New Indications & Dosage Forms For Existing Drugs

1. Lynparza (olaparib) Tablets

New Indication Approved: December 27, 2019
Date of Original Approval: December 19, 2014
Lynparza (olaparib) is a first-in-class oral poly ADP ribose polymerase (PARP) inhibitor indicated for the treatment of ovarian cancer, breast cancer and pancreatic cancer.

2. Fiasp (insulin aspart) Injection
Patient Population Altered: December 19, 2019
Date of Original Approval: September 29, 2017
Fiasp (insulin aspart) is a rapid-acting human insulin analog indicated to improve glycemic control in adults and children with diabetes mellitus. Fiasp is a newer formulation of NovoLog, in which the addition of niacinamide (vitamin B3) helps to increase the speed of initial insulin absorption.

3. Xtandi (enzalutamide) Capsules
New Indication Approved: December 16, 2019
Date of Original Approval: August 31, 2012
Xtandi (enzalutamide) is an androgen receptor inhibitor indicated for the treatment of patients with castration-resistant prostate cancer, and metastatic castration-sensitive prostate cancer.

4. Vascepa (icosapent ethyl) Capsules
New Indication Approved: December 13, 2019
Date of Original Approval: July 26, 2012
Vascepa (icosapent ethyl) is an ethyl ester of eicosapentaenoic acid (EPA) indicated as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia, and as an adjunct to statin therapy to reduce the risk of cardiovascular events.

5. Xeljanz (tofacitinib) Tablets
New Indication Approved: December 12, 2019
Date of Original Approval: November 6, 2012
Xeljanz (tofacitinib) is an oral Janus kinase (JAK) inhibitor for the treatment of adult patients with moderately to severely active rheumatoid arthritis, active psoriatic arthritis, and moderately to severely active ulcerative colitis.

6. Tecentriq (atezolizumab) Injection
New Indication Approved: December 3, 2019
Date of Original Approval: May 18, 2016
Tecentriq (atezolizumab) is a programmed death-ligand 1 (PD-L1) blocking antibody indicated for use in the treatment of urothelial carcinoma, non-small cell lung cancer (NSCLC), triple-negative breast cancer (TNBC), and small cell lung cancer (SCLC).

7. Calquence (acalabrutinib) Capsules
New Indication Approved: November 21, 2019
Date of Original Approval: October 31, 2017
Calquence (acalabrutinib) is a highly selective, potent, Bruton tyrosine kinase (BTK) inhibitor for the treatment of mantle cell lymphoma (MCL), and chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma.

8. Fluzone Quadrivalent (influenza virus vaccine, inactivated) Suspension for Intramuscular Injection
New Formulation Approved: November 4, 2019
Date of Original Approval: June 7, 2013
Fluzone Quadrivalent is an inactivated influenza virus vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.

9. Liletta (levonorgestrel) Intrauterine Device
New Dosage Regimen: October 25, 2019
Date of Original Approval: February 26, 2015
Liletta (levonorgestrel) is a hormonal intrauterine device (IUD) for use by women to prevent pregnancy for up to six years.

10. Baxdela (delafloxacin) Tablets and Injection
New Indication Approved: October 24, 2019
Date of Original Approval: June 19, 2017

Baxdela (delafloxacin) is a fluoroquinolone antibacterial indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia (CABP) caused by designated susceptible bacteria.

11. Zejula (niraparib) Capsules
New Indication Approved: October 23, 2019
Date of Original Approval: March 27, 2017
Zejula (niraparib) is an oral, poly ADP-ribose polymerase (PARP) inhibitor for the treatment of patients with ovarian, fallopian tube, or primary peritoneal cancer.

12. Cinvanti (aprepitant) Injection
New Dosage Regimen: October 21, 2019
Date of Original Approval: November 9, 2017
Cinvanti (aprepitant) is a polysorbate 80 free, intravenous formulation of aprepitant, a substance P/neurokinin-1 (NK_1) receptor antagonist indicated for the prevention of chemotherapy-induced nausea and vomiting (CINV).

13. Stelara (ustekinumab) Injection
New Indication Approved: October 18, 2019
Date of Original Approval: September 25, 2009
Stelara (ustekinumab) is a human interleukin-12 and -23 antagonist indicated for the treatment of moderate to severe plaque psoriasis (Ps), active psoriatic arthritis (PsA), moderately to severely active Crohn's disease (CD), and moderately to severely active ulcerative colitis.

14. Botox (onabotulinumtoxinA) Injection
Patient Population Altered: October 18, 2019
Date of Original Approval: December 9, 1991
Botox (onabotulinumtoxinA) is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for:

- treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication
- treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of an anticholinergic medication
- prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer)
- treatment of upper and lower limb spasticity in adult patients
- treatment of upper limb spasticity in pediatric patients 2 to 17 years of age
- treatment of lower limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy
- treatment of cervical dystonia in adult patients, to reduce the severity of abnormal head position and neck pain
- treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients
- treatment of blepharospasm associated with dystonia in patients 12 years of age and older
- treatment of **strabismus** in patients 12 years of age and older.

15. Farxiga (dapagliflozin) Tablets
New Indication Approved: October 18, 2019
Date of Original Approval: January 8, 2014
Farxiga (dapagliflozin) is a sodium-glucose cotransporter 2 (SGLT2) inhibitor indicated:

- As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors.

16. Ultomiris (ravulizumab-cwvz) Injection
New Indication Approved: October 18, 2019
Date of Original Approval: December 21, 2018
Ultomiris (ravulizumab-cwvz) is a long-acting C5 complement inhibitor for:

- The treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH)
- The treatment of adults and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA).

17. Xofluza (baloxavir marboxil) Tablets
Patient Population Altered: October 16, 2019
Date of Original Approval: October 24, 2018
Xofluza (baloxavir marboxil) is a polymerase acidic (PA) endonuclease inhibitor for the treatment of influenza (the flu) in people 12 years of age and older who have had flu symptoms for no more than 48 hours and who are otherwise healthy, or at high risk of developing flu-related complications.

18. Xarelto (rivaroxaban) Tablets
New Indication Approved: October 11, 2019
Date of Original Approval: July 1, 2011
Xarelto (rivaroxaban) is a factor Xa inhibitor indicated:

- to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation
- for the treatment of deep vein thrombosis (DVT)
- for the treatment of pulmonary embolism (PE)
- for the reduction in the risk of recurrence of DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months
- for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery
- for the prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients at risk for thromboembolic complications not at high risk of bleeding
- in combination with aspirin, to reduce the risk of major cardiovascular events (cardiovascular (CV) death, myocardial infarction (MI) and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD).

19. Descovy (emtricitabine and tenofovir alafenamide) Tablets
New Indication Approved: October 3, 2019
Date of Original Approval: April 4, 2016
Descovy (emtricitabine and tenofovir alafenamide) is a nucleoside analog HIV-1 reverse transcriptase inhibitor (NRTI) and nucleotide reverse transcriptase inhibitor (NtRTI) fixed-dose combination for the treatment of HIV-1 infection, and for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection.

20. Fasenra (benralizumab) Injection
New Dosage Form Approved: October 3, 2019
Date of Original Approval: November 14, 2017
Fasenra (benralizumab) is an interleukin-5 receptor alpha-directed cytolytic monoclonal antibody indicated for the treatment of patients with severe eosinophilic asthma.

21. Entresto (sacubitril and valsartan) Tablets
Patient Population Altered: October 1, 2019
Date of Original Approval: July 7, 2015
Entresto (sacubitril and valsartan) is a neprilysin inhibitor and angiotensin II receptor blocker combination indicated:

- to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction. Entresto is usually administered in conjunction with other heart failure therapies, in place of an ACE inhibitor or other ARB.
- for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older.

References: www.drugs.com

Information collected by:
Md. Akbar Hossain
Department of Pharmacy
ASA University of Science and Technology Bangladesh