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3RD QUARTER 2018
PIPELINE REPORT

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PIPELINE AT A GLANCE

Recent Approvals

- **Epidiolex (cannabidiol)** – Treats severe, early-onset, treatment-resistant epilepsy syndromes.
- **Retacrit (epoetin alfa-epbx)** – Biosimilar to Epogen/Procrit (epoetin alfa) to treat anemia caused by chemotherapy, kidney disease anemia, and HIV medication (AZT).
- **Lucemyra (lofexidine hydrochloride)** – Approved under the Priority Review process. Used to reduce the severity of opiate withdrawal symptoms in adults.
- **Tavalisse (fostamatinib disodium)** – New 2nd line medication for chronic thrombocytopenia blood disorder (platelet disorder) where limited effective treatment options exist.
- **Aimovig (erenumab-aooe)** – A new biologic indicated for the preventive treatment of migraine headaches in adults.
- **Plenvu** – A low volume bowel prep indicated for cleansing of the colon prior to a colonoscopy.
- **Olumiant (baricitinib)** – Treatment of moderate to severe RA with an inadequate response to one or more tissue necrosis factors (Enbrel®, Humira®, Simponi®, Cimzia®, Remicade®).

Anticipated FDA Approvals

- **Ibalizumab** – Biweekly biologic injectable treatment for multidrug resistant HIV.
- **Translarna (ataluren)** – First-in-class oral indicated to treat the underlying cause of Duchenne muscular dystrophy, Previous new treatments targeted the specific nerve dysfunction.
- **Inotersen** – Under Priority Review. Prevention of hereditary TTR Amyloidosis. Currently no or limited effective treatment options.

Anticipated Biosimilars FDA Review

- **Biosimilar to Rituxan® (rituximab)** for treatment of cancer, rheumatoid arthritis, and polyangiitis.
- **Biosimilar to Herceptin® (trastuzumab)** for treatment of HER2 adjuvant breast cancer, metastatic breast cancer, and metastatic gastric cancer.

Recent FDA Approvals

Approval Date	Estimated AWP / Unit	Drug Name / Manufacturer	Treatment Indication	Disease or Administration Comments	Clinical Comments	Existing FDA Approved Treatment within Therapy Class
06/25/2018	Pending	**Epidiolex (cannabidiol)** GW Pharmaceuticals	**Seizure:** Treats severe, early-onset, treatment-resistant epilepsy syndromes including Dravet syndrome, Lennox-Gastaut syndrome (LGS), Tuberous Sclerosis Complex (TSC) and Infantile Spasms (IS) Anticipated Coverage: Rx	Initial dosage once daily oral solution Epidiolex is purified extract of plant-derived cannabidiol, one of the active ingredients in the marijuana plant	Will provide treatment options for resistant epilepsy conditions where there are limited or no approved treatment alternatives	**Treatment Options:** › Felbatol › Sodium valproate › Topiramate › Sodium valproate › Lamotrigine › Clobazam › Stiripentol › FDA designated orphan drug
06/01/2018	Pending	**Olumiant (baricitinib)** **Lilly/Incyte**	**Rheumatoid Arthritis (RA):** Treatment of moderate to severe RA with an inadequate response or intolerance to 1 or more tissue necrosis factors (Enbrel, Humira, Simponi, Cimzia, Remicade) Anticipated Coverage: Rx	Initial dosage once daily oral 4mg Used as monotherapy or in combination with methotrexate	Many biologic therapy options available for rheumatoid arthritis currently on the market. Net cost will most likely drive preferred formulary status.	**Treatment Options:** Xelzanz
05/17/2018	$6,900 / AWP per year	**Aimovig** **(erenumab-aooe)** **Amgen / Novartis**	**Migraine (CGRP Inhibitors):** Indicated for the prevention of migraine headaches in adults Anticipated Coverage: Rx	Monthly self-administered SubQ injection Monthly injection and self-administration may improve compliance and reduce episode frequency Approx. 39 million Americans suffer from migraine, 3x more common in women	Almovig is the only prevention drug directly targeted to the cause of the migraine headache PBM will most likely implement step therapy or PA criteria requiring trials of lower cost preventive therapies first	**Preventative Treatment Options:** Botox, beta blockers, calcium channel blockers, tricyclic antidepressants, anti-seizure drugs
05/16/2018	Pending	**Lucemyra (lofexidine hydrochloride)** **US WorldMeds**	**Opioid Withdrawal:** Indicated in adults to reduce the severity of opioid withdrawal symptoms to facilitate opioid discontinuation Anticipated Coverage: Rx	Initial dose is 3 tablets taken four times daily during peak withdrawal symptoms for up to 14 days Should not be used with drugs that cause drops in blood pressure, pulse or decreased gastric motility. Potential additive CNS depressant effects if taken with opioids, benzodiazepines, alcohol or other sedating substances.	Lessen severity of withdrawal symptoms, may not completely prevent them but Lucemyra will not treat the mental health component of addiction Indicated for use up to 14 days Potential for dangerous drops in blood pressure if taken with opioids	FDA granted Priority Review and Fast Track designations **Opioid Withdrawal Agents:** › Clonidine › Guanfacine

Recent FDA Approvals *(continued)*

Approval Date	Estimated AWP / Unit	Drug Name / Manufacturer	Treatment Indication	Disease or Administration Comments	Clinical Comments	Existing FDA Approved Treatment within Therapy Class
05/15/2018	Pending	**Retacrit (epoetin alfa-epbx)** **Pfizer**	**Hematopoietic (Blood):** Treatment of anemia due to chronic kidney disease for patients on dialysis, Zidovudine in HIV-infected patients, chemotherapy in cancer patients, and reduction of need for blood transfusion in surgery Anticipated Coverage: Rx, Medical	Retacrit is a biosimilar to the epoetin alfa reference products Procrit and Epogen Retacrit has been approved as a biosimilar, not as an interchangeable product Usual initial dose is 50-100 Units/kg SubQ three times weekly	Biosimilars have the potential to improve treatment access, increases competition and lower costs. Biosimilars are not generic drugs but forms of brand medications Retacrit has been FDA approved but the launch date and market availability may take years	› Retacrit is a biosimilar to Epogen/Procrit. › Biosimilars would be considered specialty products because they are biological products synthesized through the biotechnology manufacturing process › Retacrit is not a biosimilar to the long-acting red-blood cell stimulating product Aranesp (darbepoetin alfa)
05/07/2018	Pending	**Plenvu** **(PEG 3350, sodium ascorbate, sodium sulfate, ascorbic acid, NaCl, KCL)** **Valeant Pharma**	**Colonoscopy Bowel Prep:** Indicated for cleansing of the colon in preparation for colonoscopy in adults Anticipated Coverage: Rx	Plenvu is a two-day regimen separated into two doses that are dispensed in three packets to be mixed with water Plenvu is an osmotic laxative	Advantage of requiring less active solution (one liter or slightly over one quart) per dose compared to other bowel prep products that require larger volumes (2-3 liters)	Numerous bowel cleansing preparations are available. Tolerability and cost are the primary determinants designating a preferred product.
05/03/2018	Pending	**Andexxa (coagulation factor xa recombinant)** **Portola Pharma**	**Bleeding Reversal:** Indicated for patients treated with Zarelto (rivaroxaban) and Eliquis (apixaban), when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding Anticipated Coverage: Medical	Dose is based on which medication (Xarelto, Eliquis) need to be reversed Usual dosage 400mg-800mg infused IV Andexxa is a recombinant modified human Factor Xa protein	Andexxa received accelerated approval, orphan drug status and a breakthrough therapy designation from the FDA First drug indicated to reverse anticoagulation effects of Xarelto and Eliquis	This indication is approved under accelerated approval based on the change from baseline in anti-FXa activity in healthy volunteers No current alternative exists to reverse the anticoagulant effects of Xarelto and Eliquis
04/17/2018	$11,340 / 30 day	**Tavalisse (fostamatinib disodium)** **Rigel Pharma**	**Immunosuppressants:** Treatment of chronic and persistent immune thrombocytopenia (ITP) in adults when other therapies have failed May become first line treatment for Chronic ITP Anticipated Coverage: Rx	Tavalisse prevents platelet destruction in immune thrombocytopenia Initial dose is 100 mg orally twice daily; may increase dose if platelet count has not increased after 1 month	Tavalisse will provide a new treatment option for a condition where there are limited effective treatment options Patients have varying degrees of treatment response and many do not respond to existing therapy	**Treatment Options:** › Steroids › Splenectomy › Approx. 24 / 100,000 patients suffer from ITP in the US › Total US prevalence is 65,000

Recent FDA Approvals *(continued)*

Approval Date	Estimated AWP / Unit	Drug Name / Manufacturer	Treatment Indication	Disease or Administration Comments	Clinical Comments	Existing FDA Approved Treatment within Therapy Class
04/17/2018	$4,080/ AWP unit 1 Month Therapy (150lb adult): $22,195	**Crysvita (burosumab-twza)** **Ultragenyx Pharma**	**Vit-D Deficiency Rickets X-linked Hypophosphatemia (XLH):** Anticipated Coverage: Rx	Adult Dose: 1mg/kg SubQ monthly Pediatric Dose: 0.8 mg/kg SubQ biweekly Pediatric Symptoms: Bowed or bent legs, short stature, bone pain, severe dental pain, impaired bone growth Adult Symptoms: Joint pain, impaired mobility, tooth abscesses, hearing loss	First FDA-approved medication for the treatment of this rare form of Rickets affecting approximately American 12,000 adults and 3,000 children Vitamin D therapy is not effective in this form of Rickets	**XLH Hypophosphatemia Agents:** › Phosphate replacement, Calcitriol › FDA granted Breakthrough Therapy Orphan Drug designation
03/21/2018	Pending	**Ilumya (tildrakizumab-asmn)** Sun Pharma	**Inflammatory Disease Plaque Psoriasis:** Immunosuppressant treatment of moderate-to-severe plaque psoriasis Anticipated Coverage: Rx	100mg SubQ dose at weeks 0, 4, then every 12 weeks thereafter Anti-interleukin (IL)-23p19 monoclonal antibody subcutaneous biologic injection Many biologic therapy options available for plaque psoriasis currently on the market	**Second line** behind TNF treatments and 2nd line oral treatments due to being injectable Predicted - Anti-interleukin therapy will eventually be accepted as 1st line therapy due to targeted treatment + greater efficacy	**Injectable Options:** › Enbrel (etanercept) › Humira (adalimumab) › Siliq (brodalumab) › Stelara (ustekinumab) › Cosentyx (secukinumab) › Taltz (ixekizumab) › Tremfya (guselkumab) › Net cost will most likely drive preferred formulary status
03/06/2018	$1,024 / AWP unit Loading dose = $10,240 Maintenance dose = $4,096	**Trogarzo (ibalizumab-uiyk)** Theratechnol-ogies/TaiMed Biologics	**HIV:** Multi-drug resistant HIV infection used in combination with other antiretrovirals Anticipated Coverage: Medical New Class of antiretroviral humanized monoclonal antibody	2000mg IV infusion loading dose, 800mg IV every 2 weeks maintenance dosing Advantage of not requiring daily oral dosing, Bimonthly dosing may help improve patient compliance and clinical outcomes HIV patients with multidrug resistant are high risk of HIV complications and morbidity	Trogarzo will help HIV patients who have faced treatment failures to other currently available therapies or who have exhausted all other HIV therapy options Multidrug resistant HIV therapy options will be of greater future importance	**HIV multidrug resistant options:** › Fuzeon (enfuvirtide) SC injection Aptivus (tipranavir) oral › Intelence (etravirine) oral › FDA granted Breakthrough Therapy Orphan Drug designation
02/12/2018	$26,880 / 28 day	**Symdeko (tezacaftor/ivacaftor)** Vertex Pharma	**Cystic Fibrosis:** Ages 12 and older who have F508del homozygous genetic mutation Anticipated Coverage: Rx	Packaged as tezacaftor 100mg/ ivacaftor 150mg combination tablets taken by mouth every morning and ivacaftor 150mg tab taken by mouth every evening	CF patient frequency with homozygous F508del mutation is estimated 1/ 228,006 people This is used to treat a very specific gene mutation and no other treatment is available	**F580del homozygous mutation:** Orkambi (ivacaftor/ lumacaftor) **F508 residual function mutation:** Kalydeco (ivacaftor) FDA breakthrough therapy designation

Recent FDA Approvals *(continued)*

Approval Date	Estimated AWP / Unit	Drug Name / Manufacturer	Treatment Indication	Disease or Administration Comments	Clinical Comments	Existing FDA Approved Treatment within Therapy Class
02/07/2018	$3,535 / 30 day	**Biktarvy (bictegravir/ emtricitabine/ tenofovir alafenamide)** Gilead	**HIV:** Complete combination treatment of HIV infection in adults Antiretroviral therapy recommended for all HIV patients Anticipated Coverage: Rx	**Fixed-dose combination** of bictegravir (an integrase strand transfer inhibitor), emtricitabine (a nucleoside reverse transcriptase inhibitor), and tenofovir alafenamide (a prodrug that converts to tenofovir, then to tenofovir diphosphate that terminates DNA chain by incorporating into the viral DNA)	Combo will offer complete treatment regimen Combination medication will provide another combination HIV therapy option	**HIV Complete Treatment Oral Combo Regimen:** › Triumeq › Stribild › Atripla › Complera › Genvoya › Odefsey
02/08/2018	$1,962 / 30 day	**Symfi (efavirenz/ lamivudine/ tenofovir disoproxil fumarate)** Mylan	**HIV:** Complete regimen for the treatment of HIV infection in adult and pediatric patients weighing at least 35 kg Anticipated Coverage: Rx	Dosing orally once daily will help improve patient compliance and clinical outcomes 95% adherence needed to maintain viral suppression	Once daily complete treatment regimen for pediatrics and adults Combination medication will provide another combination HIV therapy option	**HIV Complete Treatment Oral Combo Regimen:** › Triumeq › Stribild › Atripla › Complera › Genvoya › Odefsey
01/29/2018	$153 / 300 ml bottle	**Firvanq (vancomycin)** Oral Solution CutisPharma	**Infection:** Oral Solution antibiotic for treatment of Clostridium difficile associated diarrhea and Staphylococcus aureus enterocolitis Anticipated Coverage: Rx	Only FDA approved oral vancomycin liquid solution C.Difficile infections cost $4.8 billion/yr in US hospital/healthcare costs	Anticipation Firvanq oral solution will provide a less costly FDA approved formulation compared to Vancocin capsule (approx. $1,200 for 7-day supply)	**Infection:** Vancocin (vancomycin) Oral Capsule

Anticipated FDA Approvals

Expected FDA Review Date	Drug Name / Manufacturer	Disease Category	Disease or Administration Comments	Clinical Comments	Existing FDA Approved Treatment within Therapy Class
07/2018	**Poteligeo (mogamulizum-ab)** Kyowa Hakko Kirin	**Cancer Lymphoma:** 2nd-line treatment of cutaneous T-cell lymphoma (CTCL) Monoclonal antibody for treatment of the most common types of CTCL (mycosis fungoides and sézary syndrome) Anticipated Coverage: Medical	Dosage once weekly IV infusion for 1 month, then every other week	CTCL is a rare type of non-Hodgkin's lymphoma - 7.7 cases / 1 million people per year Combined incidence of mycosis fungoides and sézary syndrome - 6.4 cases/1 million people per year	**Treatment Options:** › Chemotherapy - mercaptopurine, cyclophosphamide › Targeted therapy - palbociclib, ibrutinib, bevacizumab › Immunotherapy - Pembrolizumab, › tisagenlecleucel › FDA breakthrough therapy designation

Anticipated FDA Approvals *(continued)*

Expected FDA Review Date	Drug Name / Manufacturer	Disease Category	Disease or Administration Comments	Clinical Comments	Existing FDA Approved Treatment within Therapy Class
07/06/2018	**Inotersen** Ionis/Akcea	**Hereditary Amyloidosis (hATTR):** Treats patients with the rare disease of hereditary amyloidosis Anticipated Coverage: Rx	Initial dosage once weekly SubQ injection hATTR is a progressive fatal disease associated with congestive heart failure, atrial fibrillation, GI and bladder problems, kidney failure and peripheral nerve pain	Inotersen will provide a treatment options where there are limited or no effective treatment alternatives Approx. 10,000-20,000 Americans have hereditary ATTR amyloidosis	**Treatment Options:** › Liver and/or heart transplant › Supportive therapies › FDA designated orphan drug
08/26/2018	**lanadelumab** Shire	**Hereditary Angioedema (HAE):** Prevention of hereditary angioedema attacks in patients 12 years and older First monoclonal antibody treatment for angioedema attack prevention Anticipated Coverage: Rx	Initial dosage every 2 weeks SubQ injection Mechanism: Biologic plasma kallikrein inhibitor	Being reviewed under the priority approval and orphan drug status process New mechanism of action treatment option to help control HAE Offers potential to change the HAE treatment guidelines	**Prevention Treatment Options:** › Haegarda › Danazol › Cinryze › FDA designated orphan drug
08/30/2018	**damoctocog alfa pegol** Bayer	**Hemophilia A:** Treatment of hemophilia A in adults and adolescents 12 years of age and over Anticipated Coverage: Medical	Initial dosage once weekly or every 5 days via IV infusion to prevent bleeding episodes Approx. 20,000 Americans with hemophilia, 80% are Hemophilia A	Can be used on-demand and prophylactically Offers an extended half-life which may result in decreased frequency of infusions for hemophilia A patients	**Therapy Options:** › Hemlibra › FEIBA (anti-inhibitor coagulant complex) › NovoSeven RT (coagulation factor › VIIa, recombinant)
10/2018	**Cemiplimab** Sanofi/ Regeneron	**Skin Cancer:** Advanced or metastatic cutaneous squamous cell carcinoma (CSCC) Anticipated Coverage: Medical	Dosage IV infusion (every 2 weeks) Advanced CSCC is the deadliest non-melanoma skin cancer, 7,000 US deaths / year	Offers option to locally advanced CSCC patients who are not candidates for surgery There is limited evidence of the effectiveness of system chemotherapy	**Therapy Options:** › EGFR inhibitors - Erbitux (cetuximab), Vectibix (panitumumab), Iressa (gefitnib), Tarceva (erlotinib) › Platinum-based chemotherapy regimen (cisplatinum/bleomycin/ fluorouracil) › FDA designated Breakthrough Therapy
TBD 2018	Translarna (ataluren) PTC Therapeutics	**Duchenne Muscular Dystrophy:** Anticipated Coverage: Rx	Administered orally three times a day Designed to restore and form functional muscle proteins in patients with genetic disorders caused by a nonsense mutation	First-in-class oral indicated to treat the underlying cause of Duchenne muscular dystrophy Previous new treatments targeted the specific nerve dysfunction MD is a progressive muscle disorder characterized by loss of muscle tissue, weakness, and instability	**Muscular Dystrophy Agents:** › Prednisone › Emflaza (deflazacort) › Exondys 51 – IV Infusion

Biosimilar Pipeline

FDA Approval Date	Launch Date	Biosimilar Name	Biosimilar AWP Cost	Reference Product	Reference Product AWP Cost	Interchangeable	Disease Category
May 2018	To Be Determined	Retacrit (epoetin alfa-epbx)	TBD Upon Launch	Epogen Procrit (Epoetin Alfa)	Epogen 2000u - $39.79 Procrit 2000u- $61.74	Interchangeability is not anticipated	**Hematopoietic:** Treatment of anemia due to chronic kidney disease, Zidovudine in HIV-infected patients, chemotherapy in cancer patients, and reduction of allogeneic red blood cell transfusion in patients' elective surgery
Expected FDA Review TBD 2018	To Be Determined	CT-P6 (Trastuzumab)	TBD Upon Launch	Herceptin (trastuzumab)	$1,815.64 150mg Inj	Interchangeability is not anticipated	**Cancer:** Treatment of Human Epidermal growth factor Receptor 2 (HER2) adjuvant breast cancer, metastatic breast cancer, and metastatic gastric cancer
Expected FDA Review October 2018	To Be Determined	SB3 (Trastuzumab)	TBD Upon Launch			Interchangeability is not anticipated	
December 2017	June 2019	Ogivri (trastuzumab-dkst)	TBD Upon Launch			No	
Expected FDA Review TBD 2018	To Be Determined	Grastofil (filgrastim)	TBD Upon Launch	Neupogen (filgrastim)	$797.15 Prefilled Syringe (480mcg/0.8ml)	Interchangeability is not anticipated	**Hematopoietic:** Acute myeloid leukemia receiving induction or consolidation chemotherapy, Cancer receiving myelosuppressive chemotherapy, Cancer undergoing bone marrow transplantation, Severe chronic neutropenia, Undergoing autologous peripheral blood progenitor cell collection and therapy. Treatment of neutropenia-related conditions in cancer patients receiving myelosuppressive chemotherapy
March 2015	September 2015	Zarxio** (filgrastim-sndz)	$658.48 (480mcg/ 0.8ml)			No	
August 2013	2015	Granix** (tbo-filgrastim)	$715.65 (480mcg/ 0.8ml)			No	
September 2017	July 2019	Mvasi (bevacizumab-awwb)	TBD Upon Launch	Avastin (bevacizumab)	$233.25 (100mg/4ml)	No	**Cancer:** Treatment of Metastatic colorectal cancer, Non-squamous non-small cell lung cancer, Glioblastoma, Metastatic renal cell carcinoma, Persistent, recurrent, or metastatic carcinoma of the cervix
December 2017	To Be Determined	Ixifi (infliximab-qbtx)	TBD Upon Launch	Remicade (infliximab)	$1,401.38 100mg Inj	Interchangeability is not anticipated	**Immunological Agent:** Ankylosing spondylitis, Crohn's disease (fistulizing), adult, Crohn's disease, adult and pediatric (6 years or older), Plaque psoriasis, Psoriatic arthritis, Rheumatoid arthritis in combination with methotrexate, Ulcerative colitis, adult
April 2017	July 2017	Renflexis ** (infliximab-abda)	$904.07 (100mg)			No	
April 2016	November 2016	Inflectra ** (infliximab-dyyb)	$1,135.54 (100mg/ 20ml)			No	

** Above indicate launched products.

Biosimilar Pipeline *(continued)*

FDA Approval Date	Launch Date	Biosimilar Name	Biosimilar AWP Cost	Reference Product	Reference Product AWP Cost	Interchangeable	Disease Category
August 2017	2023	Cyltezo (adalimumab-adbm)	TBD Upon Launch	Humira (adalimumab)	$2,923.22 Prefilled Syringe	No	**Immunosuppressant:** Treatment of rheumatoid arthritis, plaque psoriasis, Crohn's disease, and ulcerative colitis
September 2016	2023	Amjevita (adalimumab-atto)	TBD Upon Launch			No	
August 2016	2019-2025	Erelzi (etanercept-szzs)	TBD Upon Launch	Enbrel (etanercept)	$1,491.43 Prefilled Syringe	No	**Immunosuppressant:** Ankylosing spondylitis, Juvenile idiopathic arthritis (2 years or older), Plaque psoriasis adult, Psoriatic arthritis, Rheumatoid arthritis
Expected FDA Review July 2018	To Be Determined	Truxima (rituximab)	TBD Upon Launch	Rituxan (rituximab)	$5,420.28 (500mg/50ml)	Interchangeability is not anticipated	**Cancer:** Treatment of patients with non-Hodgkin's lymphoma, chronic lymphocytic leukemia, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis.
June 2018	July 2018	Fulphiila (pegfilgrastim-jmdb)	TBD Upon Launch	Neulasta (pegfilgrastim)	$377.80 (300mcg/ml)	No	**Hematopoietic:** Reduce incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia
Expected FDA Review TBD 2018-2019	To Be Determined	Lapelga TPI-120 CHS-1701 (pegfilgrastim)	TBD Upon Launch			Interchangeability is not anticipated	

The above information was assembled from government and clinical resources for knowledge purposes only. Information and drugs were selected by clinicians based on therapy and potential clinical impact without any manufacturer affiliations or conflicts of interest. Approval status, dates, and AWP price are subject to variation. Medispan is used as independent reference source for AWP costs. This document should not be exclusively used for decision-making purposes.

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