pharmpiX

RX BENEFIT MANAGEMENT

PharmNOTES

Summary about new FDA products,
generic medication, medical products,
and WHAT IS IN THE PIPELINE.
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Table of Contents

	Page
News	3
New FDA Approved Products	4-25
Olumiant™ (baricitinib)	4-5
Fulphila™ (pegfilgrastim-jmdb)	6-7
Moxidectin	8-9
Nocdurna™ (desmopressin acetate)	10-12
Epidiolex™ (cannabidiol)	13-15
Zemdri™ (plazomicin)	16-17
Mektovi™ (binimetinib)	18-20
Braftovi™ (encorafenib)	21-23
Qbrexza™ (glycopyrronium)	24-25
New FDA Approved Indications	26-28
New FDA Approved Formulation	29
New First-Time Generic Drug Approval	30
Pipeline	31
References	32

NEWS……

Drug Issue	Date	News/Event
Alert regarding adverse events reported after receiving eye injections of product compounded by Guardian Pharmacy Services containing triamcinolone-moxifloxacin	06/14/2018	Some patients reported adverse events after receiving eye injections of Guardian's Pharmacy Services (Dallas, Texas) compounded triamcinolone-moxifloxacin product during cataract surgery. Reported symptoms included vision impairment, poor night vision, loss of color perception, and significant reductions in best-corrected visual acuity and visual fields. The FDA identified multiple substances in Guardian's product, including poloxamer 407 and poloxamer 407 degradants. The amount of poloxamer 407 was found to be much greater than the maximum amount of poloxamers in FDA-approved ophthalmic products for topical administration, and the safety profile of drug products intended for intravitreal injection containing poloxamer 407 is unknown. Recommendations for compounding pharmacies: • Compounding pharmacies should determine, based on the route of administration and the organ or tissue involved, whether the excipients are safe in the amount that will be present in the administered dose. • Compounding pharmacies also should consider whether the compounding process will generate degradants of such ingredients. Recommendations for all healthcare professionals: • Because compounded products are not evaluated by FDA for safety, effectiveness, or quality, health professionals should consult the compounding pharmacy about the safety information related to the excipients in the compounded products they plan to inject into their patients. • Healthcare professionals are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program: For more details regarding this issue, visit the FDA's 2018 Safety Alerts for Human Medical Products at: https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm590808.htm

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Olumiant™ (baricitinib) Tablets, for oral use / Eli Lilly and Company	Antirheumatic Janus kinase (JAK) inhibitor	Treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies **Limitations of use** Use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended **Black box warning** Serious infections, malignancy, and thrombosis	05/31/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 2 mg once daily. • May be used as monotherapy or in combination with methotrexate or other non-biologic DMARDs. • Avoid initiation or interrupt in patients with hemoglobin less than 8 g/dL. • Avoid initiation or interrupt in patients with an Absolute Lymphocyte Count (ANC) less than 500 cells/mm3 . • Avoid use in patients with active, serious infection, including localized infections. **DOSAGE FORMS AND STRENGTHS** Tablets (not scored): 2 mg. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Concomitant use:** Avoid live vaccines; update immunizations prior to therapy initiation. • **Endocrine and metabolic:** Elevation of lipid parameters have been reported (e.g. total cholesterol, LDL, and HDL); monitoring required. • **Gastrointestinal:** Perforation have been reported; use cautiously in patients with increased risk (eg.g.history of diverticulitis); promptly evaluate any new onset of abdominal symptoms. • **Hematologic:** Neutropenia, lymphopenia, and anemia have been reported; avoid initiation if present; monitoring required; dosage adjustment or therapy interruption may be needed. • **Hepatic:** (1) Elevation of liver enzymes has been reported; monitoring required; therapy interruption may be needed. (2) Use not recommended with severe impairment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Olumiant™ (baricitinib) Tablets, for oral use / Eli Lilly and Company (continuation)	Antirheumatic Janus kinase (JAK) inhibitor	Treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies **Limitations of use** Use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended **Black box warning** Serious infections, malignancy, and thrombosis	05/31/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Immunologic:** Viral reactivation, including herpes virus reactivation (e.g. herpes zoster), have been reported; therapy interruption may be needed. • **Renal:** Use not recommended with estimated GFR less than 60 mL/min/1.73 m(2). **ADVERSE REACTIONS** Most common adverse reactions: upper respiratory tract infections, nausea, herpes simplex, and herpes zoster. **DRUG INTERACTIONS** • Not recommended in patients taking strong Organic Anion Transporter 3 (OAT3) inhibitors (e.g. probenecid). **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and effectiveness in pediatric patients have not been established. • **Geriatric use:** No overall differences in safety or effectiveness were observed between patients aged 65 and older and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. • **Hepatic impairment:** Not recommended in patients with severe hepatic impairment. • **Renal impairment:** Not recommended in patients with moderate or severe renal impairment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Fulphila™ (pegfilgrastim-jmdb) Injection, for subcutaneous use / Mylan N.V.	Blood modifier agent Leukocyte growth factor --- Note: Biosimilar to Neulasta™ (pegfilgrastim)	To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia **Limitations od use** Not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation	06/04/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 6 mg administered subcutaneously once per chemotherapy cycle. • Do not administer between 14 days before and 24 hours after administration of cytotoxic chemotherapy. • Use weight based dosing for pediatric patients weighing less than 45 kg. **DOSAGE FORMS AND STRENGTHS** Injection: 6 mg/0.6 mL solution in a single-dose prefilled syringe for manual use only. **CONTRAINDICATIONS** • History of serious allergic reactions to human granulocyte colony-stimulating factors such as pegfilgrastim or filgrastim products. **WARNINGS AND PRECAUTIONS** • **Cardiovascular:** Capillary leak syndrome with varying severity and frequency has been reported; characterized by hypotension, hypoalbuminemia, edema, and hemoconcentration; may be life-threatening with delayed treatment. • **Hematologic:** (1) Sickle cell disorder; severe and sometimes fatal sickle cell crisis may occur.(2) Leukocytosis has been reported; monitoring recommended. • **Immunologic:** (1) Serious allergic reactions, including anaphylaxis, have been reported, usually with initial exposure but may recur within days after discontinuance of initial anti-allergic treatment; permanently discontinue if serious allergic reaction occurs. (2) Potential for tumor growth stimulatory effects on any malignant tumor type, including myeloid malignancies and myelodysplasia (unapproved uses), cannot be ruled out. • **Lymphatic:** Splenic rupture, including fatalities, has been reported.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Fulphila™ (pegfilgrastim-jmdb) Injection, for subcutaneous use / Mylan N.V. (continuation)	Blood modifier agent Leukocyte growth factor --- Note: Biosimilar to Neulasta™ (pegfilgrastim)	To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia **Limitations od use** Not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation	06/04/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Renal:** Glomerulonephritis has been reported; reduction of dose or interruption may be necessary. • **Respiratory:** Acute respiratory distress syndrome (ARDS) has been reported; discontinue use if ARDS develops. **ADVERSE REACTIONS** Most common adverse reactions: bone pain and pain in extremity. **DRUG INTERACTIONS** No drug interactions studies have been conducted. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** The safety and effectiveness of pegfilgrastim have been established in pediatric patients. No overall differences in safety were identified between adult and pediatric patients based on post-marketing surveillance and review of the scientific literature. • **Geriatric use:** No overall differences in safety or effectiveness were observed between patients aged 65 and older and younger patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Moxidectin Tablets, for oral use / Medicines Development for Global Health	Anti-infective agent Anthelmintic	Treatment of onchocerciasis due to Onchocerca volvulus in patients aged 12 years and older **Limitations of use** • Moxidectin Tablets do not kill adult O. volvulus parasites. Follow-up is advised • The safety and efficacy of repeat administration of Moxidectin Tablets in patients with O. volvulus has not been studied	04/13/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 8 mg (four 2 mg tablets) as a single oral dose, with or without food. **DOSAGE FORMS AND STRENGTHS** Tablets: 2 mg. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Cardiovascular:** (1) Symptomatic orthostatic hypotension has been reported; usually occurred on days 1 and 2 post-treatment. (2) Severe edema and worsening onchodermatitis may occur in patients with hyper-reactive onchodermatitis (sowda); symptomatic treatment may be necessary. • **Immunologic:** Mazzotti reaction (cutaneous, ophthalmologic, and/or systemic reactions), varying in severity, may occur with increased incidences in patients with higher microfilarial burden. Symptomatic treatments (e.g. as oral hydration, recumbency, intravenous normal saline, and/or parenteral corticosteroids for orthostatic hypotension), antihistamines and/or analgesics may be necessary. • **Neurologic:** Encephalopathy may develop and be fatal in patients who are also infected with Loa loa; diagnostic screening for loiasis is recommended prior to treatment in patients exposed to Loa loa-endemic areas. **ADVERSE REACTIONS** Most common adverse reactions: eosinophilia, pruritus, musculoskeletal pain, headache, lymphopenia, tachycardia, rash, abdominal pain, hypotension, pyrexia, leukocytosis, influenza-like illness, neutropenia, cough, lymph node pain, dizziness, diarrhea, hyponatremia and peripheral swelling.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Moxidectin Tablets, for oral use / Medicines Development for Global Health (continuation)	Anti-infective agent Anthelmintic	Treatment of onchocerciasis due to Onchocerca volvulus in patients aged 12 years and older **Limitations of use** • Moxidectin Tablets do not kill adult O. volvulus parasites. Follow-up is advised • The safety and efficacy of repeat administration of Moxidectin Tablets in patients with O. volvulus has not been studied	04/13/2018	**DRUG INTERACTIONS** No major drug-drug interactions have been identified. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** The safety and effectiveness have been established in pediatric patients 12 years of age and older • **Geriatric use:** No overall differences in safety or effectiveness were observed between patients aged 65 years and older and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Nocdurna™ (desmopressin acetate) Tablets, for subingual use / Ferring Pharmaceuticals Inc.	Vasopressin analog	Treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void **Black box warning** Hyponatremia	06/21/2018	**DOSAGE AND ADMINISTRATION** The recommended dose for women is 27.7 mcg daily, one hour before bedtime, administered sublingually without water. The recommended dose for men is 55.3 mcg daily, one hour before bedtime, administered sublingually without water. **DOSAGE FORMS AND STRENGTHS** Sublingual Tablets: 27.7 mcg of desmopressin acetate (equivalent to 25 mcg of desmopressin) and 55.3 mcg of desmopressin acetate (equivalent to 50 mcg of desmopressin). **CONTRAINDICATIONS** • Hyponatremia or a history of hyponatremia. • Polydipsia. • Concomitant use with loop diuretics or systemic or inhaled glucocorticoids. • Estimated glomerular filtration rate below 50 mL/min/1.73 m2. • Syndrome of inappropriate antidiuretic hormone secretion (SIADH). • During illnesses that can cause fluid or electrolyte imbalance. • Heart failure. • Uncontrolled hypertension. **WARNINGS AND PRECAUTIONS** • **Beers Criteria:** Avoid use in elderly patients for the treatment of nocturia or nocturnal polyuria due to high risk of hyponatremia. Consider use of safer alternatives. • **Cardiovascular:** Fluid retention may occur, monitoring recommended in patients with New York Heart Association Class I congestive heart failure.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Nocdurna™ (desmopressin acetate) Tablets, for subingual use / Ferring Pharmaceuticals Inc. (continuation)	Vasopressin analog	Treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void **Black box warning** Hyponatremia	06/21/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Endocrine and Metabolic:** (1) Severe hyponatremia has been reported; restrict fluid during administration and monitor patients. Increased risk in patients 65 years of age or older, female patients, or those on concomitant medications that increase the risk of hyponatremia (e.g. tricyclic antidepressants, selective serotonin reuptake inhibitors, nonsteroidal anti-inflammatory drugs, chlorpromazine, opiate analgesics, carbamazepine, lamotrigine, thiazide diuretics and chlorpropamide). (2) Use with caution in patients with conditions associated with fluid and electrolyte imbalance (e.g. cystic fibrosis, heart failure, and renal disorders due to risk of hyponatremia). (3) Excessive fluid intake may increase risk of water intoxication and hyponatremia; fluid restriction recommended. (4) Excessive water intake and conditions associated with increased intake such as extremely hot weather and vigorous exercise during primary nocturnal enuresis treatment with oral tablet may increase risk of hyponatremia. (5) Fluid retention may occur; use not recommended in those with increased intracranial pressure or those with a history of urinary retention. **ADVERSE REACTIONS** Most common adverse reactions: dry mouth, hyponatremia or blood sodium decreased, and dizziness. **DRUG INTERACTIONS** • **Drugs that may increase the risk of hyponatremia:** Monitor serum sodium more frequently when Nocdurna™ is concomitantly used with drugs that may increase the risk of hyponatremia (e.g. tricyclic antidepressants, selective serotonin re-uptake inhibitors, chlorpromazine, opiate analgesics, thiazide diuretics, NSAIDs, lamotrigine, chlorpropamide and, carbamazepine).

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Nocdurna™ (desmopressin acetate) Tablets, for subingual use / Ferring Pharmaceuticals Inc. (continuation)	Vasopressin analog	Treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void **Black box warning** Hyponatremia	06/21/2018	**USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and effectiveness have not been established in pediatric patients. • **Geriatric use:** Studies of desmopressin have shown an increased risk of hyponatremia in patients 65 years of age or older compared to those younger than 65 years of age. • **Renal impairment:** No dose adjustment is required for patients with an eGFR at or above 50 mL/min/1.73 m2. However, Nocdurna™ is contraindicated in patients with an eGFR below 50 mL/min/1.73 m2.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Epidiolex™ (cannabidiol) Oral Solution / GW Pharmaceuticals plc	Anticonvulsant Cannabidiol (CBD) Notes: • Epidolex™ is a prescription pharmaceutical formulation of highly-purified, marijuana plant-derived cannabidiol (CBD) • Orphan drug designation	Treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients two years of age or older	06/25/2018	**DOSAGE AND ADMINISTRATION** The recommended starting dose is 2.5 mg/kg taken twice daily (5 mg/kg/day). After one week, the dosage can be increased to a maintenance dosage of 5 mg/kg twice daily (10 mg/kg/day). Based on individual clinical response and tolerability, the dose can be increased up to a maximum recommended maintenance dosage of 10 mg/kg twice daily (20 mg/kg/day). • Dosage adjustment is recommended for patients with moderate or severe hepatic impairment. • Obtain serum transaminases (ALT and AST) and total bilirubin levels in all patients prior to starting treatment. **DOSAGE FORMS AND STRENGTHS** Oral solution: 100 mg/mL. **CONTRAINDICATIONS** • Hypersensitivity to cannabidiol or any of the ingredients in Epidiolex™. **WARNINGS AND PRECAUTIONS** • **Hepatic:** Hepatocellular injury, including dose-related elevations of liver transaminases, have been reported with some cases associated with hospitalization. Increased risk in patients concomitantly taking valproate or clobazam and with elevated baseline transaminase levels; monitoring recommended. Therapy interruption or discontinuation may be necessary. • **Immunologic:** Hypersensitivity reactions have been reported and may require antihistamines; discontinue therapy if hypersensitivity reactions occur. • **Neurologic:** Somnolence and sedation, including lethargy, has been reported; increased risk in patients concomitantly taking clobazam. Other central nervous system depressants, including alcohol, may potentiate effects; monitoring recommended.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Epidiolex™ (cannabidiol) Oral Solution / GW Pharmaceuticals plc (continuation)	Anticonvulsant Cannabidiol (CBD) Notes: • Epidolex™ is a prescription pharmaceutical formulation of highly-purified, marijuana plant-derived cannabidiol (CBD) • Orphan drug designation	Treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients two years of age or older	06/25/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Psychiatric:** Increased incidences of suicidal behavior or ideation may occur; monitoring recommended. • **Withdrawal:** Gradually withdrawal therapy due to the risk of increased seizure frequency and status epilepticus. **ADVERSE REACTIONS** Most common adverse reactions: somnolence; decreased appetite; diarrhea; transaminase elevations; fatigue, malaise, and asthenia; rash; insomnia, sleep disorder, and poor quality sleep; and infections. **DRUG INTERACTIONS** • **Moderate or strong inhibitors of CYP3A4 or CYP2C19:** Consider dose reduction of Epidiolex™. • **Strong inducer of CYP3A4 or CYP2C19:** Consider dose increase of Epidiolex™. • **Substrates of UGT1A9, UGT2B7, CYP2C8, CYP2C9, and CYP2C19 (e.g. clobazam):** Consider a dose reduction of these subtrates. • **Substrates of CYP1A2 and CYP2B6:** May also require dose adjustment **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm. There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to antiepileptic drugs (AEDs) during pregnancy. Encourage women who are taking Epidiolex™ during pregnancy to enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry. • **Pediatric use:** Safety and effectiveness for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome have been established in patients 2 years of age and older. Safety and effectiveness in pediatric patients below 2 years of age have not been established.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Epidiolex™ (cannabidiol) Oral Solution / GW Pharmaceuticals plc (continuation)	Anticonvulsant Cannabidiol (CBD) Notes: • Epidolex™ is a prescription pharmaceutical formulation of highly-purified, marijuana plant-derived cannabidiol (CBD) • Orphan drug designation	Treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients two years of age or older	06/25/2018	**USE IN SPECIFIC POPULATIONS** (continuation) • **Geriatric use:** Clinical trials did not include any patients aged above 55 years to determine whether or not they respond differently from younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. • Hepatic impairment: Does not require dosage adjustments in patients with mild hepatic impairment. Dosage adjustments are necessary in patients with moderate or severe hepatic impairment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Zemdri™ (plazomicin) Injection, for intravenous use / Achaogen, Inc.	Aminoglycoside antibacterial	Treatment complicated urinary tract infections (cUTI), including pyelonephritis, in patients 18 years of age or older • As only limited clinical safety and efficacy data are available, reserve Zemdri™ for use in patients who have limited or no alternative treatment options • To reduce the development of drug-resistant bacteria and maintain effectiveness of Zemdri™ and other antibacterial drugs, Zemdri™ should be used only to treat infections that are proven or strongly suspected to be caused by susceptible microorganisms **Black box warning** Nephrotoxicity, ototoxicity, neuromuscular blockade and fetal harm	06/25/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 15 mg/kg every 24 hours by intravenous (IV) infusion over 30 minutes. Recommended duration of treatment is 4 to 7 days for cUTI, including pyelonephritis. • To use in patients 18 years of age or older with creatinine clearance greater than or equal to 90 mL/min • Assess creatinine clearance in all patients prior to initiating therapy and daily during therapy • See Full Prescribing Information for dosage adjustment recommendations for patients with renal impairment **DOSAGE FORMS AND STRENGTHS** Zemdri™ injection 500 mg/10 mL (50 mg/mL) is a single-dose vial containing plazomicin sulfate equivalent to 500 mg plazomicin free base. **CONTRAINDICATIONS** • Known hypersensitivity to any aminoglycoside. **WARNINGS AND PRECAUTIONS** • **Gastrointestinal:** Clostridium difficile-associated diarrhea (CDAD) has been reported with systemic antibacterial drugs and may range in severity from mild diarrhea to fatal colitis; CDAD has been reported to occur more than 2 months after administration. If suspected or confirmed, antibacterial drugs not directed against Clostridium difficile may need to be discontinued; manage fluid and electrolyte levels as appropriate, supplement protein intake, monitor treatment and institute surgical evaluation as clinically indicated. • **Immunologic:** Serious and occasionally fatal hypersensitivity (e.g. anaphylactic) reactions have been reported in patients receiving aminoglycoside antibacterial drugs; if allergic reaction occurs, discontinue therapy. • **Otic:** Reversible hypoacusis has been reported.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Zemdri™ (plazomicin) Injection, for intravenous use / Achaogen, Inc. (continuation)	Aminoglycoside antibacterial	Treatment complicated urinary tract infections (cUTI), including pyelonephritis, in patients 18 years of age or older • As only limited clinical safety and efficacy data are available, reserve Zemdri™ for use in patients who have limited or no alternative treatment options • To reduce the development of drug-resistant bacteria and maintain effectiveness of Zemdri™ and other antibacterial drugs, Zemdri™ should be used only to treat infections that are proven or strongly suspected to be caused by susceptible microorganisms **Black box warning** Nephrotoxicity, ototoxicity, neuromuscular blockade and fetal harm	06/25/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Renal:** Nephrotoxicity has been reported; if worsening renal function occurs, asses the benefit of continuing therapy. **ADVERSE REACTIONS** Most common adverse reactions: decreased renal function, diarrhea, hypertension, headache, nausea, vomiting and hypotension. **DRUG INTERACTIONS** No major drug-drug interactions have been identified. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Aminoglycosides can cause fetal harm. • **Lactation:**. • **Pediatric use:** Safety and effectiveness in patients less than 18 years of age have not been established. • **Renal impairment:** Plazomicin total body clearance was significantly decreased in patients with CrCl greater than or equal to 15 to less than 60 mL/min compared to patients with CrCl greater than or equal to 60 mL/min. Monitor CrCl daily and adjust dosage accordingly. There is insufficient information to recommend a dosage regimen in patients with CrCl less than 15 mL/min or on renal replacement therapy, including hemodialysis or continuous renal replacement therapy. For patients with CrCl greater than or equal to 15 mL/min and less than 90 mL/min, Therapeutic Drug Monitoring is recommended. Monitor plazomicin trough concentrations and adjust dosage accordingly.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Mektovi™ (binimetinib) Tablets, for oral use / Array BioPharma Inc.	Antineoplastic agent Kinase inhibitor	In combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test	06/27/2018	**DOSAGE AND ADMINISTRATION** The recommended dose e is 45 mg orally twice daily in combination with encorafenib. For patients with moderate or severe hepatic impairment the recommended dose is 30 mg orally twice daily. • Confirm the presence of BRAF V600E or V600K mutation in tumor specimens prior to the initiation. **DOSAGE FORMS AND STRENGTHS** Tablets: 15 mg. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Cardiovascular:** Cardiomyopathy, including symptomatic and asymptomatic declines in left ventricular ejection fraction, has been reported with binimetinib in combination with encorafenib; monitoring recommended; dose reduction, interruption, or discontinuation may be required. • **Hematologic:** (1) VTE, including pulmonary embolism, has occurred with binimetinib in combination with encorafenib; dose reduction, interruption, or discontinuation may be required. (2) Hemorrhage, including severe and fatal cases, has been reported with binimetinib in combination with encorafenib; dose reduction, interruption, or discontinuation may be necessary. • **Hepatic:** Hepatotoxicity can occur with binimetinib in combination with encorafenib; monitoring recommended; dose reduction, interruption, or discontinuation may be required. • **Musculoskeletal:** Rhabdomyolysis may occur with binimetinib in combination with encorafenib; monitoring recommended; dose reduction, interruption, or discontinuation may be required.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Mektovi™ (binimetinib) Tablets, for oral use / Array BioPharma Inc. (continuation)	Antineoplastic agent Kinase inhibitor	In combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test	06/27/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Ophthalmic:** Ocular toxicities, including serous retinopathy, retinal vein occlusion, and uveitis, have been reported with binimetinib in combination with encorafenib; monitoring recommended; dose reduction, interruption, or discontinuation may be required. • **Respiratory:** Interstitial lung disease, including pneumonitis, has been reported with binimetinib in combination with encorafenib; dose reduction, interruption, or discontinuation may be required. **ADVERSE REACTIONS** Most common adverse reactions: fatigue, nausea, diarrhea, vomiting, and abdominal pain. **DRUG INTERACTIONS** No major drug-drug interactions have been identified. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm. • **Females and males of reproductive potential:** Verify the pregnancy status of females of reproductive potential prior to initiating. Advise females of reproductive potential should use effective contraception during treatment and for at least 30 days after the last dose. • **Lactation:** Advise not to breastfeed. • **Pediatric use:** Safety and effectiveness have not been established in pediatric patients. • **Geriatric use:** No overall differences in safety or effectiveness were observed between patients aged 65 years and older and younger patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Mektovi™ (binimetinib) Tablets, for oral use / Array BioPharma Inc. (continuation)	Antineoplastic agent Kinase inhibitor	In combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test	06/27/2018	**USE IN SPECIFIC POPULATIONS** (continuation) • **Hepatic impairment:** Concentrations may increase in patients with moderate or severe hepatic impairment. Dose adjustment is not recommended in patients with mild hepatic impairment (total bilirubin > 1 and ≤ 1.5 × ULN and any AST or total bilirubin ≤ ULN and AST > ULN). Reduce the dose for patients with moderate (total bilirubin > 1.5 and ≤ 3 × ULN and any AST) or severe (total bilirubin levels > 3 × ULN and any AST) hepatic impairment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Braftovi™ (encorafenib) Capsules, for oral use / Array BioPharma Inc.	Antineoplastic agent Kinase inhibitor	In combination with binimetinib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test **Limitations of use** Not indicated for treatment of patients with wild-type BRAF melanoma	06/27/2018	**DOSAGE AND ADMINISTRATION** The recommended dose e is 450 mg orally once daily in combination with binimetinib. • Confirm the presence of BRAF V600E or V600K mutation in tumor specimens prior to the initiation. **DOSAGE FORMS AND STRENGTHS** Capsules: 50 mg and 75 mg. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **BRAF wild-type melanoma (unapproved use):** Increased cell proliferation in BRAF wild-type cells has occurred with in vitro exposure to BRAF inhibitors; confirm BRAF V600E mutation status prior to initiation of treatment. • **Cardiovascular:** Dose-dependent QT prolongation may occur; increased risk in patients with known long QT syndromes, clinically significant bradyarrhythmias, severe or uncontrolled heart failure, and concomitant use of other QT prolonging drugs; monitoring recommended and dose reduction, interruption, or discontinuation may be necessary. • **Concomitant use:** Avoid use of moderate or strong CYP3A4 inhibitors, moderate or strong CYP3A4 inducers, hormonal contraceptives, and other agents with known potential to prolong QT/QTc interval. • **Dermatologic:** Increased risk of dermatologic adverse reactions with single agent use compared with combination use with binimetinib; dose reduction may be necessary if binimetinib is interrupted or discontinued. • **Hematologic:** Hemorrhage has been reported, including severe and fatal cases; interruption, dose reduction, or discontinuation may be necessary.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Braftovi™ (encorafenib) Capsules, for oral use / Array BioPharma Inc. (continuation)	Antineoplastic agent Kinase inhibitor	In combination with binimetinib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test **Limitations of use** Not indicated for treatment of patients with wild-type BRAF melanoma	06/27/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Malignancy:** New primary malignancies, cutaneous (ie, cutaneous squamous cell carcinoma, keratoacanthoma, basal cell carcinoma) and non-cutaneous, have occurred; monitoring recommended and discontinuation may be necessary. • **Ophthalmic:** Uveitis has been reported, including iritis and iridocyclitis; monitoring recommended and dose reduction, interruption, or discontinuation may be required. **ADVERSE REACTIONS** Most common adverse reactions: fatigue, nausea, vomiting, abdominal pain, and arthralgia. **DRUG INTERACTIONS** (continuation) • **Strong or moderate CYP3A4 inhibitors**: Concomitant use may increase encorafenib plasma concentration. If concomitant use cannot be avoided, modify dose. • **Strong or moderate CYP3A4 inducers:** Concomitant use may decrease encorafenib plasma concentrations. Avoid concomitant use. • **Sensitive CYP3A4 substrates:** Concomitant use with Braftovi™ may increase toxicity or decrease efficacy of these agents. Avoid hormonal contraceptives. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm; women of reproductive potential should use effective non-hormonal contraception to avoid pregnancy during treatment and for 2 weeks after the last dose.

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Braftovi™ (encorafenib) Capsules, for oral use / Array BioPharma Inc. (continuation)	Antineoplastic agent Kinase inhibitor	In combination with binimetinib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test **Limitations of use** Not indicated for treatment of patients with wild-type BRAF melanoma	06/27/2018	**USE IN SPECIFIC POPULATIONS** (continuation) • **Females and males of reproductive potential:** (1) Verify the pregnancy status of females of reproductive potential prior to initiating. Advise females of reproductive potential to use effective contraception during treatment and for 2 weeks after the final dose. Counsel patients to use a non-hormonal method of contraception since Braftovi™ has the potential to render hormonal contraceptives ineffective. (2) Use of Braftovi™ may impact fertility in males. • **Lactation:** Advise not to breastfeed. • **Pediatric use:** Safety and effectiveness have not been established in pediatric patients. • **Geriatric use:** No overall differences in safety or effectiveness were observed between patients aged 65 years and older and younger patients. • **Hepatic impairment:** Dose adjustment is not recommended in patients with mild hepatic impairment (Child-Pugh Class A). A recommended dose has not been established for patients with moderate (Child-Pugh Class B) or severe (Child-Pugh Class C) hepatic impairment. • **Renal impairment:** No dose adjustment is recommended for patients with mild to moderate renal impairment (CrCl 30 to < 90 mL/min). A recommended dose has not been established for patients with severe renal impairment (CrCl < 30 mL/min).

New FDA Approved Products

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Qbrexza™ (glycopyrronium) Cloth, for topical use / Dermira, Inc.	Anticholinergic	Treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older	06/29/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is apply once daily to both axillae using a single cloth. **DOSAGE FORMS AND STRENGTHS** Cloth: A single-use cloth pre-moistened with 2.4% glycopyrronium solution. **CONTRAINDICATIONS** • Having mcedical conditions that can be exacerbated by the anticholinergic effect of Qbrexza™ (e.g. glaucoma, paralytic ileus, unstable cardiovascular status in acute hemorrhage, severe ulcerative colitis, toxic megacolon complicating ulcerative colitis, myasthenia gravis, Sjogren's syndrome). **WARNINGS AND PRECAUTIONS** • **Worsening of urinary retention:** Use with caution in patients with a history or presence of documented urinary retention. • **Control of body temperature:** In the presence of high ambient temperature, heat illness may occur; avoid use if patients develop generalized lack of sweating when exposed to hot or very warm environmental temperatures • **Operating machinery or an automobile:** Transient blurred vision may occur with use of Qbrexza™. If blurred vision occurs, discontinue use of Qbrexza™ until symptoms resolve; avoid operating a motor vehicle or other machinery until symptoms resolve. **ADVERSE REACTIONS** Most common adverse reactions: dry mouth, mydriasis, oropharyngeal pain, headache, urinary hesitation, vision blurred, nasal dryness, dry throat, dry eye, dry skin, constipation, local skin reactions

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Qbrexza™ (glycopyrronium) Cloth, for topical use / Dermira, Inc. (continuation)	Anticholinergic	Treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older	06/29/2018	**DRUG INTERACTIONS** • **Anticholinergics:** Coadministration of Qbrexza™ with anticholinergic medications may result in additive interaction leading to an increase in anticholinergic adverse effects. Avoid coadministration of Qbrexza™ with other anticholinergic-containing drugs. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and efficacy are not established in patients under 9 years of age. • **Geriatric use:** Clinical trials did not include sufficient numbers of subjects age 65 years and older to determine whether they respond differently from younger subjects. • **Renal impairment:** The elimination of glycopyrronium is severely impaired in patients with renal failure.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Mircera™ (epoetin beta-methoxy polyethylene glycol) Injection / Roche	Blood modifier agent Erythropoiesis-stimulating agent (ESA)	For the treatment of anemia associated with chronic renal failure **Patient population altered:** For the treatment of pediatric patients 5 to 17 years of age on hemodialysis who are converting from another ESA after their hemoglobin level was stabilized with an ESA	06/07/2018	For conversion from another ESA, Mircera™ is dosed intravenously once every 4 weeks based on total weekly epoetin alfa or darbepoetin alfa dose at time of conversion.
Rituxan™ (rituximab) Injection, for intravenous use / Genentech	Antineoplastic agent CD20-directed cytolytic antibody	For the treatment of patients with non-Hodgkin's lymphoma, chronic lymphocytic leukemia, rheumatoid arthritis, Wegener's granulomatosus, microscopic polyangiitis, and pemphigus vulgaris **New indication:** For the treatment of adults with moderate to severe pemphigus vulgaris	06/07/2018	Pemphigus vulgaris (PV) is a rare, serious, potentially life-threatening condition characterized by progressive painful blistering of the skin and mucous membranes. Rituxan is the first biologic therapy approved by the FDA for PV. The FDA granted an orphan drug designation to Rituxan™ for the treatment of PV.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Venclexta™ (venetoclax) Tablets / AbbVie and Genentech	Antineoplastic agent B-cell lymphoma-2 (BCL-2) inhibitor	For the treatment of patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) **New indication:** In combination with Rituxan™ (rituximab) for the treatment of people with CLL or SLL, with or without 17p deletion, who have received at least one prior therapy	06/08/2018	Venclexta™ was previously approved as a single agent for the treatment of people with CLL, with 17p deletion, as detected by an FDA approved test, who have received at least one prior therapy. With this new approval, the indication for Venclexta™ as a single agent was also updated to include the treatment of people with CLL or SLL, with or without 17p deletion, who have received at least one prior therapy.
Keytruda™ (pembrolizumab) for Injection / Merck	Antineoplastic agent PD-1 (programmed death receptor-1)-blocking antibody	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 indications:** (1) For the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 [Combined Positive Score (CPS) ≥1] as determined by an FDA-approved test (2) For the treatment of adult and pediatric patients with refractory primary mediastinal large B-cell lymphoma (PMBCL), or who have relapsed after two or more prior lines of therapy	(1) 06/12/2018 (2) 06/13/2018	With this two new indications, Keytruda™ is now the first anti-PD-1 therapy approved for the treatment of advanced cervical cancer (providing a new second-line option for certain patients), and for the treatment of PMBCL, a type of non-Hodgkin lymphoma.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Avastin™ (bevacizumab) Injection / Genentech, Inc.	Antineoplastic agent 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:** In combination with chemotherapy (carboplatin and paclitaxel), followed by Avastin™ as a single agent, for the treatment of women with advanced (stage III or IV) ovarian cancer following initial surgical resection	06/13/2018	The approval was based on data from the pivotal Phase III GOG-0218 trial. Women who received Avastin™ in combination with chemotherapy, and continued use of Avastin™ alone, had a median progression-free survival (PFS) of 18.2 months compared to 12.0 months in women who received chemotherapy alone (HR=0.62; 95% CI 0.52 - 0.75, p<0.0001). This PFS benefit was achieved with a fixed-duration treatment (up to 22 cycles of Avastin™ total).

New FDA Approved Formulations

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Nocdurna™ (desmopressin acetate) Sublingual Tablets / Ferring Pharmaceuticals Inc.	Vasopressin analog	Treatment of nocturia due to nocturnal polyuria in adults	06/21/2018	Nocdurna™ is the first sublingual tablet for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void.
Aristada™ (aripiprazole lauroxil) Injection / Alkermes, Inc.	Atypical antipsychotic	Treatment of schizophrenia	06/29/2018	The FDA has approved two-month Aristada™ extended-release injectable suspension for the treatment of schizophrenia. Aristada™: • Is now FDA-approved in four doses and three dosing duration options: o 441 mg, 662 mg or 882 mg once monthly, o 882 mg once every six weeks, and o 1064 mg once every two months. • Can be initiated at any dose or interval, offering a range of flexibility to patients and healthcare providers.
Nuplazid™ (pimavanserin) Tablets and Capsules / Acadia Pharmaceuticals, Inc.	Antipsychotic Non-dopaminergic, selective serotonin inverse agonist (SSIA)	Treatment of psychosis associated with Parkinson's disease	06/29/2018	The FDA has approved a new capsule dose formulation and a new tablet strength of Nuplazid™ for the treatment of patients living with hallucinations and delusions associated with Parkinson's disease psychosis. The approval of a 34 mg Nuplazid™ capsule formulation will provide patients with the recommended 34 mg once daily dose in a single, small capsule, reducing patient pill burden versus the current administration of two 17 mg tablets. In addition, the approval of a 10 mg tablet provides a lower dosage strength for those patients who are concomitantly receiving strong cytochrome 3A4 inhibitors which can inhibit the metabolism of Nuplazid™.

New First Time Generic Drug Approval

Drug/Manufacturer	Therapeutic Class	Date	Comments
Clindamycin Phosphate and Benzoyl Peroxide Topical Gel 1.2%/ 3.75% / Taro Pharmaceuticals Inc.	Antiacne; Antibacterial	06/05/2018	Generic for: Onexton™
Buprenorphine Hydrochloride and Naloxone Hydrochloride Sublingual Film 2 mg/0.5 mg, 8 mg/2 mg, 4 mg/1 mg and 12 mg/3 mg / Dr. Reddy's Laboratories SA; Mylan Technologies Inc. (8 mg/2 mg and 12 mg/3 mg only)	Dependency agent; Opioid medication; Narcotic	06/14/2018	Generic for: Suboxone Sublingual Film

Source: https://www.drugs.com/generic-approvals.html

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Drug/Manufacturer	Date	Indications	Comments	Impact
Duaklir™ (aclidinium bromide and formoterol fumarate) / Circassia Pharmaceuticals plc	06/01/2018	Treatment for: Chronic Obstructive Pulmonary Disease	Duaklir Pressair is a long-acting muscarinic antagonist (LAMA) and long-acting beta agonist (LABA) fixed dose combination maintenance bronchodilator in development for the treatment of COPD. Circassia submits a NDA for Duaklir Pressair.	Moderate
Gimoti™ (metoclopramide) Nasal Spray / Evoke Pharma, Inc.	06/04/2018	Treatment for: Gastroparesis	Gimoti™ is an intranasal formulation of the approved drug metoclopramide in development for the treatment of symptoms associated with gastroparesis in women. Evoke submits a NDA for Gimoti™.	Moderate
APL-130277 (apomorphine) Sublingual Film / Sunovion Pharmaceuticals Inc.	06/12/2018	Treatment for: Parkinson's Disease (PD)	APL-130277 is a novel formulation of the approved dopamine agonist apomorphine in development for the on-demand management of OFF episodes associated with PD. The FDA has accepted the NDA for apomorphine sublingual film (APL-130277).	Moderate
Iclaprim Intravenous Injection / Motif Bio plc	06/14/2018	Treatment for: Skin and Structure Infection	Iclaprim is an investigational broad-spectrum diaminopyrimidine antibiotic in development for the treatment of acute bacterial skin and skin structure infections (ABSSSIs). Motif submits a NDA for iclaprim.	High

Soruce: https://www.drugs.com/new-drug-applications.html

References:

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- Micromedex® Solutions - Truven Health Analytics (www.micromedexsolutions.com)
- Pharmacist Letter (www.pharmacistletter.com)
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