Sirturo® (bedaquiline) tablets to be used along with other drugs to treat tuberculosis (TB). Granted approval for a 20mg tablet that can be mixed with liquids or soft foods for patients who have trouble swallowing whole tablets, Sirturo now is indicated for children as young as 5 years old who weigh at least 15kg and who have TB that has resisted therapy with previous drug regimens. The recommended dose for children is weight based. At least three other TB drugs must be taken at the same time, as well.

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

New Formulation of Ferriprox Approved **05/19/2020**

Ferriprox® (deferiprone – Chiesi Global Rare Diseases) tablets, an oral chelating agent, were approved to treat patients who have iron overload due to blood transfusions for treating thalassemia syndromes. The new form allows for twice-daily dosing instead of the previous three-times a day formulation first approved. Thalassemias are rare hereditary conditions that reduce the body's production of hemoglobin. Where the resulting decrease in oxygen supplies can cause heart, liver and spleen damage, as well as anemia. Ferriprox and similar chelators, such as Exjade® (deferasirox – Novartis/generics) tablets and Jadenu® (deferasirox – Novartis/generics) tablets and granules, remove the excess iron.

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

First Generic for Vascepa Approved, but not Launched **05/21/2020**

After a U.S. District Court decision invalidated some of the patents on Vascepa® (icosapent ethyl – Amarin) capsules, 1gm, Hikma Pharmaceuticals USA won FDA approval for a generic. The derivative of eicosapentaenoic acid (EPA) is used to reduce triglycerides (TG) for patients who have severely high TG levels. Late last year, Vascepa received an additional FDA indication for combination use with the highest tolerated dose of a statin to reduce the risk of several established cardiovascular (CV) diseases or for patients who have diabetes along with two or more additional risk factors for CV disease. A launch date for Hikma's generic is uncertain as Amarin appealed the court ruling. At least one other generic manufacturer has settled with Amarin not to release a generic to Vascepa until 2029.

Formulary Status: Vascepa is a tier 2 preferred brand drug on the National Formulary

Warning for Extended-Release Metformin **05/28/2020**

The FDA released a notice about unacceptable amounts of a probable cancer-causing chemical NDMA in some tablets of extended-release metformin. Not all manufacturers are affected and no immediate-release tablets are believed to contain excess NDMA. Although short-term ingestion of NDMA in the small amounts found in the tested tablets is not likely to cause cancer, repeated exposure over very long periods may slightly increase the risk. Patients who are concerned about their extended-release metformin should continue to take it and discuss an alternative product with their healthcare providers.

IMPENDING FDA REVIEWS SCHEDULED FOR THE NEXT 2 WEEKS:

*05/*25: Instiladrin® (nadofaragene firadenovec – Ferring Pharmaceuticals/FerGene): treatment of patients who have non-muscle invasive bladder cancer and are unresponsive to Bacillus Calmette-Guerin (BCG) vaccine; intravesical infusion.

*05/*25: Artesunate – La Jolla Pharmaceutical): Treatment for severe malaria: intravenous infusion

*05/*26: Dupixent® (dupilumab – Regeneron Pharmaceuticals): New indication to treat children aged 6 to 11 years old who have moderate-to-severe eczema; subcutaneous injection

*06/*04: Recarbrio® (cilastatin/relebactam/imipenem - Merck): New indication for the antibacterial combination to treat adult patients who have hospital-acquired bacterial pneumonia; IV

GENERAL INFORMATION:

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