pharmpiX

RX BENEFIT MANAGEMENT

PharmNOTES

Summary about new FDA products,
generic medication, medical products,
and WHAT IS IN THE PIPELINE.
From: JUNE 2017

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Pharmacy
Benefit
Management
Expires 12/01/2019

Table of Contents

NEWS……

- No security warning published during June 2017.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Symjepi™ (epinephrine) Injection, for intramuscular or subcutaneous use / Adamis Pharmaceuticals Corporation	Non-selective alpha and beta-adrenergic receptor agonist	Emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects (e.g., order Hymenoptera, which include bees, wasps, hornets, yellow jackets and fire ants) and biting insects (e.g., triatoma, mosquitoes), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g., radiocontrast media) and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.	06/15/2017	**DOSAGE AND ADMINISTRATION** This product delivers 0.3 mg epinephrine injection (0.3 mL) and is intended for patients who weigh 30 kg or more (approximately 66 pounds or more). **DOSAGE FORMS AND STRENGTHS** For Injection: Single-dose pre-filled syringe for manual injection, containing 0.3 mg/0.3 mL epinephrine sterile solution for injection. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Emergency Treatment:** Is intended for immediate administration as emergency supportive therapy and is not intended as a substitute for immediate medical care. In conjunction with the administration of epinephrine, the patient should seek immediate medical or hospital care. More than two sequential doses of epinephrine should only be administered under direct medical supervision. • **Injection-related Complications:** Should only be injected into the anterolateral aspect of the thigh. ○ Do not inject intravenously – May result in cerebral hemorrhage due to sharp rise in blood pressure. ○ Do not inject into buttock – May not provide effective treatment of anaphylaxis. ○ Do not inject into digits, hands or feet – may result in loss of blood flow to the affected area. ○ Hold leg firmly during injection.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Symjepi™ (epinephrine) Injection, for intramuscular or subcutaneous use / Adamis Pharmaceuticals Corporation **(continuation…)**	Non-selective alpha and beta-adrenergic receptor agonist	Emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects (e.g., order Hymenoptera, which include bees, wasps, hornets, yellow jackets and fire ants) and biting insects (e.g., triatoma, mosquitoes), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g., radiocontrast media) and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.	06/15/2017	**WARNINGS AND PRECAUTIONS (continuation…)** • **Serious Infections at the Injection Site:** Rare cases of serious skin and soft tissue infections, including necrotizing fasciitis and myonecrosis caused by Clostridia (gas gangrene), have been reported at the injection site following epinephrine injection for anaphylaxis. Clostridium spores can be present on the skin and introduced into the deep tissue with subcutaneous or intramuscular injection. While cleansing with alcohol may reduce presence of bacteria on the skin, alcohol cleansing does not kill Clostridium spores. • **Allergic Reactions Associated with Sulfite:** The presence of a sulfite in this product should not deter administration of the drug for the treatment of serious allergic or other emergency situations even if the patient is sulfite-sensitive. • **Disease Interactions:** Epinephrine should be administered with caution to patients with heart disease (including patients with cardiac arrhythmias, coronary artery or organic heart disease, or hypertension), hyperthyroidism, diabetes, elderly individuals, and pregnant women. Patients with Parkinson's disease may notice a temporary worsening of symptoms. **ADVERSE REACTIONS** Most common adverse reactions: anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache, and/or respiratory difficulties. **DRUG INTERACTIONS** • Patients who receive epinephrine while concomitantly taking cardiac glycosides, diuretics, or anti- arrhythmics should be observed carefully for the development of cardiac arrhythmia.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Symjepi™ (epinephrine) Injection, for intramuscular or subcutaneous use / Adamis Pharmaceuticals Corporation **(continuation…)**	Non-selective alpha and beta-adrenergic receptor agonist	Emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects (e.g., order Hymenoptera, which include bees, wasps, hornets, yellow jackets and fire ants) and biting insects (e.g., triatoma, mosquitoes), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g., radiocontrast media) and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.	06/15/2017	**DRUG INTERACTIONS (continuation…)** • The effects of epinephrine may be potentiated by tricyclic antidepressants, monoamine oxidase inhibitors, levothyroxine sodium, and certain antihistamines, notably chlorpheniramine, tripelennamine, and diphenhydramine. • The cardiostimulating and bronchodilating effects of epinephrine are antagonized by beta-adrenergic blocking drugs, such as propranolol. • The vasoconstricting and hypertensive effects of epinephrine are antagonized by alpha-adrenergic blocking drugs, such as phentolamine. • Ergot alkaloids may also reverse the pressor effects of epinephrine. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** There are no adequate and well controlled studies of the acute effect of epinephrine in pregnant women. Epinephrine should be used for treatment of anaphylaxis during pregnancy in the same manner as it is used in non-pregnant patients. • **Lactation:** There is no information regarding the presence of epinephrine in human milk, the effects on breastfed infants, or the effects on milk production. Epinephrine should be used in the same manner in breastfeeding and non- breastfeeding patients. • **Pediatric Use:** Symjepi™ may be given safely to pediatric patients at a dosage appropriate to body weight • **Geriatric Use:** Symjepi™ should be administered with caution in elderly individuals, who may be at greater risk for developing adverse reactions after epinephrine administration.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Cotempla™ XR-ODT (methylphenidate) Extended-Release Disintegrating Tablets, for oral use / Neos Therapeutics, Inc.	Central nervous system (CNS) stimulant **CONTROLLED SUBSTANCE** Schedule II	Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age **BLACK BOX WARNING** CNS stimulants, including methylphenidate extended-release orally disintegrating tablets, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy.	06/19/2017	**DOSAGE AND ADMINISTRATION** The recommended starting dose is 17.3 mg given orally once daily in the morning. Dosage may be increased weekly in increments of 8.6 mg to 17.3 mg per day. • Daily dosage above 51.8 mg is not recommended. **DOSAGE FORMS AND STRENGTHS** Extended-Release Orally Disintegrating Tablets: 8.6 mg, 17.3 mg and 25.9 mg. **CONTRAINDICATIONS** • Known hypersensitivity to methylphenidate or product components. • Concurrent treatment with a monoamine oxidase inhibitor (MAOI), or use of an MAOI within the preceding 14 days. **WARNINGS AND PRECAUTIONS** • **Black Box Warning:** CNS stimulants, including COTEMPLA XR-ODT, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy. • **Serious Cardiovascular Reactions:** Sudden death has been reported in association with CNS stimulants at recommended doses in children and adolescents with structural cardiac abnormalities or other serious heart problems. In adults, sudden death, stroke, and myocardial infarction have been reported. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmias, or coronary artery disease. • **Blood Pressure and Heart Rate Increases:** Monitor blood pressure and pulse. Consider the benefits and risks in patients for whom an increase in blood pressure or heart rate would be problematic.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Cotempla™ XR-ODT (methylphenidate) Extended-Release Disintegrating Tablets, for oral use / Neos Therapeutics, Inc. **(continuation…)**	Central nervous system (CNS) stimulant **CONTROLLED SUBSTANCE** Schedule II	Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age **BLACK BOX WARNING** CNS stimulants, including methylphenidate extended-release orally disintegrating tablets, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy.	06/19/2017	**WARNINGS AND PRECAUTIONS (continuation…)** • **Psychiatric Adverse Reactions:** Use of stimulants may cause psychotic or manic symptoms in patients with no prior history, or exacerbation of symptoms in patients with pre-existing psychiatric illness. Evaluate for bipolar disorder prior to COTEMPLA XR-ODT use. • **Priapism:** Cases of painful and prolonged penile erections and priapism have been reported with methylphenidate products. Immediate medical attention should be sought if signs or symptoms or prolonged penile erections or priapism are observed. • **Peripheral Vasculopathy, including Raynaud's Phenomenon:** Stimulants used to treat ADHD are associated with peripheral vasculopathy, including Raynaud's phenomenon. Careful observation for digital changes is necessary during treatment with ADHD stimulants. • **Long-term Suppression of Growth:** Monitor height and weight at appropriate intervals in pediatric patients. **ADVERSE REACTIONS** Most common adverse reactions: appetite decreased, insomnia, nausea, vomiting, dyspepsia, abdominal pain, weight decreased, anxiety, dizziness, irritability, affect lability, tachycardia, and blood pressure increased. **DRUG INTERACTIONS** • **MAO Inhibitors (e.g. selegiline, tranylcypromine, isocarboxazid, phenelzine, linezolid, methylene blue):** Concomitant use of MAOIs and CNS stimulants can cause hypertensive crisis. Do not administer COTEMPLA™-XR ODT concomitantly with MAOIs or within 14 days after discontinuing MAOI treatment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Cotempla™ XR-ODT (methylphenidate) Extended-Release Disintegrating Tablets, for oral use / Neos Therapeutics, Inc. **(continuation…)**	Central nervous system (CNS) stimulant **CONTROLLED SUBSTANCE** Schedule II	Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age **BLACK BOX WARNING** CNS stimulants, including methylphenidate extended-release orally disintegrating tablets, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy.	06/19/2017	**DRUG INTERACTIONS (continuation…)** • **Gastric pH Modulators (e.g. omeprazole, famotidine, sodium bicarbonate):** May change the release profile and alter the pharmacodynamics of COTEMPLA-XR ODT. Concomitant use of Cotempla™ XR-ODT with a gastric pH modulator (e.g. a H2-blocker or a proton pump inhibitor) is not recommended. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Published studies and post-marketing reports on methylphenidate use during pregnancy are insufficient to inform a drug-associated risk of adverse pregnancy-related outcomes. There are risks to the fetus associated with the use of central nervous system (CNS) stimulants during pregnancy. • **Lactation:** Limited published literature, based on breast milk sampling from five mothers, reports that methylphenidate is present in human milk. There are no reports of adverse effects on the breastfed infant and no effects on milk production. Long- term neurodevelopmental effects on infants from stimulant exposure are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for COTEMPLA XR-ODT and any potential adverse effects on the breastfed child from COTEMPLA XR-ODT or from the underlying maternal condition. • **Pediatric Use:** The long-term efficacy of methylphenidate in pediatric patients has not been established. Safety and effectiveness of COTEMPLA XR-ODT in pediatric patients below 6 years of age have not been established. • **Geriatric Use:** COTEMPLA XR-ODT has not been studied in patients over the age of 65 years.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Baxdela™ (delafloxacin) Injection for intravenous use and Tablets for oral use / Melinta Therapeutics	Fluoroquinolone antibacterial • Active against both gram-positive and gram-negative pathogens (including MRSA)	Treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria. **BLACK BOX WARNING** Fluoroquinolones have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together, including tendinitis and tendon rupture, peripheral neuropathy, and central nervous system effects. Discontinue delafloxacin immediately and avoid the use of fluoroquinolones, including delafloxacin, in patients who experience any of these serious adverse reactions. Fluoroquinolones may exacerbate muscle weakness in patients with myasthenia gravis. Avoid delafloxacin in patients with known history of myasthenia gravis.	06/19/2017	**DOSAGE AND ADMINISTRATION** The recommended dose for injection is 300 mg by intravenous infusion over 60 minutes, every 12 hours. The recommended dose for tablets is 450-mg give orally every 12 hours for 5 to 14 days total duration. **DOSAGE FORMS AND STRENGTHS** For Injection: 300 mg of delafloxacin (equivalent to 433 mg delafloxacin meglumine) as a lyophilized powder in a single dose vial for reconstitution and further dilution before intravenous infusion. Oral Tablets: 450 mg delafloxacin (equivalent to 649 mg delafloxacin meglumine). **CONTRAINDICATIONS** • Known hypersensitivity to BAXDELA or other fluoroquinolones. **WARNINGS AND PRECAUTIONS** • **Black Box Warning:** Serious adverse reactions including tendinitis and tendon rupture, peripheral neuropathy, and central nervous system effects. • **Hypersensitivity Reactions:** May occur after first or subsequent doses of BAXDELA. Discontinue BAXDELA at the first sign of a skin rash or any other sign of hypersensitivity. • **Clostridium difficile-associated diarrhea:** Evaluate if diarrhea occurs. **ADVERSE REACTIONS** Most common adverse reactions: nausea, diarrhea, headache, transaminase elevations and vomiting.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Baxdela™ (delafloxacin) Injection for intravenous use and Tablets for oral use / Melinta Therapeutics **(continuation…)**	Fluoroquinolone antibacterial • Active against both gram-positive and gram-negative pathogens (including MRSA)	Treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria. **BLACK BOX WARNING** Fluoroquinolones have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together, including tendinitis and tendon rupture, peripheral neuropathy, and central nervous system effects. Discontinue delafloxacin immediately and avoid the use of fluoroquinolones, including delafloxacin, in patients who experience any of these serious adverse reactions. Fluoroquinolones may exacerbate muscle weakness in patients with myasthenia gravis. Avoid delafloxacin in patients with known history of myasthenia gravis.	06/19/2017	**DRUG INTERACTIONS** • Chelation Agents (Antacids, Sucralfate, Metal Cations, Multivitamins): Fluoroquinolones form chelates with alkaline earth and transition metal cations. Oral administration of BAXDELA with antacids containing aluminum or magnesium, with sucralfate, with metal cations such as iron, or with multivitamins containing iron or zinc, or with formulations containing divalent and trivalent cations such as didanosine buffered tablets for oral suspension or the pediatric powder for oral solution, may substantially interfere with the absorption of BAXDELA, resulting in systemic concentrations considerably lower than desired. Therefore, BAXDELA should be taken at least 2 hours before or 6 hours after these agents. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** The limited available data with BAXDELA use in pregnant women are insufficient to inform a drug-associated risk of major birth defects and miscarriages. • **Lactation:** There are no data available on the presence of delafloxacin in human milk, the effects on the breast-fed infant, or the effects on milk production. • **Pediatric Use:** Use in patients under 18 years of age is not recommended. • **Geriatric Use:** Geriatric patients are at increased risk for developing severe tendon disorders including tendon rupture when being treated with a fluoroquinolones. This risk is further increased in patients receiving concomitant corticosteroid therapy. Caution should be used when prescribing BAXDELA to elderly patients especially those on corticosteroids.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Baxdela™ (delafloxacin) Injection for intravenous use and Tablets for oral use / Melinta Therapeutics **(continuation…)**	Fluoroquinolone antibacterial • Active against both gram-positive and gram-negative pathogens (including MRSA)	Treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria. **BLACK BOX WARNING** Fluoroquinolones have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together, including tendinitis and tendon rupture, peripheral neuropathy, and central nervous system effects. Discontinue delafloxacin immediately and avoid the use of fluoroquinolones, including delafloxacin, in patients who experience any of these serious adverse reactions. Fluoroquinolones may exacerbate muscle weakness in patients with myasthenia gravis. Avoid delafloxacin in patients with known history of myasthenia gravis.	06/19/2017	**USE IN SPECIFIC POPULATIONS (continuation…)** • **Renal Impairment:** The dose of BAXDELA intravenous infusion in patients with severe renal impairment (eGFR 15-29 mL/min/1.73 m2) should be decreased to 200 mg intravenously every 12 hours; the dose of oral BAXDELA in patients with severe renal impairment is 450mg orally every 12 hours. BAXDELA is not recommended in patients with End Stage Renal Disease [ESRD] (eGFR of <15 mL/min/1.73 m2). Closely monitor serum creatinine levels in patients with severe renal impairment receiving intravenous delafloxacin. If serum creatinine level increases occur, consider changing to oral delafloxacin. Discontinue BAXDELA if eGFR decreases to <15 mL/min/1.73 m2.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Mydayis™ (amphetamine mixed salts) Capsules, for oral use / Shire US, Inc.	Central nervous system (CNS) stimulant **CONTROLLED SUBSTANCE** Schedule II	Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 13 years and older. **BLACK BOX WARNING** CNS stimulants, including dextroamphetamine/ amphetamine extended-release capsules, other amphetamine-containing products, and methylphenidate, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy. Misuse of amphetamines may cause sudden death and serious cardiovascular adverse reactions.	06/20/2017	**DOSAGE AND ADMINISTRATION** For patients 13 to 17 years old patients: The recommended initial dose is 12.5 mg orally once daily in the morning. For titration, may increase to MAX, 25 mg/day after 1 week. Periodically reassess long-term use and adjust dosage as appropriate For patients 18 to 55 years old: The recommended initial dose is 12.5 mg or 25 mg orally once daily in the morning. For titration, may increase daily dose in 12.5-mg increments at weekly intervals up to MAX, 50 mg/day. Periodically reassess long-term use and adjust dosage as appropriate. **DOSAGE FORMS AND STRENGTHS** Extended Release Oral Capsule: 12.5 MG, 25 MG, 37.5 MG, 50 MG **CONTRAINDICATIONS** • Advanced arteriosclerosis • Agitated states • Concomitant use or use within 14 days of MAOI administration, including linezolid or IV methylene blue; may result in hypertensive crisis • Concomitant use of sibutramine • Glaucoma • History of drug abuse • Hypersensitivity or idiosyncrasy to amphetamine, or other product components • Hyperthyroidism • Moderate to severe hypertension • Symptomatic cardiovascular disease

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Mydayis™ (amphetamine mixed salts) Capsules, for oral use / Shire US, Inc. **(continuation…)**	Central nervous system (CNS) stimulant **CONTROLLED SUBSTANCE** Schedule II	Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 13 years and older. **BLACK BOX WARNING** CNS stimulants, including dextroamphetamine/ amphetamine extended-release capsules, other amphetamine-containing products, and methylphenidate, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy. Misuse of amphetamines may cause sudden death and serious cardiovascular adverse reactions.	06/20/2017	**WARNINGS AND PRECAUTIONS** • **Black box warning:** (1) Abuse and dependence may occur; assessment of risk prior to initiation and monitoring recommended. (2) Administration of amphetamines for prolonged periods should be avoided as this may lead to drug dependence. (3) Sudden death and serious cardiovascular events may occur with amphetamine misuse. • **Beers Criteria:** Avoid in elderly patients with insomnia due to CNS stimulant effects. • **Administration:** Medication errors are possible during dispensing or with substitutions that may possibly lead to overdosage due to different amphetamine base compositions and pharmacokinetic profiles. Do not substitute Mydayis(TM) on a mg-per-mg basis with other amphetamine products. • **Cardiovascular:** (1) Sudden death has been reported with CNS stimulant treatment in patients with structural cardiac abnormalities or serious cardiac problems including cardiomyopathy, coronary artery disease, and serious heart rhythm abnormalities; avoid use. (2) Blood pressure and heart rate increases have been reported and may impact underlying medical conditions such as preexisting hypertension, heart failure, recent myocardial infarction, or ventricular arrythmia; monitoring recommended. (3) Myocardial infarction, stroke, and death have been reported with stimulant treatment at usual doses in adults. Avoid use in patient with structural cardiac abnormalities or serious cardiac problems including cardiomyopathy, coronary artery disease, and serious heart rhythm abnormalities. (4) Peripheral vasculopathy (eg, Raynaud phenomenon) has been reported and may result in digital ulceration and soft tissue breakdown. Monitoring is recommended and dosage adjustment or discontinuation may be necessary. • **Concomitant use:** Avoid use of gastrointestinal alkalizing agents (eg, antacids).

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Mydayis™ (amphetamine mixed salts) Capsules, for oral use / Shire US, Inc. **(continuation…)**	Central nervous system (CNS) stimulant **CONTROLLED SUBSTANCE** Schedule II	Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 13 years and older. **BLACK BOX WARNING** CNS stimulants, including dextroamphetamine/ amphetamine extended-release capsules, other amphetamine-containing products, and methylphenidate, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy. Misuse of amphetamines may cause sudden death and serious cardiovascular adverse reactions.	06/20/2017	**WARNINGS AND PRECAUTIONS (continuation…)** • **Endocrine and metabolic:** Growth suppression may occur with consistent use; monitoring recommended and treatment interruption may be necessary. • **Neurologic:** (1) Seizures may occur due to a lowering of the convulsive threshold, particularly in patients with a seizure history or EEG abnormalities; discontinue if occur. (2) History of motor and phonic tics; risk of exacerbation. (3) History of Tourette syndrome; risk of exacerbation. • **Ophthalmic:** Visual disturbances, including difficulties with accommodation and blurring of vision, have been reported. • **Psychiatric:** (1) Aggressive behavior and hostility have been reported; monitoring recommended. (2) Bipolar disorder; treatment may precipitate a mixed/manic episode. (3) Preexisting psychosis; treatment may exacerbate symptoms of behavior disturbance and thought disorder. (4) Psychotic or manic symptoms (eg, hallucinations, delusional thinking, or mania) may occur in children or adolescents with no prior history of psychotic illness at usual doses; discontinuation may be necessary. • **Serotonin syndrome:** Serotonin syndrome may occur, especially with concurrent use with other serotonergic drugs (eg, MAOIs (including IV methylene blue and linezolid), SSRIs, serotonin norepinephrine reuptake inhibitors, triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, St John's wort), or CYP2D6 inhibitors that may increase amphetamine exposure; consider alternative therapy or adjust dosage if concomitant use is necessary. Monitoring recommended; immediately discontinue both agents if symptoms occur. **ADVERSE REACTIONS** Most common adverse reactions: trouble sleeping, decreased appetite, dry mouth, increased heart rate, anxiety, nausea, irritability, weight loss.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Mydayis™ (amphetamine mixed salts) Capsules, for oral use / Shire US, Inc. **(continuation…)**	Central nervous system (CNS) stimulant **CONTROLLED SUBSTANCE** Schedule II	Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 13 years and older. **BLACK BOX WARNING** CNS stimulants, including dextroamphetamine/ amphetamine extended-release capsules, other amphetamine-containing products, and methylphenidate, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy. Misuse of amphetamines may cause sudden death and serious cardiovascular adverse reactions.	06/20/2017	**DRUG INTERACTIONS** • Concurrent use with MONOAMINE OXIDASE INHIBITORS may result in hypertensive crisis (headache, hyperpyrexia, hypertension). • Concurrent use of SIBUTRAMINE and CENTRALLY ACTING APPETITE SUPPRESSANTS may result in an increased risk of hypertension and tachycardia. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Category C. • **Lactation:** • **Pediatric Use:** Mydayis is not for use in children 12 years and younger. • **Geriatric Use:** Avoid in elderly patients with insomnia due to CNS stimulant effects. • **Renal impairment:** In adults with ADHD (Severe, GFR 15 to less than 30 mL/min/1.73 m(2) → Initial, 12.5 mg orally once daily in the morning; MAX, 25 mg/day. In pediatric patients with ADHD (Severe): MAX, 12.5 mg/day. Not recommended for use in in patients with ADHD and ESRD (GFR less than 15 mL/min/1.73 m2). • **Insomnia or anorexia in patients with narcolepsy:** Reduce dosage.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments

Rituxan Hycela™ (rituximab and hyaluronidase human) Injection, for subcutaneous use / Genentech, Inc.	Antineoplastic agent
	
	Rituximab is a CD20-directed cytolytic antibody
	
	Hyaluronidase human is an endoglycosidase
		Treatment of adult patients with follicular lymphoma (FL), diffuse large B-cell lymphoma (DLBCL), and chronic lymphocytic leukemia (CLL).
		
		BLACK BOX WARNING
		Severe, including fatal, mucocutaneous reactions can occur in patients receiving rituximab-containing products, including rituximab and hyaluronidase human, recombinant. Hepatitis B Virus (HBV) reactivation can occur in patients treated with rituximab-containing products, including rituximab and hyaluronidase human, recombinant, in some cases resulting in fulminant hepatitis, hepatic failure, and death. Screen all patients for HBV infection before treatment initiation, and monitor patients during and after treatment with rituximab and hyaluronidase human, recombinant. Discontinue rituximab and hyaluronidase human, recombinant and concomitant medications in the event of HBV reactivation. Progressive Multifocal Leukoencephalopathy (PML), including fatal PML, can occur in patients receiving rituximab-containing products, including rituximab and hyaluronidase human, recombinant.
			06/22/2017	**DOSAGE AND ADMINISTRATION**
				For FL and DLBCL: Administer 1,400 mg/23,400 Units (1,400 mg rituximab and 23,400 Units hyaluronidase human) subcutaneously according to recommended schedule
				
				For CLL: Administer 1,600 mg/26,800 Units (1,600 mg rituximab and 26,800 Units hyaluronidase human) subcutaneously according to recommended schedule.
				
				• All patients must receive at least one full dose of a rituximab product by intravenous infusion before receiving RITUXAN HYCELA by subcutaneous injection.
				• Premedicate with acetaminophen and antihistamine before each dose; In addition, consider premedication with glucocorticoids.
				• Administer specified volume into subcutaneous tissue of abdomen:
				  ○ 11.7 mL from 1,400 mg/23,400 Units vial over approximately 5 minutes.
				  ○ 13.4 mL from 1,600 mg/26,800 Units vial over approximately 7 minutes.
				• Observe 15 minutes following administration.
				
				DOSAGE FORMS AND STRENGTHS
				For Injection: 1,400 mg rituximab and 23,400 Units hyaluronidase human per 11.7 mL (120 mg/2,000 Units per mL) solution in a single-dose vial; 1,600 mg rituximab and 26,800 Units hyaluronidase human per 13.4 mL (120 mg/2,000 Units per mL) solution in a single-dose vial.
				
				CONTRAINDICATIONS
				None.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Rituxan Hycela™ (rituximab and hyaluronidase human) Injection, for subcutaneous use / Genentech, Inc. **(continuation…)**	Antineoplastic agent Rituximab is a CD20-directed cytolytic antibody Hyaluronidase human is an endoglycosidase	Treatment of adult patients with follicular lymphoma (FL), diffuse large B-cell lymphoma (DLBCL), and chronic lymphocytic leukemia (CLL). **BLACK BOX WARNING** Severe, including fatal, mucocutaneous reactions can occur in patients receiving rituximab-containing products, including rituximab and hyaluronidase human, recombinant. Hepatitis B Virus (HBV) reactivation can occur in patients treated with rituximab-containing products, including rituximab and hyaluronidase human, recombinant, in some cases resulting in fulminant hepatitis, hepatic failure, and death. Screen all patients for HBV infection before treatment initiation, and monitor patients during and after treatment with rituximab and hyaluronidase human, recombinant. Discontinue rituximab and hyaluronidase human, recombinant and concomitant medications in the event of HBV reactivation. Progressive Multifocal Leukoencephalopathy (PML), including fatal PML, can occur in patients receiving rituximab-containing products, including rituximab and hyaluronidase human, recombinant.	06/22/2017	**WARNINGS AND PRECAUTIONS** • **Black box warning:** (1) Severe, including fatal, mucocutaneous reactions (ie, paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis) can occur in patients receiving rituximab-containing products; discontinue if reactions occur. (2) Hepatitis B Virus (HBV) reactivation has been reported and may result in fulminant hepatitis, hepatic failure, and death; screen all patients for HBV infection prior to treatment initiation. Monitoring during and after treatment recommended; reactivation has occurred up to 24 months following treatment completion. Discontinue if HBV reactivation occurs. (3) JC virus infection resulting in progressive multifocal leukoencephalopathy (PML), including fatal PML, has been reported; discontinue if PML develops. • **Administration:** Severe infusion-related reactions, including fatal ones, have been reported; onset may range from 30 minutes to 2 hours after starting first IV infusion. • **Cardiovascular:** (1) Increased risk of adverse reaction in patients with cardiac conditions or a history of cardiopulmonary adverse events; monitoring recommended. (2) Cardiac adverse reactions, including myocardial infarction, ventricular fibrillation, and cardiogenic shock may occur; monitoring recommended in high risk patients. • **Concomitant use:** Live virus vaccine use prior to or during rituximab therapy not recommended. • **Dermatologic:** Cutaneous and injection-site reactions have been reported; may occur up to 24 hours after administration. • **Gastrointestinal:** Cases of abdominal pain and bowel obstruction and perforation, some fatal, has been reported; evaluate patient if symptoms of obstruction occur.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Rituxan Hycela™ (rituximab and hyaluronidase human) Injection, for subcutaneous use / Genentech, Inc. **(continuation…)**	Antineoplastic agent Rituximab is a CD20-directed cytolytic antibody Hyaluronidase human is an endoglycosidase	Treatment of adult patients with follicular lymphoma (FL), diffuse large B-cell lymphoma (DLBCL), and chronic lymphocytic leukemia (CLL). **BLACK BOX WARNING** Severe, including fatal, mucocutaneous reactions can occur in patients receiving rituximab-containing products, including rituximab and hyaluronidase human, recombinant. Hepatitis B Virus (HBV) reactivation can occur in patients treated with rituximab-containing products, including rituximab and hyaluronidase human, recombinant, in some cases resulting in fulminant hepatitis, hepatic failure, and death. Screen all patients for HBV infection before treatment initiation, and monitor patients during and after treatment with rituximab and hyaluronidase human, recombinant. Discontinue rituximab and hyaluronidase human, recombinant and concomitant medications in the event of HBV reactivation. Progressive Multifocal Leukoencephalopathy (PML), including fatal PML, can occur in patients receiving rituximab-containing products, including rituximab and hyaluronidase human, recombinant.	06/22/2017	**WARNINGS AND PRECAUTIONS (continuation…)** • **Immunologic:** (1) Cytokine release syndrome, sometimes indistinguishable from hypersensitivity reactions, may occur within 1 to 2 hours of initiating the infusion. Has been associated with acute respiratory failure and death; patients with a history of pulmonary insufficiency or those with pulmonary tumor infiltration at higher risk; monitoring required and treatment interruption necessary if syndrome occurs. (2) Hypersensitivity and anaphylactic reactions may occur; premedication and monitoring required. Treatment interruption may be necessary if symptoms occur. (3) Increased risk of adverse reaction in patients with high numbers of circulating malignant cells (greater than or equal to 25,000/mm(3)); monitoring recommended. (4) Serious and fatal infections (ie, new or reactivated cytomegalovirus, herpes simplex, parvovirus B19, varicella zoster, West Nile, and hepatitis B and C) have occurred; including in some patients with prolonged hypogammaglobulinemia (ie, more than 11 months after rituximab exposure), discontinuation may be necessary. Renal: Severe and fatal renal toxicity cases have been reported, especially in patients with tumor lysis syndrome as well as patients receiving concomitant cisplatin therapy (unapproved use); monitoring recommended and discontinuation may be necessary. • **Reproductive:** May cause fetal harm during pregnancy; advise use of effective contraception in women of reproductive potential during and 12 months after discontinuation. • **Respiratory:** Increased risk of adverse reaction in patients with pulmonary conditions or a history of cardiopulmonary adverse events; monitoring recommended. • **Tumor lysis syndrome (TLS):** TLS, some cases fatal, has been reported with monotherapy, typically within 12 to 24 hours after the first infusion; administer prophylaxis in high-risk patients with high numbers of circulating malignant cells (25,000/mm(3) or greater) or high tumor burden; monitoring recommended.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Rituxan Hycela™ (rituximab and hyaluronidase human) Injection, for subcutaneous use / Genentech, Inc. **(continuation…)**	Antineoplastic agent Rituximab is a CD20-directed cytolytic antibody Hyaluronidase human is an endoglycosidase	Treatment of adult patients with follicular lymphoma (FL), diffuse large B-cell lymphoma (DLBCL), and chronic lymphocytic leukemia (CLL). **BLACK BOX WARNING** Severe, including fatal, mucocutaneous reactions can occur in patients receiving rituximab-containing products, including rituximab and hyaluronidase human, recombinant. Hepatitis B Virus (HBV) reactivation can occur in patients treated with rituximab-containing products, including rituximab and hyaluronidase human, recombinant, in some cases resulting in fulminant hepatitis, hepatic failure, and death. Screen all patients for HBV infection before treatment initiation, and monitor patients during and after treatment with rituximab and hyaluronidase human, recombinant. Discontinue rituximab and hyaluronidase human, recombinant and concomitant medications in the event of HBV reactivation. Progressive Multifocal Leukoencephalopathy (PML), including fatal PML, can occur in patients receiving rituximab-containing products, including rituximab and hyaluronidase human, recombinant.	06/22/2017	**ADVERSE REACTIONS** Most common adverse reactions: • In FL: infections, neutropenia, nausea, constipation, cough, and fatigue • In DLBCL: infections, neutropenia, alopecia, nausea, and anemia • In CLL: infections, neutropenia, nausea, thrombocytopenia, pyrexia, vomiting, and injection site erythema **DRUG INTERACTIONS** • Renal toxicity when used in combination with cisplatin. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Based on human data, rituximab-containing products can cause adverse developmental outcomes including B-cell lymphocytopenia in infants exposed to rituximab in-utero. There are no available data on RITUXAN HYCELA use in pregnant women to inform a drug-associated risk of major birth defects and miscarriage. • **Lactation:** Advise not to breastfeed during treatment and for at least 6 months after the last dose of RITUXAN HYCELA due to the potential for serious adverse reactions in breastfed infants. • **Pediatric Use:** The safety and effectiveness of RITUXAN HYCELA in pediatric patients have not been established. • **Geriatric Use:** No overall differences in safety or effectiveness were observed between patients 65 years old or more and younger subjects. • **Females and Males of Reproductive Potential:** Rituximab-containing products can cause fetal harm. Females of childbearing potential should use effective contraception while receiving RITUXAN HYCELA and for 12 months following treatment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Haegarda™ (C1 esterase inhibitor (human)) Injection, for subcutaneous use / CSL Behring	C1-esterase inhibitor (C1-INH)	Replacement therapy to prevent (routine prophylaxis) Hereditary Angioedema (HAE) attacks in adolescent and adult patients.	06/22/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is 60 international units/kg subQ twice a week (every 3 or 4 days). **DOSAGE FORMS AND STRENGTHS** For Injection: White lyophilized powder supplied in single-use vials containing 2000 or 3000 International Units (IU) of C1-INH. **CONTRAINDICATIONS** • Hypersensitivity reactions, life-threatening (eg, anaphylaxis), to human C1 esterase inhibitors. **WARNINGS AND PRECAUTIONS** • Administration: Self-administration; due to risk of airway obstruction during acute laryngeal hereditary angioedema attacks, immediate medical attention is recommended in addition to self-administration of drug. • Hematologic: (1) Thrombotic events have been reported, with a possible increased risk in patients with immobility, morbid obesity, atherosclerosis, indwelling venous catheter or access device, history of thrombosis, or concomitant use of oral contraceptives or certain androgens; monitoring recommended in patients with risk factors. (2) Thrombosis has occurred with high doses IV treatment for prevention or therapy of capillary leak syndrome and during or after cardiac surgery (unapproved indication and dose). • Immunologic: (1) Hypersensitivity reactions (eg, hives, tightness of chest, wheezing, hypotension, and anaphylaxis) may occur during or after injection; exercise caution for treatment choice as symptoms may be similar to hereditary angioedema; epinephrine should be immediately available for acute hypersensitivity. (2) Infectious agent transmission may occur, including a risk of exposure to viruses, Creutzfeldt-Jakob disease or variant Creutzfeldt-Jakob disease, and other pathogens.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Haegarda™ (C1 esterase inhibitor (human)) Injection, for subcutaneous use / CSL Behring **(continuation…)**	C1-esterase inhibitor (C1-INH)	Replacement therapy to prevent (routine prophylaxis) Hereditary Angioedema (HAE) attacks in adolescent and adult patients.	06/22/2017	**ADVERSE REACTIONS** Most common adverse reactions: injection site reaction, hypersensitivity, nasopharyngitis and dizziness. **DRUG INTERACTIONS** None. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** There are no prospective clinical data from HAEGARDA use in pregnant women. • **Lactation:** There is no information regarding the excretion of HAEGARDA in human milk, the effect on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for HAEGARDA and any potential adverse effects on the breastfed infant from HAEGARDA or from the underlying maternal condition. • **Pediatric Use:** The safety and effectiveness of HAEGARDA were evaluated in a subgroup of six patients 12 to <17 years of age in the randomized, double-blind, placebo-controlled, crossover, routine prophylaxis trial. Results of subgroup analysis by age were consistent with overall study results. • **Geriatric Use:** The safety and effectiveness of HAEGARDA were evaluated in a subgroup of eight patients 65 to 72 years of age in the randomized, double-blind, placebo-controlled, crossover, routine prophylaxis trial. Results of subgroup analysis by age were consistent with overall study results.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Bevyxxa™ (betrixaban) Capsules, for oral use / Portola Pharmaceuticals Inc.	Factor Xa inhibitor anticoagulant	Extended-duration prophylaxis of venous thromboembolism (VTE) in at-risk adult patients hospitalized for an acute medical illness. **BLACK BOX WARNING** Spinal/Epidural Hematoma: Epidural or spinal hematomas may occur in patients treated with betrixaban who are receiving neuraxial anesthesia or undergoing spinal puncture. The risk of these events may be increased by the use of in-dwelling epidural catheters or concomitant use of medical products affecting hemostasis. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures.	06/23/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is an initial 160 mg orally as a single dose, followed by 80 mg once daily at the same time each day with food for 35 to 42 days. **DOSAGE FORMS AND STRENGTHS** Capsules: 40 mg and 80 mg **CONTRAINDICATIONS** • Active pathological bleeding. • Severe hypersensitivity reaction to betrixaban. **WARNINGS AND PRECAUTIONS** • **Black box warning:** Epidural or spinal hematomas may occur in patients treated with betrixaban who are receiving neuraxial anesthesia or undergoing spinal puncture, especially with the use of in-dwelling epidural catheters or concomitant medications affecting hemostasis. These hematomas may result in long-term or permanent paralysis; consider risks when scheduling patients for spinal procedures. Monitoring recommended; urgent treatment required. • **Concomitant use:** Avoid use in patients with severe renal impairment receiving concomitant P-gp inhibitors.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Bevyxxa™ (betrixaban) Capsules, for oral use / Portola Pharmaceuticals Inc. **(continuation…)**	Factor Xa inhibitor anticoagulant	Extended-duration prophylaxis of venous thromboembolism (VTE) in at-risk adult patients hospitalized for an acute medical illness. **BLACK BOX WARNING** Spinal/Epidural Hematoma: Epidural or spinal hematomas may occur in patients treated with betrixaban who are receiving neuraxial anesthesia or undergoing spinal puncture. The risk of these events may be increased by the use of in-dwelling epidural catheters or concomitant use of medical products affecting hemostasis. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures.	06/23/2017	**WARNINGS AND PRECAUTIONS (continuation…)** • **Hematologic:** (1) Increased risk for bleeding, including serious or fatal bleed, has been observed with use. Use of concomitant medications affecting hemostasis (eg, aspirin or other antiplatelet agents, anticoagulants, heparin, thrombolytic agents, SSRIs, selective serotonin norepinephrine reuptake inhibitors, and NSAIDs) increases bleed risk. Monitoring is recommended, and discontinuation may be necessary. (2) Risk of bleeding events may be increased in patients with severe renal impairment. Monitoring recommended; dosage adjustment may be necessary. (3) Anticoagulant effect has no established reversal agent, which may be expected to persist for 72 hours following last dose. Discontinue use if bleed is suspected. (4) Use proper procedure and timing of administration for spinal/epidural anesthesia or puncture to decrease risk of hematoma. **ADVERSE REACTIONS** Most common adverse reactions: bleeding **DRUG INTERACTIONS** • P-gp inhibitors increase the blood levels of betrixaban. Reduce BEVYXXA dose. • Anticoagulants: Avoid concomitant use. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Use only if potential benefit outweighs the potential risk to the mother or fetus. • **Lactation:** No data are available regarding the presence of betrixaban or its metabolites in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production. • **Pediatric Use:** Safety and effectiveness in pediatric patients have not been established.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Bevyxxa™ (betrixaban) Capsules, for oral use / Portola Pharmaceuticals Inc. **(continuation…)**	Factor Xa inhibitor anticoagulant	Extended-duration prophylaxis of venous thromboembolism (VTE) in at-risk adult patients hospitalized for an acute medical illness. **BLACK BOX WARNING** Spinal/Epidural Hematoma: Epidural or spinal hematomas may occur in patients treated with betrixaban who are receiving neuraxial anesthesia or undergoing spinal puncture. The risk of these events may be increased by the use of in-dwelling epidural catheters or concomitant use of medical products affecting hemostasis. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures.	06/23/2017	**USE IN SPECIFIC POPULATIONS (continuation…)** • **Geriatric Use:** No clinically significant differences in safety or effectiveness were observed between older and younger patients. • **Renal Impairment:** Patients with severe renal impairment (CrCl ≥ 15 to < 30 mL/min computed by Cockcroft-Gault using actual body weight) taking BEVYXXA may have an increased risk of bleeding events. Reduce dose. • **Patients on Concomitant P-gp Inhibitors:** These patients may have an increased risk of bleeding. Reduce dose of BEVYXXA in patients receiving or starting P-gp inhibitors. Avoid use of BEVYXXA in patients with severe renal impairment receiving concomitant P-gp inhibitors. • **Hepatic impairment:** Patients may have intrinsic coagulation abnormalities. Avoid use

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Triptodur™ (triptorelin) Injection, for intramuscular use / Arbor Pharmaceuticals, LLC	Antineoplastic Agent; Gonadotropin releasing hormone (GnRH) agonist	Treatment of pediatric patients aged 2 years and older with central precocious puberty (CPP).	06/30/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is a single intramuscular injection of 22.5 mg once every 24 weeks. • Monitor response with LH levels after a GnRH or GnRH agonist stimulation test, basal LH, or serum concentration of sex steroid levels beginning 1 to 2 months following initiation of therapy, during therapy as necessary to confirm maintenance of efficacy, and with each subsequent dose. • Measure height every 3-6 months and monitor bone age periodically. **DOSAGE FORMS AND STRENGTHS** For Injection: 22.5 mg of triptorelin as a powder cake for reconstitution to extended-release injectable suspension, with the co-packaged 2 mL of diluent Sterile Water for Injection. **CONTRAINDICATIONS** • Known hypersensitivity to triptorelin or any other component of the product, or other GnRH agonists or GnRH. • Women who are or may become pregnant. Expected hormonal changes that occur with Triptodur treatment increase the risk for pregnancy loss and fetal harm when administered to a pregnant woman. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus. **WARNINGS AND PRECAUTIONS** • **Initial Rise of Gonadotropins and Sex Steroid Levels:** An increase in clinical signs and symptoms of puberty may be observed during the first 2- 4 weeks of therapy since gonadotropins and sex steroids rise above baseline because of the initial stimulatory effect of the drug.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Triptodur™ (triptorelin) Injection, for intramuscular use / Arbor Pharmaceuticals, LLC **(continuation…)**	Antineoplastic Agent; Gonadotropin releasing hormone (GnRH) agonist	Treatment of pediatric patients aged 2 years and older with central precocious puberty (CPP).	06/30/2017	**WARNINGS AND PRECAUTIONS (continuation…)** • **Convulsions:** Have been observed in patients with or without a history of seizures, epilepsy, cerebrovascular disorders, central nervous system anomalies or tumors, and in patients on concomitant medications that have been associated with convulsions. **ADVERSE REACTIONS** Most common adverse reactions: injection site reactions, menstrual (vaginal) bleeding, hot flush, headache, cough, and infections (bronchitis, gastroenteritis, influenza, nasopharyngitis, otitis externa, pharyngitis, sinusitis, and upper respiratory tract infection). **DRUG INTERACTIONS** • Hyperprolactinemic drugs should not be used concomitantly with triptorelin since hyperprolactinemia reduces the number of pituitary GnRH receptors. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** TRIPTODUR is contraindicated in women who are pregnant since expected hormonal changes that occur with TRIPTODUR treatment increase the risk for pregnancy loss. • **Lactation:** There are no data on the presence of triptorelin in human milk, or the effects of the drug on the breastfed infant, or on milk production. • **Pediatric Use:** The safety and effectiveness of TRIPTODUR have not been established in pediatric patients less than 2 years old.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Dysport™ (abobotulinumtoxinA) Injection / IPSEN Biopharmaceuticals, Inc.	Acetylcholine release inhibitor and neuro-muscular blocking agent	Indicated for the treatment of cervical dystonia, for the temporary improvement in the appearance of moderate to severe glabellar lines, for the treatment of spasticity in adults, and the treatment of lower limb spasticity in pediatric patients. **New indication:** Treatment of Lower Limb Spasticity in Adults	06/14/2017	In July 2015, Dysport™ was approved for the treatment of upper limb spasticity in adults. In July 2016, Dysport™ was approved to treat pediatric patients with lower limb spasticity aged two and older, making it the first and only botulinum toxin that the FDA approved for this indication. A Phase III, multi-center, prospective, double-blind, randomized placebo-controlled study evaluated the efficacy and safety of Dysport™ for the treatment of lower limb spasticity in a population of 381 adult patients (253 received Dysport™ and 128 received placebo.) Patients had lower limb spasticity (MAS score >2 in the affected ankle joint for toxin naïve patients or MAS score >3 in the affected ankle joint for toxin non-naïve patients at least four months since the last botulinum toxin injection in the affected lower limb) and were at least six months post-stroke or post-traumatic brain injury. Adult patients treated with Dysport™ showed improvement in muscle tone at the ankle joint, measured by the mean change from baseline on the Modified Ashworth Scale (MAS) at Week 4. The duration of response for the majority of patients within the study was between 12-16 weeks. In this study, some patients experienced a longer duration of response (approximately 20 weeks). The most common adverse reactions were: falls, muscular weakness, and pain in extremity.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Darzalex™ (daratumumab) Injection / Janssen Biotech, Inc.	Human anti-CD38 monoclonal antibody	Indicated for the treatment of patients with multiple myeloma. **New indication:** In combination with pomalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.	06/16/2017	The approval was based on data from the Phase I (MMY1001, EQUULEUS) study of daratumumab in combination with pomalidomide and dexamethasone in relapsed or refractory multiple myeloma. The study included 103 patients (median age: 64 years) with multiple myeloma who had received prior treatment with a proteasome inhibitor (PI) and an immunomodulatory agent. Patients in the study had received a median of 4 prior lines of therapy, and 74% of patients had received prior autologous stem cell transplant (ASCT). Eighty-nine percent of patients were refractory to lenalidomide and 71% were refractory to bortezomib; 64% of patients were refractory to bortezomib and lenalidomide. Patients in the study received 16 mg/kg daratumumab in combination with pomalidomide and dexamethasone. The overall response rate in the study was 59% (95% CI: 49.1%, 68.8%), with very good partial response (VGPR) achieved in 28% of patients. Complete response (CR) was achieved in 6% of patients and stringent CR (sCR) was achieved in 8% of patients. The median time to response was 1 month (range: 0.9 to 2.8 months). The median duration of response was 13.6 months (range: 0.9+ to 14.6+ months). The most frequent adverse reactions (>20%) in the study were: infusion reactions, diarrhea, nausea, vomiting, fatigue, pyrexia, upper respiratory tract infection, muscle spasms, cough and dyspnea.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Vectibix™ (Panitumumab) / Amgen	Antineoplastic agent, Fully human monoclonal anti-epidermal growth factor receptor (EGFR) antibody	Indicated as monotherapy for the treatment of patients with EGFR-expressing mCRC after disease progression after prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy. **New indication:** For patients with wild-type *RAS* (defined as wild-type in both *KRAS* and *NRAS* as determined by an FDA-approved test for this use) metastatic colorectal cancer (mCRC) as first-line therapy in combination with FOLFOX and as monotherapy following disease progression after prior treatment with fluoropyrimidine, oxaliplatin, and irinotecan-containing chemotherapy.	06/30/2017	As part of this new indication, the FDA approved the first multigene, next-generation sequencing-based test to identify the *RAS* mutation status of a patient's tumor. Next-generation sequencing is a novel diagnostics test technique that makes a more personalized medicine approach possible. This companion diagnostic helps physicians identify patients that are more likely to benefit from treatment with Vectibix™. The approval of a refined indication for the treatment of patients with wild-type *RAS* mCRC was based on a retrospective analysis from the PRIME study and prospective, pre-defined analyses from the Phase 3 '0007 study. The '0007 study evaluated the efficacy of Vectibix™ plus best supportive care (BSC) versus BSC alone in patients with chemorefractory, wild-type *KRAS* mCRC. Data from a key secondary endpoint showed that patients with wild-type *RAS* (exons 2, 3, and 4 of *KRAS* and *NRAS*) mCRC treated with Vectibix™ plus BSC resulted in a statistically significant improvement in overall survival (OS) of 10 months compared to 6.9 months for patients treated with BSC alone (HR=0.70; 95 percent CI: 0.53, 0.93, *p*=0.0135). The safety profile of Vectibix™ in patients with wild-type *RAS* mCRC is consistent with that seen previously in patients with wild-type *KRAS* mCRC. Most common adverse reactions (≥ 20 percent) of Vectibix™ as monotherapy are skin rash with variable presentations, paronychia, fatigue, nausea and diarrhea. Most common adverse reactions (≥ 20 percent) with Vectibix™ plus FOLFOX are diarrhea, stomatitis, mucosal inflammation, asthenia, paronychia, anorexia, hypomagnesemia, hypokalemia, rash, acneiform dermatitis, pruritus and dry skin. The most common serious adverse reactions (≥ 2 percent difference between treatment arms) were diarrhea and dehydration.

New FDA Approved Formulation

- No new formulations approved during June 2017.

New First Time Generic Drug Approval

Drug/Manufacturer	Therapeutic Class	Date	Comments
Mesalamine Delayed-Release Tablets 1.2g / Zydus Pharmaceuticals (USA) Inc.	Anti-inflammatory, Anti-ulcer, Gastrointestinal agent	06/05/2017	Generic for: Lialda™
Emtricitabine and Tenofovir Disoproxil Fumarate Tablets 200 mg/300 mg / Teva Pharmaceuticals USA	Anti-retroviral agent	06/08/2017	Generic for: Truvada™
Sevelamer Carbonate for Oral Suspension 800 mg/packet and 2.4 g/ packet / Aurobindo Pharma Ltd.	Bile acid sequestrant	06/13/2017	Generic for: Renvela™ for Oral Suspension
Eletriptan Hydrobromide Tablets 20 mg (base) and 40 mg (base) / Zydus Pharmaceuticals USA, Inc.	Antimigraine	06/16/2017	Generic for: Relpax™

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

PIPELINE……

Drug/Manufacturer	Date	Indications	Comments	Impact
Bictegravir, emtricitabine and tenofovir alafenamide / Gilead Sciences, Inc.	06/12/2017	Treatment for: HIV Infection	Bictegravir, emtricitabine and tenofovir alafenamide is an investigational integrase strand transfer inhibitor and emtricitabine/tenofovir alafenamide (FTC/TAF) combination in development for the treatment of HIV-1 infection in adults.	Moderate
Tavalisse (fostamatinib) / Rigel Pharmaceuticals, Inc.	06/19/2017	Treatment for: Immune Thrombocytopenia	Fostamatinib is an investigational oral spleen tyrosine kinase (SYK) inhibitor in development for the treatment of patients with chronic and persistent immune thrombocytopenia (ITP).	High
Jatenzo (testosterone undecanoate) - formerly Rextoro / Clarus Therapeutics, Inc.	06/26/2017	Treatment for: Hypogonadism – Male	Jatenzo (testosterone undecanoate) is an oral testosterone replacement therapy in development for the treatment of low testosterone in hypogonadal men. Clarus Therapeutics, Inc. re-submits Jatenzo NDA Following Positive Results of inTUne Trial. New submission addresses all points raised by the FDA in the Complete Response Letter (CRL) issued to Clarus.	Moderate
KIT-302 (amlodipine and celecoxib) / Kitov Pharmaceuticals Holdings Ltd.	06/26/2017	Treatment for: Hypertension, Osteoarthritis	KIT-302 (amlodipine and celecoxib) is a calcium channel blocker and nonsteroidal anti-inflammatory drug combination in development for the treatment of both hypertension and pain associated with osteoarthritis.	Moderate
Twirla™ (ethinyl estradiol and levonorgestrel) Transdermal System / Agile Therapeutics, Inc.	06/27/2017	Treatment for: Contraception	Twirla™ (ethinyl estradiol and levonorgestrel transdermal system) is an investigational low-dose combined hormonal contraceptive. Agile Therapeutics, Inc. resubmitted and NDA in response to a February 2013 Complete Response Letter (CRL) from the FDA, which recommended that Agile conduct a new clinical trial and provide additional information on the manufacturing process for Twirla. The resubmitted NDA includes efficacy and safety data from the new Phase 3 clinical trial (also known as the SECURE trial), the requested manufacturing information, and a summary response to the CRL.	Low

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

PIPELINE……

Drug/Manufacturer	Date	Indications	Comments	Impact
Trevyent (treprostinil) / SteadyMed Ltd.	06/30/2017	Treatment for: **Pulmonary Arterial Hypertension**	Trevyent (treprostinil) is a preservative-free, parenteral formulation of the approved vasodilatory prostacyclin analogue treprostinil delivered via the proprietary PatchPump infusion system for the treatment of pulmonary arterial hypertension (PAH).	Moderate

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

References:

- Drugs.com (www.drugs.com)
- Food and Drug Administration (www.fda.gov)
- Micromedex® Truven Health Analytics (www.micromedexsolutions.com)
- Pharmacist Letter (www.pharmacistletter.com)