Specialty Pharmacy Pipeline

Drugs to Watch

Anticipated Launches | Q4 2018-Q1 2019

CVSHealth

Therapeutic Category	Product Name, Route of Administration and Manufacturer[1]	Proposed Indication[1]	Phase of Study[1]	Disease Prevalence and Background	Select Available FDA-Approved Therapies	Comments
Amyloidosis	Tegsedi (inotersen) subcutaneous (SC) injection Akcea Therapeutics/Ionis Pharmaceuticals	The treatment of hereditary transthyretin amyloidosis (hATTR) with polyneuropathy, also known as familial amyloid polyneuropathy	Approved 10/05/2018	Amyloidosis is characterized by abnormal protein (amyloid) deposition in various organs and tissues and results in progressive organ dysfunction.[2] hATTR is a rare type of amyloidosis caused by a genetic mutation. Patients with hATTR may have symptoms primarily involving the peripheral nerves (polyneuropathy), though the heart is frequently affected as well. It is estimated that hATTR affects 1 in 100,000 Caucasians in the United States but is more common in African-Americans.[2]	Onpattro (patisiran)	Inotersen would be an alternative to recently approved Onpattro (patisiran). It will be included in Specialty Guideline Management. *Anticipated impact: replacement spend*

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Multiple Sclerosis (MS)	Mavenclad (cladribine) oral EMD Serono	The treatment of highly active relapsing multiple sclerosis (RMS)	Pending U.S. Food and Drug Administration (FDA) approval 12/30/2018	MS is an autoimmune disorder affecting the nerves of the brain and spinal cord. The protective nerve covering is damaged, leading to a variety of symptoms that can include vision changes, numbness, vertigo, bladder and bowel symptoms, weakness, muscle spasms and eventually to profound disability.[3] MS affects approximately 400,000 people in the U.S. The condition is mostly diagnosed between the ages of 15 and 50 and is more common in women.[3] Relapsing MS is the most common form of the disease, affecting about 85% of MS patients.[4] In RMS, patients have attacks (relapses) that are followed by periods of recovery (remissions). Most people with RMS eventually transition to SPMS, which is characterized by progressive worsening of neurologic functions without relapses and remissions. Within 10 and 25 years of MS diagnosis, about 50% and 90% of MS patients, respectively, will convert to SPMS.[4]	**SC/IM injections:** Avonex, Rebif (interferon beta-1a); Betaseron, Extavia (interferon beta-1b); Plegridy (peginterferon beta 1a); Copaxone (glatiramer) **Oral:** Aubagio (teriflunomide), Gilenya (fingolimod), Tecfidera (dimethyl fumarate) **Infused:** Lemtrada (alemtuzumab), Ocrevus (ocrelizumab), Tysabri (natalizumab)	Cladribine has a unique administration schedule and offers a highly effective treatment option for MS. It will be included in the Specialty Guideline Management subsequent to approval. *Anticipated impact: replacement spend*
	siponimod oral Novartis	The treatment of secondary progressive multiple sclerosis (SPMS)	Pending FDA approval 01/01/2019		Novantrone (mitoxantrone) IV approved but seldom used due to toxicity. Disease modifying treatments for RMS are used off-label.	If approved, siponimod will be the first oral treatment option for delaying disability progression in SPMS patients. It will be included in Specialty Guideline Management. *Anticipated impact: replacement spend*

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Oral Oncology	larotrectinib oral Loxo Oncology/ Array Biopharma/ Bayer	The treatment of relapsed or refractory unresectable or metastatic solid tumors with neurotrophic tropomyosin receptor kinase (NTRK)-fusion proteins	Pending FDA approval 11/26/2018	NTRK mutations are relatively rare, but occur across many tumor types, including some forms of breast, lung, and colorectal cancers. It is estimated there are fewer than 5,000 patients in the U.S. with NTRK fusion proteins.[5] Larotrectinib is believed to be tissue agnostic, i.e., effective for tumors with the NTRK biomarker, regardless of tissue origin.	Traditional IV chemotherapy used off-label.	Larotrectinib has been granted Breakthrough Therapy designation. If approved, it would be the first targeted drug for NTRK fusion protein mutations and would be included in Specialty Guideline Management. *Anticipated impact: replacement spend (shift from medical to pharmacy benefit)*
	gilteritinib oral Astellas	The treatment of relapsed or refractory acute myeloid leukemia (AML) in patients with FLT3 mutations	Pending FDA approval 11/29/2018	AML is a type of blood cancer that starts in certain immature blood cells and progresses quickly.[6] The average lifetime risk for AML is less than 0.5%. It occurs most commonly in individuals 45 years of age and older. Nearly one-third of patients diagnosed with AML have the FLT3 mutation, which is associated with poor outcomes.[7]	Traditional IV chemotherapy used off-label.	If approved, gilteritinib would be the first targeted agent for FLT3-mutant AML in patients who have failed other therapies. It will be included in Specialty Guideline Management. *Anticipated impact: replacement spend (shift from medical to pharmacy benefit)*
	glasdegib oral Pfizer	The first-line treatment of AML, in combination with low-dose chemotherapy	Pending FDA approval 12/27/2018		Traditional IV chemotherapy	Glasdegib would be an oral therapy option for patients who are not candidates for intensive IV chemotherapy. This agent will be included in Specialty Guideline Management. *Anticipated impact: replacement spend (shift from medical to pharmacy benefit)*

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Oral Oncology (continued)	lorlatinib oral Pfizer	The treatment of relapsed or refractory advanced non-small cell lung cancer (NSCLC) in patients with anaplastic lymphoma kinase (ALK) mutations	Pending FDA approval 11/12/2018	Lung cancer is the second most common cause of cancer and is the leading cause of cancer death in the U.S.[8] NSCLC is responsible for 80 to 85% of all lung cancer cases.[8] The ALK mutation is present in approximately 5% of NSCLC patients.[9]	Alecensa (alectinib), Alunbrig (brigatinib), Xalkori (crizotinib), Zykadia (ceritinib)	The FDA has granted Breakthrough Therapy designation to lorlatinib. Upon approval, it would provide an additional treatment for relapsed or refractory ALK-positive NSCLC. Lorlatinib will be included in Specialty Guideline Management. *Anticipated impact: replacement spend*
	talazoparib oral Pfizer	The treatment of HER2-negative advanced or metastatic BRCA-mutated breast cancer	Pending FDA approval 12/07/2018	BRCA mutations increase the risk of developing breast cancer. About 12% of women will have breast cancer in their lifetime; however, up to 65% of women with BRCA mutations develop breast cancer. Breast cancer is characterized by the presence or absence of certain receptors, markers, and mutations. BRCA-mutated breast cancer is present in up to 10% of cases and tends to be aggressive and occur in younger women.[10]	Lynparza (olaparib)	Talazoparib would provide another oral, targeted treatment option for BRCA-mutant breast cancer. Talazoparib will be included in Specialty Guideline Management. *Anticipated impact: replacement spend*
Postpartum Depression (PPD)	Zulresso (brexanolone) IV infusion Sage Therapeutics	The treatment of moderate to severe postpartum depression	Pending FDA approval 12/19/2018	PPD is a serious mood disorder that can last for many weeks or months after delivering a baby.[11] Some women with moderate to severe PPD may experience suicidal ideation or obsessive thoughts of harming their infants. Up to 1 in 7 women experiences PPD. About 25 to 50% of women will have a recurrence after a subsequent pregnancy.[12]	None (traditional oral antidepressant medications used off-label)	Zulresso (brexanolone) has been granted Breakthrough Therapy designation. If approved, it would be the first drug indicated for PPD and would offer a highly effective, rapidly acting treatment. *Anticipated impact: incremental spend; primarily medical benefit*

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[1] RxPipeline, September 2018.
[2] National Organization for Rare Disorders. Available at https://rarediseases.org/rare-diseases/amyloidosis/. Accessed March 27, 2018.
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[5] Loxo Oncology Pipeline presentation. Available at https://ir.loxooncology.com/docs/events/LOXO_19-Dec-2016_Call_Slides.pdf. Accessed June 25, 2018.
[6] American Cancer Society. About acute myeloid leukemia (AML). Available at https://www.cancer.org/cancer/acute-myeloid-leukemia/about.html. Accessed March 26, 2018.
[7] Bienz, et al. Risk Assessment in Patients with acute myeloid leukemia and a normal karyotype. Available at https://www.ncbi.nlm.nih.gov/pubmed/15746041. Accessed July 2, 2018.
[8] American Cancer Society. Non-small cell lung cancer. Available at https://www.cancer.org/cancer/non-small-cell-lung-cancer.html. Accessed March 26, 2018.
[9] My Cancer Genome. Lung Cancer. Available at https://www.mycancergenome.org/content/disease/lung-cancer. Accessed June 25, 2018.
[10] Genetics: Breast Cancer Risk Factors. Available at https://www.breastcancer.org/risk/factors/genetics. Accessed September 19, 2018.
[11] American Psychological Association. Available at http://www.apa.org/pi/women/resources/reports/postpartum-depression.aspx. Accessed September 6, 2018.
[12] American Family Physician. Available at https://www.aafp.org/afp/2010/1015/p926.html. Accessed September 6, 2018.

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