

July 2021

**COM-2021-032**

Dear provider of pharmaceutical services,

Attached you will find an update of new indications and first-time generics approved by the U.S. Food and Drugs Administration (FDA) from January 2021 to March 2021.

For more details regarding FDA approvals, you can visit the FDA website ([www.fda.gov](http://www.fda.gov)) and other trustworthy drug information sources. If you would like to, you can subscribe to receive email updates with important FDA news and information as they become available at the [FDA Subscription Management Center](#).

PharmPix is committed to the health and wellness of our members. It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: <https://www.pharmpix.com/providers/>.

Regards,

PharmPix Clinical Department



**NEW FDA-APPROVED INDICATIONS  
(January 2021 – March 2021)**

|                          | <b>Drug name /<br/>Manufacturer</b>  | <b>Therapeutic class</b>                             | <b>Previous FDA- approved<br/>indication(s)</b>   | <b>New FDA-approved<br/>indication(s)</b>   |
|--------------------------|--|--|---|---|
| <b>January<br/>2021</b>  | <b>XALKORI<br/>(CRIZOTINIB)<br/>CAPSULES / PFIZER<br/>INC.</b>   | Antineoplastic agent                                 | Treatment of patients with advanced non-small cell lung cancer whose tumors are ALK-positive or ROS1-positive   | Treatment of pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma that is anaplastic lymphoma kinase (ALK)-positive |
|                          | <b>DARZALEX FASPRO<br/>(DARATUMUMAB<br/>AND<br/>HYALURONIDASE-<br/>FIHJ) INJECTION /<br/>JANSSEN<br/>PHARMACEUTICALS,<br/>INC.</b> | Antineoplastic agent                                 | Treatment of multiple myeloma   | Treatment of light chain (AL) amyloidosis   |
|                          | <b>ENHERTU (FAM-<br/>TRASTUZUMAB<br/>DERUXTECAN-NXKI)<br/>INJECTION /<br/>ASTRAZENECA AND<br/>DAIICHI SANKYO<br/>COMPANY</b>       | Antineoplastic agent                                 | Treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting  | Treatment of adult patients with locally advanced or metastatic HER2 positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen     |
|                          | <b>OPDIVO<br/>(NIVOLUMAB)<br/>INJECTION /<br/>BRISTOL-MYERS<br/>SQUIBB COMPANY</b>   | Antineoplastic agent                                 | Treatment of melanoma, non-small cell lung cancer, small cell lung cancer, malignant pleural mesothelioma, renal cell carcinoma, classical Hodgkin lymphoma, squamous cell carcinoma of the head and neck, urothelial carcinoma, MSI-H or dMMR metastatic colorectal cancer, hepatocellular carcinoma, and esophageal squamous cell carcinoma | In combination with CABOMETYX (cabozantinib) for the first-line treatment of patients with advanced renal cell carcinoma  |
| <b>February<br/>2021</b> | <b>GOCOVRI<br/>(AMANTADINE<br/>HYDROCHLORIDE)<br/>EXTENDED-RELEASE<br/>CAPSULES / ADAMAS<br/>PHARMACEUTICALS,<br/>INC.</b>         | Central nervous system agent;<br>Antiparkinson agent | Treatment of dyskinesia in patients with Parkinson’s disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications   | As an adjunctive treatment to levodopa/carbidopa in patients with Parkinson’s disease experiencing “off” episodes   |
|                          | <b>LIBTAYO<br/>(CEMIPLIMAB-<br/>RWLC) INJECTION /<br/>SANOFI</b>   | Antineoplastic agent                                 | Treatment of cutaneous squamous cell carcinoma (CSCC)   | Treatment of advanced basal cell carcinoma (BCC), previously treated with a hedgehog pathway inhibitor (HHI) or for whom an HHI is not appropriate  |



|                  | Drug name /<br>Manufacturer   | Therapeutic class                  | Previous FDA- approved<br>indication(s)  | New FDA-approved<br>indication(s)  |
|------------------|---|------------------------------------|--|--|
| February<br>2021 | <b>HUMIRA<br/>(ADALIMUMAB)<br/>INJECTION / ABBVIE<br/>INC.</b>  | Tumor Necrosis<br>Factor Inhibitor | Treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, crohn's disease, psoriasis, juvenile idiopathic arthritis, ulcerative colitis, hidradenitis suppurativa, and certain types of uveitis  | Patient population altered to include treatment of moderately to severely active ulcerative colitis in pediatric patients 5 years of age and older   |
| March<br>2021    | <b>LORBRENA<br/>(LORLATINIB)<br/>TABLETS / PFIZER<br/>INC.</b>  | Antineoplastic agent               | Treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on crizotinib and at least one other ALK inhibitor for metastatic disease; or whose disease has progressed on alectinib or ceritinib as the first ALK inhibitor therapy for metastatic disease   | First-line treatment patients with ALK-positive NSCLC  |
|                  | <b>YESCARTA<br/>(AXICABTAGENE<br/>CILOLEUCEL)<br/>SUSPENSION FOR<br/>INTRAVENOUS<br/>INFUSION / KITE<br/>PHARMA, INC.</b> | Antineoplastic agent               | To treat adult patients with certain types of large B-cell lymphoma who have not responded to or who have relapsed after at least two other kinds of treatment   | Treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy   |
|                  | <b>ARCALYST<br/>(RILONACEPT)<br/>INJECTION /<br/>REGENERON<br/>PHARMACEUTICALS,<br/>INC.</b>                              | Immunological agent                | Long term treatment of two Cryopyrin-Associated Periodic Syndromes (CAPS) disorders: Familial Cold Auto-Inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)   | Treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children 12 years and older  |
|                  | <b>KEYTRUDA<br/>(PEMBROLIZUMAB)<br/>FOR INJECTION /<br/>MERCK</b>   | Antineoplastic agent               | Treatment of melanoma, non-small cell lung cancer, small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high (TMB-H) cancer, cutaneous squamous cell carcinoma, and triple-negative breast cancer | Treatment of patients with locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) (tumors with epicenter 1 to 5 centimeters above the GEJ) carcinoma that is not amenable to surgical resection or definitive chemoradiation in combination with platinum- and fluoropyrimidine-based chemotherapy |
|                  | <b>MYRBETRIQ<br/>(MIRABEGRON)<br/>TABLETS /<br/>ASTELLAS PHARMA<br/>GLOBAL DEV INC</b>                                    | <b>Genitourinary<br/>agent</b>     | Treatment of adult overactive bladder (OAB)  | Treatment of neurogenic detrusor overactivity (NDO) in pediatric patients aged 3 years and OLDER AND WEIGHING 35 KG OR MORE  |

|               | Drug name /<br>Manufacturer  | Therapeutic class    | Previous FDA- approved<br>indication(s)  | New FDA-approved<br>indication(s)   |
|---------------|--|----------------------|--|---|
| March<br>2021 | VYXEOS<br>(CYTARABINE AND<br>DAUNORUBICIN)<br>INJECTION / JAZZ<br>PHARMACEUTICALS<br>PLC | Antineoplastic agent | Treatment of adults with two<br>types of acute myeloid leukemia<br>(AML): newly diagnosed<br>therapy-related AML (t-AML) or<br>AML with myelodysplasia-<br>related changes (AML-MRC) | Patient population altered to<br>include the treatment of newly-<br>diagnosed therapy-related acute<br>myeloid leukemia (t-AML) or<br>AML with myelodysplasia-<br>related changes (AML-MRC) in<br>pediatric patients aged one year<br>and older |

References:

- U.S. Food and Drug Administration (FDA). Available at: [www.fda.gov](http://www.fda.gov)
- New Indications & Dosage Forms for Existing Drugs. Drugs.com. Available at: <https://www.drugs.com/new-indications.html>



**FDA-APPROVED GENERICS  
(January 2021 – March 2021)**

|               | Drug name / Manufacturer   | Therapeutic class                    | Indication(s)   | Generic for: |
|---------------|--|--------------------------------------|---|--------------|
| January 2021  | FERUMOXYTOL INTRAVENOUS SOLUTION EQ 510MG IRON/17ML / SANDOZ INC.  | Hematopoietic agent; Iron            | <ul style="list-style-type: none"> <li>Chronic kidney disease - Iron deficiency anemia</li> <li>Iron deficiency anemia, Intolerant or unsatisfactory response to oral iron</li> </ul> | Feraheme     |
|               | IMIQUIMOD TOPICAL CREAM 3.75% / TARO PHARMACEUTICAL INDUSTRIES LTD.  | Dermatological agent                 | <ul style="list-style-type: none"> <li>Actinic keratosis</li> <li>Condyloma acuminatum of the ano-genital region</li> </ul>   | Zyclara      |
| February 2021 | LINACLOTIDE CAPSULES 145 MCG AND 290 MCG / MYLAN PHARMACEUTICALS INC.  | Gastrointestinal agent               | <ul style="list-style-type: none"> <li>Idiopathic constipation, chronic</li> <li>Irritable bowel syndrome characterized by constipation</li> </ul>                                    | Linzess      |
|               | LOTEPREDNOL ETABONATE OPHTHALMIC GEL 0.5% / AKORN OPERATING COMPANY LLC  | Ophthalmologic agent; Corticosteroid | Post-operative inflammation and pain following ocular surgery   | Lotemax Gel  |
|               | APREMILAST TABLETS 10 MG, 20 MG AND 30 MG / UNICHEM LABORATORIES LTD.  | Anti-inflammatory agent              | Plaque psoriasis  | Otezla       |
|               | DROXIDOPA CAPSULES 100 MG, 200 MG AND 300 MG / AJANTA PHARMA LIMITED; ALKEM LABORATORIES LIMITED; ANNORA PHARMA PRIVATE LIMITED; AUROBINDO PHARMA LIMITED; HIKMA PHARMACEUTICALS USA INC.; LUNDBECK PHARMACEUTICALS LLC; LUPIN PHARMACEUTICALS, INC.; MSN LABORATORIES PRIVATE LIMITED; SCIEGEN PHARMACEUTICALS, INC.; SUN PHARMACEUTICAL INDUSTRIES, INC.; TASMAN PHARMA INC.; TEVA PHARMACEUTICALS USA, INC.; ZYDUS PHARMACEUTICALS (USA) INC. | Vasopressor                          | Neurogenic orthostatic hypotension  | Northera     |
| March 2021    | No new first-time generic approved during March 2021.  |                                      |   |              |

References:

- U.S. Food and Drug Administration (FDA). Available at: [www.fda.gov](http://www.fda.gov)
- Latest Generic Drug Approvals. Drugs.com. Available at: <https://www.drugs.com/generic-approvals.html>

