Specialty Pharmacy Pipeline

Drugs to Watch

Anticipated Launches | Q4 2016–Q1 2017

CVSHealth

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Anticipated Launches – 4th Quarter 2016 to 1st Quarter 2017

Therapeutic Category	Product Name, Route of Administration and Manufacturer[1]	Proposed Indication[1]	FDA Phase of Study[1]	Disease Prevalence	Select Available FDA-Approved Therapies	Comments — CVS Health Initial Recommendations
Atopic Dermatitis	dupilumab Subcutaneous injection Regeneron Pharmaceuticals/ Sanofi	The treatment of moderate-to-severe atopic dermatitis (AD) in adults	Pending U.S. Food and Drug Administration (FDA) approval	AD is a type of eczema characterized by itchy lesions and is often associated with allergic disorders (e.g., asthma, rhinitis or hay fever).[2] Open or crusted sores and skin infections may also occur. AD affects 2% to 10% of adults in the United States; of those, ~32% have moderate symptoms and ~15% have severe symptoms.[3]	Traditional therapy includes emollients, topical steroids and topical calcineurin inhibitors (Elidel [pimecrolimus], Protopic [tacrolimus])	The FDA has granted Breakthrough Therapy designation to dupilumab and is expected to review the application by the 1st quarter of 2017. If approved, dupilumab would be the first biologic agent for the treatment of AD. Dupilumab will be included in Specialty Guideline Management subsequent to approval.
Hepatitis	tenofovir alafenamide Oral Gilead Sciences	The treatment of chronic hepatitis B virus (HBV) infection	Pending FDA approval	Hepatitis B is a viral disease that can lead to liver damage or failure, liver cancer and death.[4] Approximately 850,000 to 2.2 million people in the United States have chronic HBV infection. It is estimated that 1,800 deaths occur annually in the United States due to chronic HBV infection.	**Oral antiviral agents:** Baraclude (entecavir), Epivir HBV (lamivudine), Hepsera (adefovir), Tyzeka (telbivudine), Viread (tenofovir disoproxil fumarate)	The FDA is expected to review the application by November 11, 2016. CVS Caremark® recommends at your discretion, the management of tenofovir alafenamide with the same clinical management tools you use for other antiviral agents for the treatment of HBV.
Multiple Sclerosis	Ocrevus (ocrelizumab) Intravenous injection Biogen/Genentech	The treatment of primary progressive multiple sclerosis (PPMS) and the treatment of relapsing-remitting multiple sclerosis (RRMS)	Pending FDA approval	MS is a chronic disease that damages the protective covering of nerves leading to a variety of symptoms ranging from numbness in the arms/legs to paralysis or loss of vision.[5] In RRMS, attacks (relapses) are followed by periods of recovery (remissions). In PPMS, relapses can occur but periods of remission do not. The risk of developing MS is approximately 1 in 750 but rises to 1 in 40 to 1 in 80 for individuals with a close relative with MS. MS is at least 2 to 3 times more common in women than in men. RRMS is the most common form accounting for ~85% while PPMS accounts for ~15% of cases.	**IV infusion agents:** Lemtrada (alemtuzumab), Tysabri (natalizumab) **IM/SC injection agents:** Avonex, Rebif (interferon beta 1a); Betaseron, Extavia (interferon beta-1b); glatiramer (Copaxone and generic); Plegridy (peginterferon beta 1a), Zinbryta (daclizumab) **Oral agents:** Aubagio (teriflunomide) Gilenya (fingolimod) Tecfidera (dimethyl fumarate)	The FDA is expected to review the application by December 28, 2016. Ocrevus was granted Breakthrough Therapy designation for the treatment of PPMS and, if approved, would provide the first disease modifying therapy for PPMS. Ocrevus will be included in Specialty Guideline Management subsequent to approval.

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Muscular Dystrophy	deflazacort Oral Marathon Pharmaceuticals	The treatment of Duchenne muscular dystrophy (DMD)	Pending FDA approval	Muscular dystrophy is a group of genetic disorders characterized by progressive muscle weakness and degeneration.[6] Heart and respiratory muscle wasting can be life threatening. DMD and a milder form, Becker muscular dystrophy, typically only affect males. Males with DMD typically live into their twenties. In the United States, approximately 15 per 100,000 males from 5-24 years of age are reported to have DMD.[7]	Corticosteroids (e.g., prednisone) may be offered	The FDA is expected to review the application for deflazacort by February 9, 2017. If approved, deflazacort would provide a symptomatic therapy for DMD. Deflazacort will be included in Specialty Guideline Management subsequent to approval.
Oral Oncology	rucaparib Oral Clovis Oncology/Pfizer	The treatment of advanced ovarian cancer with deleterious BRCA-mutated tumors in patients previously treated with two or more prior therapies	Pending FDA approval	Ovarian cancer is the fifth leading cause of cancer death in women.[8] Approximately 12 new cases of ovarian cancer per 100,000 women occur yearly.[9] The risk of developing ovarian cancer is increased in women who have the BRCA genetic mutation. BRCA mutations occur in ~10% to ~15% of cases of ovarian cancer.[10]	Lynparza (olaparib)	The FDA has granted Breakthrough Therapy designation to rucaparib and is expected to review the application by February 23, 2017. Rucaparib will be included in Specialty Guideline Management subsequent to approval.
	telotristat Oral Lexicon Pharmaceuticals	The treatment of carcinoid syndrome	Pending FDA approval	Carcinoid tumors are a rare type of cancer that begins in certain cells (typically in the intestinal tract, lungs, stomach or pancreas) that produce hormones.[11] These tumors may stimulate overproduction of the hormones and can lead to carcinoid syndrome which is characterized by flushing and diarrhea. Approximately 10% of patients with carcinoid tumors develop carcinoid syndrome.	octreotide (generic, Sandostatin, Sandostatin LAR), Somatuline Depot (lanreotide)	The FDA is expected to review the application by February 28, 2017. If approved, telotristat will provide an oral agent for patients with insufficient response to an injectable product. Telotristat will be included in Specialty Guideline Management subsequent to approval.

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Psoriasis	Siliq (brodalumab) Subcutaneous injection Valeant Pharmaceuticals	The treatment of moderate-to-severe plaque psoriasis	Pending FDA approval	It is estimated that approximately 2.2% of the U.S. population has psoriasis.[12] Plaque psoriasis is the most common form of psoriasis and is characterized by elevated, inflamed, scaly skin. These plaques are most often visible on the elbows, knees and scalp.	**SC injectable biologic agents:** Cosentyx (secukinumab), Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Taltz (ixekizumab) **Selected oral agents:** methotrexate (e.g., Trexall), Otezla (apremilast)	The FDA is expected to review the application by November 16, 2016. Siliq will be included in Specialty Guideline Management subsequent to approval.
Rheumatoid Arthritis	baricitinib Oral Eli Lilly/Incyte	The treatment of moderate-to-severe rheumatoid arthritis (RA)	Pending FDA approval	RA is an autoimmune disorder in which the immune system attacks healthy tissues.[13] RA can cause pain, stiffness, decreased function of the hands and feet as well as other joints. Other organs such as the lungs and eyes may be affected as well. RA is estimated to affect 1.2 million Americans; approximately 75% of those affected are women.	**Selected biologic injectable agents:** Actemra (tocilizumab), Cimzia (certolizumab pegol), Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab) **Selected oral agents:** methotrexate (e.g., Trexall), Xeljanz (tofacitinib)	The FDA is expected to review the applications for baricitinib and sarilumab by January 19, 2017, and by October 30, 2016, respectively. Both agents will be included in Specialty Guideline Management subsequent to approval.
	sarilumab Subcutaneous injection Regeneron Pharmaceuticals/Sanofi	The treatment of active, moderate-to-severe rheumatoid arthritis (RA)	Pending FDA approval			
	Inflectra (infliximab-dyyb) Intravenous injection Celltrion/Pfizer	The treatment of rheumatoid arthritis (RA) in combination with methotrexate, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis, Crohn's disease, pediatric Crohn's disease and ulcerative colitis	Approved 4/5/2016		Remicade (infliximab)	Inflectra is a biosimilar of Remicade. A biosimilar is a biological product that has no clinically meaningful differences in safety, purity and potency from the reference product. Launch of Inflectra is expected to be subject to the outcome of patent litigation and may occur as early as 4Q 2016. Inflectra will be included in Specialty Guideline Management.

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