MC-Rx

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# Drug Information Updates

**Margenza Approved to Treat Breast Cancer** **12/16/2020**

Margenza™ (margetuximab-cmkb – MacroGenics) a monoclonal antibody injection was approved to treat certain forms of cancer. It attacks human epidermal growth factor receptor 2 (HER2) proteins that are on some cancer cells, and is indicated for treating adults who have (HER2+) breast cancer that has been treated at least twice with other HER2 inhibitors. One or more of the previous treatments must have been administered following metastasis. Chemotherapy (chemo) will be given along with Margenza. It is dosed once every three weeks as intravenous (IV) infusions at 15mg/kg.

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

**FDA Approves New Indication for Benlysta** **12/16/2020**

Under priority review as a breakthrough therapy, Benlysta® (belimumab – GlaxoSmithKline) got an additional indication for treatment, adults who have active nephritis (kidney inflammation) that is associated with the autoimmune condition, systemic lupus erythematosus (SLE). Benlysta has both an IV and a subcutaneous (SC) form, with the SC version only indicated for treating adults over 18 who have SLE and lupus nephritis. By IV, dosing for lupus nephritis is 10mg/kg once every two weeks for the first three doses, then once every four weeks. SC doses are given weekly at 400mg (two prefilled syringes or two auto-injectors) for four weeks, then reduced to 200mg.

*Formulary Status*: Benlysta is a tier 2 preferred specialty brand on the National Formulary

**Riabni, Third Biosimilar to Rituxan, Approved** **12/17/2020**

Riabni™ (rituximab-arrx), Amgen's biosimilar to Rituxan® (rituximab – Celgene), was approved by the FDA. It is indicated to treat adults who have non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukemia (CLL) or granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA). A monoclonal antibody, it causes B cells to disintegrate by binding to CD20 proteins on their cell surfaces. Administered as IV infusions, it has to be given by a health professional in a facility equipped to handle emergency treatment of serious side effects that it may cause.

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

**FDA Approves Klisyri for Actinic Keratosis** **12/18/2020**

Athenex received FDA approval for Klisyri® (tirbanibulin) ointment, 1%, a topical microtubule inhibitor indicated to treat adults who have actinic keratoses (skin patches from sun exposure) on the face and scalp. As many as 15% of actinic keratoses lead to skin cancers. Almirall will collaborate with Athenex to introduce Klisyri during the first quarter of 2021. Recommended dosing is one packet (250mg) per day on the affected areas for five days in a row. Areas around the eyes and mouth should be avoided completely, and hands should be washed thoroughly, right away; but treated skin should not be washed for at least eight hours after each application.

*Formulary Status*: Klisyri will be reviewed at the next P&T Committee meeting

**Orgovyx Approved for Advanced Prostate Cancer** **12/18/2020**

The FDA approved Orgovyx (relugolix – Myovant Sciences), an oral drug in the gonadotropin-releasing hormone (GnRH) receptor antagonist class, to treat advanced prostate cancer. After a 360mg dose (three tablets) on Day 1, recommended dosing is one 120mg tablet each day, either with food or on an empty stomach. No plans for launch, pricing or distribution have yet been announced.

*Formulary Status*: Orgovyx will be reviewed at the next P&T Committee meeting

**Moderna Vaccine Approved for Covid-19 Prevention** **12/18/2020**

The FDA granted an emergency use authorization for Moderna's vaccine to prevent COVID-19. Approval on the following day from the CDC allowed for immediate shipping. Administered by intramuscular (IM) injection, it needs two 100mcg doses that are 28 days apart to be fully effective. Because it can withstand higher temperatures, handling for Moderna's vaccine is less complicated than transporting and administering Pfizer's COVID-19 vaccine, which got an EUA earlier in December.

*Formulary Status*: The Moderna Covid-19 vaccine will be a tier 2 preferred vaccine on the National Formulary

**Ebolavirus Treatment Ebanga for Zaire Strain Approved** **12/21/2020**

A monoclonal antibody, Ebanga™ (ansuvimab-zykl - Ridgeback Biotherapeutics) was approved to treat ebolavirus infections caused by the Zaire strain of the virus. Approved for children as well as adults, it is given to patients as one intravenous (IV) infusion of 50mg/kg. Ebanga's approval was granted with the FDA's Breakthrough Therapy, Orphan Drug and Priority Review designations. Launch, pricing and prescribing information for Ebanga are not yet available.

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

**Expanded Indications or Regimens Granted:**

- Xpovio (selinexor): approved with regimen with bortezomib and dexamethasone for adults with multiple myelomas that have been treated at least once.
- Tagrisso® (osimertinib): approved for new indication is for adjuvant (secondary) therapy to treat adults who have early stages of non-small cell lung cancer (NSCLC) that tests positive for specific mutations (exon 19 deletions and/or exon 21 L858R mutations) in epidermal growth factor (EGFRm).
- Xeomin® (incobotulinumtoxinA): approved to treat chronic sialorrhea for children as young as two years old.
- Kineret® (anakinra): approval to treat deficiency of interleukin-1 receptor (IL-1R) antagonist (DIRA), a very rare autoimmune disorder with only a few known cases worldwide.
- Imbruvica® (ibrutinib): information added to the label by Pharmacyclics approved by FDA

## IMPENDING FDA REVIEWS SCHEDULED FOR THE NEXT 2 WEEKS:

***12/20:*** *FDA Action:* roxadustat (FibroGen): An hypoxia-inducible factor (HIF) prolyl hydroxylase (PH) inhibitor for the treatment of chemo-induced renal anemia in pre-dialysis patients who have chronic kidney disease (CKD); oral

*FDA Action:* Relumina® (relugolix – Myovant): A once-daily gonadotropin-releasing hormone (GnRH) receptor antagonist for the treatment of prostate cancer; oral

***12/26:*** *FDA Action:* vibegron (Urovant Sciences): A β3-adrenergic agonist for the treatment of adults who have symptoms of overactive bladder (OAB); oral

*FDA Action:* ansofaxine (Luye Pharma Group): A sustained-release tablet desvenlafaxine pro-drug for the treatment major depressive disorder (MDD); oral

***12/27*:** *FDA Action:* bevacizumab biosimilar (Mylan): A biosimilar to Avastin® (bevacizumab – Genentech), an angiogenesis inhibitor for the treatment of cancer; IV infusion

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*Patent Expiration:* Absorica® (isotretinoin – Ranbaxy): A settlement agreement allows Actavis to launch Dec. 27, 2020.

***12/29*:** *FDA Action*: eflornithine/sulindac (CP Pharmaceuticals) Combination of an ornithine decarboxylase inhibitor and a non-steroidal anti-inflammatory drug (NSAID) for preventive treatment of adults who have familial adenomatous polyposis (FAP); oral

*FDA Action Date*: Ontinua™ ER (arbaclofen – Osmotica): A twice-daily, extended-release muscle relaxant for the alleviation of spasticity in patients who have multiple sclerosis (MS); oral

***12/31*:** *FDA Action Date:* Aximris XR™ (oxycodone extended release – Intellipharmaceutics): An abuse-deterrent, controlled-release formulation of oxycodone for treatment of pain severe enough to require daily, round-the-clock opioids, with claims to deter abuse by oral, intranasal and intravenous pathways; oral

***01/01:*** *Patent Expiration:* Amitiza® (lubiprostone – Sucampo): A lawsuit settlement agreement allows Par Pharmaceutical to launch a generic on Jan. 1, 2021

## GENERAL INFORMATION:

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