Specialty Pharmacy Pipeline

Drugs to Watch

Anticipated Launches | Q4 2021 – Q1 2022

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
Asthma	tezepelumab SC Amgen	The treatment of severe uncontrolled asthma in patients aged 12 years and older	Pending FDA approval 01/07/2022	Asthma is a chronic condition that affects the lungs. Asthma can cause airways to narrow, swell and produce extra mucus. This can make breathing difficult and trigger coughing or wheezing upon exhaling breathing out, as well as cause shortness of breath. The Centers for Disease Control and Prevention estimates that over 25 million people in the US have asthma.[2] Of these patients, approximately 5 to 10% suffer from severe asthma.[3]	**Severe asthma agents**: Cinqair (reslizumab) IV, Dupixent (dupilumab) SC, Fasenra (benralizumab) SC, Nucala (mepolizumab) SC, Xolair (omalizumab) SC	Tezepelumab was granted Breakthrough Therapy designation for a subset of severe asthma patients that are unlikely to respond to currently approved biologic therapies and is expected to be an add-on to standard of care therapy. It will be included in Specialty Guideline Management. *Anticipated impact: Incremental spend, pharmacy benefit*
Atopic Dermatitis (AD)	abrocitinib oral Pfizer	The treatment of moderate-to-severe AD in patients aged 12 and older	Pending FDA approval 4Q 2021	AD, also referred to as eczema, is a chronic inflammatory disorder affecting the skin. Common symptoms include widespread areas of dry skin, itching, and red rashes. Scratching may lead to oozing and crusting as well as thickening and hardening of the skin. Skin infections may also occur. AD affects 10 to 20% of children and 5 to 10% of adults.[4] Approximately 40% of patients have moderate-to-severe disease.[5]	Dupixent (dupilumab) SC **Approved oral agents seeking label expansions for AD**: Olumiant (baricitinib) – pending FDA approval 4Q 2021, Rinvoq (upadacitinib) – pending FDA approval 4Q 2021 Numerous topical therapies may be used	Abrocitinib was granted Breakthrough Therapy designation and will provide an oral therapy option for moderate-to-severe AD. Due to drug class safety concerns, use of abrocitinib will likely be limited to second-line use. It will be included in Specialty Guideline Management. *Anticipated impact: Replacement spend, pharmacy benefit*

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
Cardiovascular Disorders	mavacamten oral MyoKardia/ Bristol Myers Squibb	The treatment of hypertrophic obstructive cardiomyopathy (HOCM)	Pending FDA approval 01/28/2022	HOCM is a type of genetic heart disease that causes the heart to contract with greater force. This results in an abnormally thickened heart muscle, ultimately leading to the heart's inability to relax normally and fill with blood to effectively pump to the rest of the body. Patients with HOCM are typically symptomatic and may experience chest pain, shortness of breath, fatigue, irregular heartbeat, dizziness, and lightheadedness. 1 in 500 people are affected by hypertrophic cardiomyopathy (HCM) but only approximately 15% are formally diagnosed.[6,7] Approximately 70% of patients with HCM have left ventricular tract outflow obstruction.[8]	No FDA approved agents for HOCM currently. **Off-label oral agents**: beta-blockers, calcium channel blockers, Norpace (e.g., disopyramide)	Mavacamten was granted Breakthrough Therapy designation and is expected to be the first disease-modifying drug therapy approved for the treatment of HOCM and represents an add-on therapy to standard of care in patients with symptomatic disease. It will be included in Specialty Guideline Management. *Anticipated impact: Incremental spend, pharmacy benefit*
Growth Hormone Deficiency (GHD)	somatrogon SC Opko Health/Pfizer	The treatment of GHD in pediatrics	Pending FDA approval 01/19/2022	GHD is a rare disorder which is characterized by the insufficient secretion of growth hormone, an essential hormone which maintains normal body structure and metabolism. Signs and symptoms of GHD may include slow growth, low blood sugar levels, and poor development of bones in the middle face. GHD occurs in approximately 1 in every 3,800 infants.[9]	**SC, daily administered somatropin (recombinant human growth hormone) agents:** Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Zomacton **Long-acting growth hormone agents:** Skytrofa (lonapegsomatropin-tcgd), Sogroya (somapacitan-beco) – indicated for adult GHD, in development for pediatric GHD	Somatrogon is an additional once weekly, SC, self-administered growth hormone product that will offer a less frequent administration schedule compared to daily therapies for pediatric GHD. It will be included in Specialty Guideline Management. *Anticipated impact: Replacement spend, pharmacy benefit*

75-22161A 101921

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
Human Immuno-deficiency Virus (HIV)	cabotegravir IM Pfizer/ GlaxoSmithKline/ ViiV Healthcare	The pre-exposure prophylaxis (PrEP) of HIV infection in adults	Pending FDA approval 01/24/2022	HIV is a virus which attacks the body's immune system, making individuals more vulnerable to other infections and diseases. HIV is treatable but not curable. If not treated, HIV can lead to acquired immunodeficiency syndrome. An estimated 1.2 million people are living with HIV in the US and approximately 13% are unaware they have the disease.[10]	**PrEP treatments:** emtricitabine/tenofovir disoproxil fumarate (e.g., Truvada) oral, Descovy (emtricitabine/tenofovir alafenamide) oral	Cabotegravir was granted Breakthrough Therapy designation and will provide an alternative HIV PrEP therapy with a less frequent dosing schedule compared to current options. *Anticipated impact: Replacement spend, shift to medical benefit*
	dapirivine intravaginal International Partnership for Microbicides/ Johnson & Johnson	The PrEP of HIV infection in women	Pending FDA approval 01/03/2022			Dapirivine will provide women an additional HIV PrEP therapy option. *Anticipated impact: Replacement spend, pharmacy benefit*
	lenacapavir oral and SC Gilead	The treatment of HIV infection in heavily treatment-experienced patients, in combination with other antiretroviral therapy (ART)	Pending FDA approval 02/28/2022		**ART for treatment-experienced patients with resistance**: Aptivus (tipranavir) oral, Fuzeon (enfuvirtide) SC, Intelence (etravirine) oral, Rukobia (fostemsavir) oral, Trogarzo (ibalizumab-uiyk) IV	Lenacapavir was granted Breakthrough Therapy designation and will provide an alternative therapy option for heavily treatment-experienced HIV patients. *Anticipated impact: Replacement spend, medical benefit*

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
Neuromuscular	efgartigimod IV Argenyx	The treatment of generalized myasthenia gravis (MG)	Pending FDA approval 12/17/2021	Generalized MG is a chronic autoimmune disorder that causes weakness and fatigue in multiple muscle groups including those of the eyes, face, and jaw, as well as the arms and legs. Approximately 10% of patients may develop myasthenic crisis, a severe and potentially life-threatening complication due to weakness of muscles used in breathing. MG affects approximately 14 to 40 per 100,000 individuals in the U.S.[11]	Acetylcholinesterase inhibitors (neostigmine, pyridostigmine), corticosteroids, Soliris (eculizumab) IV **Off-label agents**: immunosuppressants (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus), cyclophosphamide, methotrexate, rituximab, immune globulin IV	Efgartigimod will provide an additional option for patients with inadequate response to conventional MG treatments. It will be included in Specialty Guideline Management. *Anticipated impact: Replacement spend, medical benefit*
Oral Oncology	asciminib oral Novartis	The treatment of Philadelphia chromosome-positive, chronic myeloid leukemia in chronic phase (Ph+ CML-CP) in adults previously treated with 2 or more tyrosine-kinase inhibitors and the treatment of Ph+ CML-CP harboring the T315I mutation	Pending FDA approval 02/01/2022	CML is a type of blood cancer that starts in certain cells of the bone marrow. Symptoms of CML can include weakness, fatigue, night sweats, weight loss, fever, bone pain, and enlargement of the spleen. Approximately 62,000 people in the U.S. are living with CML.[12] Up to 20% of CML patients are estimated to have the T315I mutation.[13]	Bosulif (bosutinib) oral, Iclusig (ponatinib) oral - approved for T315I-positive CML, imatinib (e.g., Gleevec) oral, Sprycel (dasatinib) oral, Synribo (omacetaxine) SC, Tasigna (nilotinib) oral Allogeneic stem cell transplant is also a treatment option.	Asciminib was granted Breakthrough Therapy designation and will provide an additional, later-line treatment option, for patients with failure or intolerance to prior therapy. It will be included in Specialty Guideline Management. *Anticipated impact: Replacement spend, pharmacy benefit*

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
Oral Oncology (continued)	pacritinib oral CTI BioPharma	The treatment of myelofibrosis in patients with severe thrombocytopenia	Pending FDA approval 11/30/2021	Myelofibrosis is a disorder of the bone marrow which contains stem cells that will develop into red blood cells, white blood cells, or platelets. Myelofibrosis leads to abnormal blood cell production and scarring of the bone marrow. Symptoms may vary among individuals, but can include weakness, shortness of breath, inability to fight infections, easy bruising, and excessive bleeding.[14] Myelofibrosis occurs in 1.5 in 100,000 people per year in the U.S.[15]	Inrebic (fedratinib), Jakafi (ruxolitinib)	Pacritinib will offer an additional therapy option for patients with myelofibrosis and low platelet levels. It will be included in Specialty Guideline Management. *Anticipated impact: Replacement spend, pharmacy benefit*
Psoriasis	bimekizumab SC injection UCB	The treatment of moderate-to-severe plaque psoriasis in adults	Pending FDA approval 1Q 2022	Psoriasis is a chronic autoimmune disease primarily affecting the skin and joints. The most common form, plaque psoriasis, causes raised, thick, scaly patches on the skin that often can itch, cause pain, crack and bleed.[16] Psoriasis is estimated to affect 8 million Americans, or about 2.4% of the population, with the plaque psoriasis subtype accounting for 80 to 90% of cases.[17] Approximately 20% of patients have moderate-to-severe disease.[18]	**Topical agents:** Various products for mild-to-moderate psoriasis **Oral agent:** Otezla (apremilast) **SC injectable biologic agents:** Cimzia (certolizumab pegol), Cosentyx (secukinumab), Enbrel (etanercept), Humira (adalimumab), Ilumya (tildrakizumab), Siliq (brodalumab), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Taltz (ixekizumab), Tremfya (guselkumab) **IV infused biologic agents:** infliximab (Remicade and biosimilar products: Avsola, Inflectra, Renflexis)	If approved, bimekizumab would provide another subcutaneously administered option for the treatment of plaque psoriasis. It will be included in Specialty Guideline Management. *Anticipated impact: Replacement spend, pharmacy benefit*

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
Sleep Disorders	sodium oxybate extended release oral Avadel/Flamel Technologies	The treatment of excessive daytime sleepiness (EDS) and cataplexy in patients with narcolepsy	Pending FDA approval 01/15/2022	Narcolepsy is a chronic sleep disorder in which patients experience chronic and frequent attacks of extreme drowsiness during the day, also referred to as EDS. Other symptoms may include cataplexy (sudden loss of muscle tone triggered by strong emotions), sleep paralysis (temporary inability to move or speak while falling asleep or upon awakening), and hallucinations that can occur with sleep paralysis. Narcolepsy is estimated to affect 1 in 2,000 people; however, the true frequency is unknown as narcolepsy often goes undiagnosed.[19]	**Agents for EDS and/or cataplexy:** various stimulants (e.g., amphetamine-containing products, methylphenidate), armodafinil (e.g., Nuvigil), modafinil (e.g., Provigil), Sunosi (solriamfetol), Xyrem (sodium oxybate), Xywav (oxybate mixed salts), Wakix (pitolisant)	Sodium oxybate extended release will an additional therapy option for patients with narcolepsy. It will be included in Specialty Guideline Management. *Anticipated impact: Replacement spend, pharmacy benefit*

[1] RxPipeline, October 2021.
[2] Asthma and Allergy Foundation of America. Asthma Facts and Figures. Available at https://www.aafa.org/asthma-facts/ Accessed September 20, 2021.
[3] American Lung Association. Severe Asthma. Available at https://www.lung.org/lung-health-diseases/lung-disease-lookup/asthma/learn-about-asthma/severe-asthma. Accessed September 20, 2021.
[4] MedlinePlus. Atopic dermatitis. Available at: https://medlineplus.gov/genetics/condition/atopic-dermatitis/#synonyms. Accessed December 28, 2020.
[5] Asthma and Allergy Foundation of America. Atopic dermatitis is America. Available at https://www.aafa.org/media/2209/Atopic-Dermatitis-in-America-Study-Overview.pdf. Accessed January 6, 2021.
[6] American Heart Association. Hypertrophic Cardiomyopathy. Available at https://www.heart.org/en/health-topics/cardiomyopathy/what-is-cardiomyopathy-in-adults/hypertrophic-cardiomyopathy. Accessed September 17, 2021.
[7] Maron MS, Hellawell JL, Lucove JC, et al. Occurrence of clinically diagnosed hypertrophic cardiomyopathy in the United States. Am J Cardiol 2016;117:1651-4.
[8] Maron MS, Olivotto I, Zenovich AG, et al. Hypertrophic cardiomyopathy is predominantly a disease of left ventricular outflow tract obstruction. Circulation 2006;114:2232-9.
[9] You and your Hormones. Childhood-onset growth hormone deficiency. Available at https://www.yourhormones.info/endocrine-conditions/childhood-onset-growth-hormone-deficiency/. Accessed December 28, 2020.
[10] Centers for Disease Control and Prevention. HIV Basics. Available at: https://www.cdc.gov/hiv/basics/statistics.html. Accessed September 20, 2021.
[11] National Organization for Rare Disorders. Available at: https://rarediseases.org/rare-diseases/myasthenia-gravis/. Accessed June 29, 2021.
[12] National Cancer Institute. Available at: https://seer.cancer.gov/statfacts/html/cmyl.html. Accessed September 20, 2021.

[13] Nicolini FE, Mauro MJ, Martinelli G, et al. Epidemiologic study on survival of chronic myeloid leukemia and Ph(+) acute lymphoblastic leukemia patients with BCR-ABL T315I mutation. Blood. 2009;114(26):5271-5278. doi:10.1182/blood-2009-04-219410.
[14] National Organization for Rare Disorders. Available at: https://rarediseases.org/rare-diseases/primary-myelofibrosis/. Accessed June 29, 2021.
[15] Leukemia and Lymphoma Society. Available at: https://www.lls.org/sites/default/files/file_assets/FS14_Myelofibrosis_Fact%20Sheet_Final9.12.pdf. Accessed July 1, 2021.
[16] Mayo Clinic – Psoriasis. Available at https://my.clevelandclinic.org/health/diseases/6866-psoriasis. Accessed March 15, 2021.
[17] National Psoriasis Foundation. About Psoriasis. Available at https://www.psoriasis.org/about-psoriasis. Accessed March 15, 2021.
[18] Wu, J. Contemporary Management of Moderate to Severe Plaque Psoriasis. AJMC. Available at https://ajmc.s3.amazonaws.com/_media/_pdf/AJMC_A798_PlaquePsoriasis.pdf. Accessed March 15, 2021.
[19] National Organization for Rare Disorders. Available at: https://rarediseases.org/rare-diseases/narcolepsy/. Accessed June 30, 2021.