

New Indications & Dosage form for Existing Drugs

Immune globulin subcutaneous

FDA approves Hizentra (Immune Globulin subcutaneous [Human] 20% Liquid) for the treatment of patients with chronic inflammatory demyelinating polyneuropathy (CIDP)

New Indication Approved: March 15, 2018

Brentuximab vedotin

FDA expands approval of adcetris (brentuximab vedotin) for first-line treatment of stage III or IV classical hodgkin lymphoma in combination with chemotherapy.

New Indication Approved: March 20, 2018

Bevacizumab (Injection)

Avastin (bevacizumab) is a recombinant humanized monoclonal IgG1 antibody for the treatment of colorectal cancer, non-small cell lung cancer, glioblastoma, renal cell carcinoma, cervical cancer, ovarian cancer, fallopian tube cancer, and peritoneal cancer.

New Indication Approved: June 13, 2018

Pembrolizumab (Injection)

Keytruda (pembrolizumab) is a human PD-1 (programmed death receptor-1)-blocking antibody indicated for the treatment of melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, cervical cancer, and primary mediastinal large B-cell lymphoma.

New Indication Approved: June 13, 2018

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New Indication Approved: June 12, 2018

Venetoclax (Tablets)

Venclexta (venetoclax) is an oral B-cell lymphoma-2 (BCL-2) inhibitor for the treatment of patients with chronic lymphocytic leukemia (CLL) with 17p deletion.

New Indication Approved: June 8, 2018

Rituximab (Injection for Intravenous Use)

Rituxan (rituximab) is a CD20-directed cytolytic antibody indicated for the treatment of patients with non-Hodgkin's lymphoma, chronic lymphocytic leukemia, rheumatoid arthritis, Wegener's granulomatosis, microscopic polyangiitis, and pemphigus vulgaris.

New Indication Approved: June 7, 2018

Tofacitinib (Tablets)

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.

New Indication Approved: May 30, 2018

Certolizumab pegol (Injection)

Cimzia (certolizumab) is a PEGylated anti-TNF (tumor necrosis factor) biologic therapy for the treatment of Crohn's disease, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis.

New Indication Approved: May 25, 2018

Denosumab (Injection)

Prolia is a RANK ligand (RANKL) inhibitor indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, for the treatment of bone loss in patients with prostate or breast cancer undergoing hormone ablation therapy, as a treatment to increase bone mass in men with osteoporosis at high risk for fracture, and for the treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture.

New Indication Approved: May 18, 2018

Ixekizumab (Injection)

Taltz (ixekizumab) is a humanized interleukin-17A antagonist indicated for the treatment of plaque psoriasis and psoriatic arthritis.

New Indication Approved: May 17, 2018

Tocilizumab (Injection)

Actemra (tocilizumab) is a humanized interleukin-6 (IL-6) receptor-inhibiting monoclonal antibody for the treatment of rheumatoid arthritis; systemic juvenile idiopathic arthritis (SJIA); polyarticular juvenile idiopathic arthritis (PJIA); giant cell arteritis; and CAR T cell-induced severe or life-threatening cytokine release syndrome.

New Dosage Regimen: May 11, 2018

Daratumumab (Injection)

Darzalex (daratumumab) is a human anti-CD38 monoclonal antibody indicated for the treatment of patients with multiple myeloma.

New Indication Approved: May 7, 2018

Tisagenlecleucel (Suspension for Intravenous Infusion)

Kymriah (tisagenlecleucel) is a chimeric antigen receptor T cell (CAR-T) therapy for use in patients with relapsed or refractory (r/r) B-cell acute lymphoblastic leukemia (ALL) and patients with relapsed or refractory (r/r) large B-cell lymphoma.

New Indication Approved: May 1, 2018

Mirabegron (Extended Release Tablets)

Myrbetriq (mirabegron) is a β -3 adrenergic agonist indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency and urinary frequency.

New Indication Approved: April 27, 2018

Osimertinib (Tablets)

Tagrisso (osimertinib) is a tyrosine kinase inhibitor (TKI) of epidermal growth factor receptor (EGFR) indicated for the treatment of patients with metastatic EGFR T790M mutation-positive non-small cell lung cancer.

New Indication Approved: April 18, 2018

Nivolumab (Injection)

Opdivo (nivolumab) is a programmed death receptor-1 (PD-1) blocking antibody for the treatment of advanced melanoma, advanced non-small cell lung cancer, advanced renal cell carcinoma, classical Hodgkin lymphoma, advanced squamous cell carcinoma of the head and neck, urothelial carcinoma, MSI-H or dMMR metastatic colorectal cancer and hepatocellular carcinoma.

New Indication Approved: April 16, 2018

Everolimus (Tablets)

Afinitor (everolimus) is an oral once-daily inhibitor of mTOR indicated for the treatment of patients with advanced HR+, HER2- breast cancer; progressive neuroendocrine tumors of pancreatic origin (PNET); progressive neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin; advanced renal cell carcinoma; and subependymal giant cell astrocytoma (SEGA) and renal angiomyolipomas associated with tuberous sclerosis.

New Indication Approved: April 10, 2018

Rucaparib (Tablets)

Rubraca (rucaparib) is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated for the treatment of patients with deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies; and for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.

New Indication Approved: April 6, 2018

Bupivacaine liposome (Injectable Suspension)

Exparel (bupivacaine liposome injectable suspension) is a long-acting non-opioid local analgesic for postsurgical local analgesia, and for use as a nerve block (interscalene brachial plexus block) to provide pain relief following shoulder surgeries.

New Indication Approved: April 6, 2018

Blinatumomab (Injection)

Blinicyto (blinatumomab) is a bispecific CD19-directed CD3 T-cell engager indicated for the treatment of Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL), and minimal residual disease (MRD)-positive B-cell precursor ALL.

New Indication Approved: March 29, 2018

Blinatumomab

FDA expands approval of blincyto (blinatumomab) to treat minimal residual disease-positive B-Cell precursor acute lymphoblastic leukemia

New Indication Approved: March 29, 2018

Otiprio (ciprofloxacin)

Treatment for: Tympanostomy Tube Placement Surgery; Acute Otitis Externa

New Indication Approved: March 2, 2018

Source: Drugs.com

Information Collected and compiled by:

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