Specialty Pharmacy Pipeline

Drugs to Watch

Anticipated Launches | Q1 2020 – Q2 2020

CVSHealth

Therapeutic Category	Product Name, Route of Administration and Manufacturer[1]	Proposed Indication[1]	Phase of Study[1]	Disease Prevalence and Background	Select Available U.S. Food and Drug Administration (FDA) Approved Therapies	Comments
Central Nervous System	inebilizumab intravenous (IV) Viela Bio	The treatment of neuromyelitis optica spectrum disorder (NMOSD) in adults	Pending FDA approval 06/11/2020	NMOSD is a chronic autoimmune disorder affecting the central nervous system that is characterized by inflammation of the optic nerve and spinal cord. Symptoms include eye pain, vision loss, sensory loss, bowel and bladder dysfunction, and paralysis/ impaired mobility. Patients typically experience repeated attacks with periods of remission in between though permanent blindness or impaired mobility is common in recurring cases. [2] The prevalence of NMOSD is estimated to be 1-10 per 100,000 individuals. Though it can be diagnosed at any age, middle-aged women are most commonly affected and are more likely to have the recurring form than men. Approximately 80% of patients with NMOSD test positive for the aquaporin-4 (AQP-4) antibody, which has been associated with increased disease severity.[2,3]	Soliris (eculizumab) IV infusion—approved for NMOSD in adults who are AQP4+	Twice yearly inebilizumab was granted Breakthrough Therapy designation, and will provide an alternative option for AQP4+ and AQP4- NMOSD as either monotherapy or add-on therapy to oral immunosuppression (e.g., azathioprine, corticosteroids, and/or mycophenolate mofetil). It will be included in Specialty Guideline Management. *Anticipated impact: Incremental spend*
	satralizumab subcutaneous (SC) Genentech/ Roche	The treatment of NMOSD in adults and adolescents	Pending FDA approval 04/30/2020			Satralizumab was granted Breakthrough Therapy designation. It will provide the first self-administered SC option for of NMOSD and will be an alternative treatment option for AQP4+ and AQP4- NMOSD as either monotherapy or add-on therapy to oral immunosuppression (e.g., azathioprine, corticosteroids, and/or mycophenolate mofetil). Satralizumab will be included in Specialty Guideline Management. *Anticipated impact: Incremental spend*

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Multiple Sclerosis (MS)	Bafiertam (monomethyl fumarate) oral Banner Life Sciences	The treatment of relapsing forms of MS in adults	Tentative approval; 11/16/2018 Full approval expected following expiration of Tecfidera patents 06/20/2020	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 profound disability. MS affects nearly 1 million people in the United States. The condition is mostly diagnosed between the ages of 20 and 50 and is more common in women.[4] Relapsing MS is the most common form of the disease, affecting about 85% of patients, and is characterized by attacks (relapses) that are followed by periods of recovery (remissions).[5]	**Injectable/Infused Agents:** Avonex, Rebif (interferon beta-1a), Betaseron, Extavia (interferon beta-1b), glatiramer (e.g., Copaxone), Lemtrada (alemtuzumab), Ocrevus (ocrelizumab), Plegridy (peginterferon beta 1a), Tysabri (natalizumab) **Oral Agents:** Aubagio (teriflunomide), Gilenya (fingolimod), Mavenclad (cladribine), Mayzent (siponimod), Tecfidera (dimethyl fumarate), Vumerity (diroximel fumarate)	Bafiertam is bioequivalent to the active ingredient of Tecfidera, and will provide an alternative treatment option for patients with relapsing forms of MS. It will be included in Specialty Guideline Management. *Anticipated impact: Replacement spend*
	ozanimod oral Bristol-Myers Squibb/Celgene/ Receptos		Pending FDA approval 03/25/2020			Ozanimod is in the same drug class as Gilenya and Mayzent and will provide an additional treatment option for patients with relapsing forms of MS. It will be included in Specialty Guideline Management. *Anticipated impact: Replacement spend*

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Neuromuscular	risdiplam oral Genentech/ Roche/PTC Therapeutics	The treatment of types 1, 2 and 3 spinal muscular atrophy (SMA)	Pending FDA approval 05/24/2020	SMA is a rare, genetic disease caused by inadequate production of the survival motor neuron (SMN) protein. It is characterized by muscle weakness and wasting primarily in infants and children, though adults may be affected.[6] SMA affects 1 in 6,000 to 1 in 10,000 live births. There are 5 types of SMA, which are based on the severity of the disorder and the age of symptom onset. However, types 1, 2, and 3 account for over 95% of cases and typically have an onset between infancy and early childhood.[6]	**Disease-modifying therapy**: Spinraza (nusinersen) intrathecal injection (chronic therapy) **Gene therapy**: Zolgensma (onasemnogene abeparvovec-xioi) one-time IV infusion	Risdiplam was granted Breakthrough Therapy designation. It is in the same drug class as Spinraza, and will provide the first oral treatment option for SMA. It will be included in Specialty Guideline Management. *Anticipated impact: Replacement spend (shift from medical benefit)*
Osteoporosis	Bonsity (teriparatide) SC injection Alvogen/Pfenex	The treatment of postmenopausal women with osteoporosis at high risk for fracture, to increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture, and the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture	Approved; launch anticipated January 2020	Osteoporosis causes weakening and thinning of bone leading to an increased risk of fractures. It is estimated that 4.5 million women and 800,000 men over the age of 50 have osteoporosis. One in two women and one in six men 50 years and older will suffer an osteoporosis-related fracture at some point in their lives.[7] Corticosteroids can cause various adverse events including bone loss and fractures. It is estimated that 1% of the U.S. population receives long-term glucocorticoid therapy. Of these patients, more than 10% will be diagnosed with a fracture.[8]	**Infused/Injectable Agents:** Evenity (romosozumab), Forteo (teriparatide), ibandronate (e.g., Boniva), Miacalcin (calcitonin), Prolia (denosumab), Tymlos (abaloparatide), zoledronic acid (e.g., Reclast) Multiple oral agents in addition to calcitonin nasal are also approved for the prevention or treatment of osteoporosis.	Bonsity is a therapeutic equivalent of Forteo. It will be included in Specialty Guideline Management. *Anticipated impact: Replacement spend*

[1] RxPipeline, January 2020.
[2] Rare Disease Database. Available at https://rarediseases.org/rare-diseases/neuromyelitis-optica/. Accessed January 3, 2020.
[3] Jarius, S. et al. Contrasting disease patterns in seropositive and seronegative neuromyelitis optica: A multicenter study of 175 patients. Available at https://jneuroinflammation.biomedcentral.com/articles/10.1186/1742-2094-9-14. Accessed January 3, 2020.
[4] National Multiple Sclerosis Society. Available at: https://www.nationalmssociety.org/What-is-MS/MS-FAQ-s. Accessed October 2, 2019.
[5] National Multiple Sclerosis Society. Available at: https://www.nationalmssociety.org/What-is-MS/Types-of-MS. Accessed October 2, 2019.
[6] National Human Genome Research Institute. Available at https://www.genome.gov/Genetic-Disorders/Spinal-Muscular-Atrophy. Accessed January 3, 2020.
[7] American College of Rheumatology. Available at https://www.rheumatology.org/I-Am-A/Patient-Caregiver/Diseases-Conditions/Osteoporosis. Accessed July 1, 2019.
[8] Buckley L, Guyatt G, Fink HA, et al. 2017 American College of Rheumatology Guideline for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. Available at https://www.rheumatology.org/Portals/0/Files/Guideline-for-the-Prevention-and-Treatment-of-GIOP.pdf. Accessed July 1, 2019.

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