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3RD QUARTER 2020
PIPELINE REPORT

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PIPELINE HIGHLIGHTS:

Recent Approvals

- **Isturisa (osilodrostat)** – Glandular condition: Cushing's disease. Approved 3/6/2020
- **Zeposia (ozanimod)** – Multiple sclerosis. Approved 3/25/2020
- **Sevenfact (coagulation factor VII recombinant-jncw)** – Hemophilia A or B. Approved 4/1/2020
- **Koselugo (selumetinib sulphate)** – Neurological condition: neurofibromatosis type 1. Approved 4/10/2020
- **Pemazyre (pemigatinib)** – Cancer of the bile duct (cholangiocarcinoma). Approved 4/17/2020
- **Tukysa (tucatinib)** – Breast cancer. Approved 4/17/2020
- **Trodelvy (sacituzumab govitecan-hziy)** – Breast cancer, triple negative. Approved 4/22/2020
- **Tabrecta (capmatinib)** – Non-small cell lung cancer. Approved 5/6/2020
- **Retevmo (selpercatinib)** – Lung and thyroid cancers. Approved 5/8/2020
- **Qinlock (ripretinib)** – Gastrointestinal stromal tumor. Approved 5/15/2020
- **Uplizna (inebilizumab)** – Autoimmune central nervous system disease: Neuromyelitis optica spectrum disorder. Approved 6/11/2020

Anticipated FDA Approvals

- **Viaskin Peanut** – Peanut allergy. Expected FDA decision: 8/5/2020
- **Zepsyre (lurbinectedin)-** Small cell lung cancer. Expected FDA decision: 8/16/2020
- **Valrox (valoctogene roxaparvovec)** – Hemophilia A. Expected FDA decision: 8/21/2020
- **risdiplam (aka RG7916)** – Neuromuscular condition: Spinal muscular atrophy. Expected FDA decision: 8/24/2020
- **cedazuridine + decitabine (aka ASTX727) -** Leukemia and sometimes-pre-cancerous bone marrow condition. Expected FDA decision: 8/2020
- **satralizumab (aka SA237)** – Autoimmune central nervous system disease: Neuromyelitis optica spectrum disorder. Expected FDA decision: 8/2020
- **filgotinib (aka GLPG0634) -** Rheumatoid arthritis. Expected FDA decision: 3Q2020
- **Ryoncil (remestemcel-L) -** Bone marrow/stem cell transplant side effect: Graft versus host disease. Expected FDA decision: 9/30/2020

Recent FDA Approvals

Approval Date	Estimated WAC / Year & Benefit coverage	Drug Name / Manufacturer	Treatment Indication	Disease or Administration Comments	Clinical Comments	Therapy Options Approximate WAC/Year
3/6/2020	$160,600-$1,040,250 (max dose) **Financial assistance** available through the R.A.R.E.™ (Recordati, Access, Resources, and Engagement) Patient Support Program **Pharmacy benefit**	**Isturisa** osilodrostat Expected launch in Q2 or Q3 of 2020. **Novartis Recordati**	**Pituitary gland disorder**, Cushing's disease (CD)	Oral Cushing's disease can cause obesity, type 2 diabetes, high blood pressure, blood clots, bone loss, suppressed immune system, and mental/behavioral health symptoms. Dosing of Isturisa varies widely, between 2 mg and 30mg twice daily; typical doses are between 2 and 7 mg twice daily. **FDA Designations**: Orphan Drug	First-in-class drug for CD: 11-beta-hydroxylase inhibitor. Blocks formation of cortisol, an excess of which is the cause of Cushing's disease symptoms Estimated 10 to 15 per million people each year affected by Cushing's syndrome, with 70% of these having CD. Exclusively available through R.A.R.E.™ and distributed via AnovoRx specialty pharmacy.	**Therapy alternatives**: > Korlym $382,620 > Signifor and Signifor LAR $169,760
3/25/2020	**$86,001** **Copay assistance** through ZEPOSIA 360 Support™ program **Pharmacy benefit**	**Zeposia** ozanimod Bristol-Myers Squibb Celgene Receptox	**Multiple sclerosis**, clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease	Oral Does not require monitoring after first dose (Gilenya requires cardiovascular monitoring for 6 hours) or genetic testing (like Mayzent).	Sphingosine 1-phosphate (S1P) receptor modulator (same class as Gilenya and Mayzent) Also being tested for inflammatory conditions such as ulcerative colitis.	**Therapy alternatives**: > Gilenya $105,390 > Mayzent $93,367
4/1/2020	**Pricing TBD**: launch being delayed until late 2020. A copay assistance program does not appear to be available at this time. **Medical benefit**	**Brand name Sevenfact** coagulation factor VIIa recombinant-jncw LFB Biotechnologies	**Hemophilia A or B** with neutralizing antibodies	Intravenous The CDC estimates that approximately 20,000 people in the United States live with hemophilia.	Biologic product Is produced from the milk of genetically engineered rabbits. Treatment of active bleeding in people with hemophilia, or prevention of bleeding, is generally managed by use of factor VIII or factor IX infusions. However, some people develop neutralizing antibodies to these products. For these people, products such as Factor VII are used.	**Therapy alternatives** > Novoseven RT

Recent FDA Approvals *(continued)*

Approval Date	Estimated WAC / Year & Benefit coverage	Drug Name / Manufacturer	Treatment Indication	Disease or Administration Comments	Clinical Comments	Therapy Options Approximate WAC/Year
4/10/2020	**$79,607-$265,355** **Copay assistance** through AstraZeneca's Access 360 program. **Pharmacy benefit**	**Brand name Koselugo** selumetinib sulphate Array BioPharma Pfizer Astrazeneca Merch & Co	**Neurological condition**: neurofibromatosis type 1 (NF1)	Oral NF1 is an incurable, inherited disease. It is a serious condition that causes growths on skin, tumors that grow along nerves, and numerous other painful, disfiguring and life-threatening effects. Has been tested for cancer indications but not shown significant enough activity. **FDA Designations**: Breakthrough Therapy; Orphan Drug; Priority Review	MEK 1/2 inhibitor: inhibits the MEK enzyme, which can become dysregulated in people with NF gene mutations and cause uncontrolled cell replication. Being tested for use in children at least 3 years old. The Institute for Safe Medication Practices categorizes this product as having heightened risk of causing significant harm when misused.	**Therapy alternatives** None—Symptomatic only (including surgical removal of growths where possible)
4/17/2020	**$289,000** unless dose reduction or early discontinuation **Copay assistance** available through Incyte-CARES **Pharmacy benefit**	**Brand name Pemazyre** pemigatinib (aka INCB054828) Incyte	**Cancer of the bile duct** (cholangiocarcinoma), second-line for locally advanced or metastatic	Oral Each year, approximately 8,000 people in the US are diagnosed with cholangiocarcinoma. This type of cancer is often not diagnosed until prognosis is poor. **FDA Designation**: Priority Review, Orphan Drug, Breakthrough Therapy, Accelerated Approval	Fibroblast growth factor receptor (FGFR) inhibitor—reduces changes in FGFRs that are associated with cancer development. This is the first targeted therapy for this type of cancer.	**Therapy alternatives** None. There is no standard second-line therapy for cholangiocarcinoma
4/17/2020	**$314,500** unless dose reduction or early discontinuation Must be administered with trastuzumab ($13,247/yr) and capecitabine ($9030) **Total annual regimen cost, $336,777** unless dose reduction or early discontinuation **Coverage support** available through SeaGen Secure **Pharmacy benefit**	**Brand name Tukysa** tucatinib Seattle Genetics	**Breast cancer**, HER2-positive, locally advanced unresectable or metastatic, in patients who have had at least 3 HER2-directed treatments.	Oral To be used in combination with trastuzumab (Herceptin) and capecitabine **FDA Designation**: Breakthrough Therapy; Priority Review; is also part of Project Orbis, an initiative of the FDA Oncology Center of Excellence that provides a framework for concurrent submission and review of oncology drugs among participating international health authorities	Tyrosine kinase inhibitor Is included in the only therapy specifically approved for breast cancer patients with brain metastases (which will develop in up to 50% of metastatic HER2-positive breast cancer patients who make up about 15% to 20% of HER-2 + cases)	**Therapy alternatives**: > Kadcyla $160,863 > Enhertu $147,540

Recent FDA Approvals *(continued)*

Approval Date	Estimated WAC / Year & Benefit coverage	Drug Name / Manufacturer	Treatment Indication	Disease or Administration Comments	Clinical Comments	Therapy Options Approximate WAC/Year
4/22/2020	**$273,700** unless dose reduction or early discontinuation **Copay support** through the Trodelvy Savings Program. **Medical benefit**	**Brand Name Trodelvy** sacituzumab govitecan-hziy (aka IMMU-132) Immunomedics	**Breast cancer**: Refractory, metastatic hormone receptor triple negative	IV This subtype of breast cancer has very low response rate and short survival time following standard therapy; survival rate has not improved in the last 20 years. Administered on days 1 and 8 of 21-day cycles. **FDA Designations**: Accelerated Approval	**Biologic product** Monoclonal antibody/drug conjugate that targets and kills specific tumor cells. "Black box" warnings about severe drops in white blood cell count and severe diarrhea	**Therapy alternatives**: > Cisplatin: $780
5/6/2020	**$234,637** unless dose reduction or early discontinuation **Copay assistance** available through Novartis Oncology Universal Co-pay Program **Pharmacy benefit**	**Tabrecta** capmatinib (aka INC280) Novartis Incyte	**Lung cancer**, non-small cell (NSCLC), first-line and previously untreated locally advanced or metastatic METex14 mutated.	Oral The METex14 gene mutation is found in about 3-4% of patients with NSCLC, most of whom are older; 4000-5000 new cases annually. **FDA Designations**: Breakthrough Therapy; Priority Review; Accelerated Approval	C-Met inhibitor—inhibits functions associated with the c-Met protein, which is abnormal in many tumor types, and if not inhibited promotes tumor growth. First targeted agent for NSCLC with a MET exon-14 skipping mutation, which is associated with aggressive disease and a poor prognosis.	**Therapy alternatives** None
5/8/2020	**$206,004-$247,200** unless dose reduction or early discontinuation **Copay Assistance** may be available through Lilly Oncology Support Center **Pharmacy benefit**	**Retevmo** selpercatinib (aka LOXO-292) Loxo Oncology Eli Lilly	**Lung and thyroid cancers**: advanced RET fusion-positive non-small cell lung cancer (NSCLC); RET-mutant medullary thyroid cancer (MTC); and RET fusion-positive thyroid cancer.	Oral Weight-based dosing Approximately 10%–20% of thyroid cancers and 2% of NSCLCs have RET mutations **FDA Designations**: Breakthrough Therapy; Accelerated Review, Orphan Drug; Priority Review	RET inhibitor (first drug in class)—inhibits an enzyme that can cause tumors when mutated. Some clinically relevant drug interactions.	**Therapy alternatives** NSCLC: > Alectinib $187,318 Thyroid: > Lenvatinib $77,139 > Sorafenib $291,723 Both: > Vandetinib $15,660 > Cabozantinib $58,659

Recent FDA Approvals *(continued)*

Approval Date	Estimated WAC / Year & Benefit coverage	Drug Name / Manufacturer	Treatment Indication	Disease or Administration Comments	Clinical Comments	Therapy Options Approximate WAC/Year
5/15/2020	**$384,000** unless dose reduction or early discontinuation **Copay assistance** through Deciphera AccessPoint **Pharmacy benefit**	**Brand name Qinlock** ripretinib (aka DCC-2618) Deciphera	**GI Tract cancer**, gastro-intestinal stromal tumor (GIST)	Oral **FDA Designations**: Orphan Drug, Fast Track; Priority Review; Breakthrough Therapy	Broad-spectrum KIT and PDGFRa inhibitor—inhibits mutations in the KIT gene associated with GIST. Shown to cut risk of progression or death by 85% in patients previously treated with drugs such as Gleevec, Sutent and Stivarga. Cardiac side effects require monitoring.	**Therapy alternatives** > Ayvakit $384,000 > Sutent $163,244 > Stivarga $234,562 > Nexavar $243,105 > Tasigna $191,829 > Sprycel $195,874 > Votrient $167,871
6/11/2020	**Price TBD** **Medical Benefit**	**Uplizna** (inebilizumab-cdon) AstraZeneca MedImmune Viela	**Autoimmune central nervous system disease**: Neuromyelitis optica spectrum disorder (NMOSD)	IV NMOSD is rare and debilitating, sometimes causing blindness and motor dysfunction. Often misdiagnosed as multiple sclerosis. NMOSD is more prevalent in women than men. **FDA Designations**: Breakthrough Therapy; Orphan Drug.	**Biologic product** Anti-CD19 antibody: Monoclonal antibody that depletes the overabundance of immune cells which contributes to NMOSD. Second product approved for this indication (Soliris was approved in June 2019). Prior to that, treatments were symptomatic only.	**Therapy alternatives** > Rituximab $18,790 > Soliris $678,381

Anticipated FDA Approvals

Expected FDA Review Date	Drug Name / Manufacturer	Indication	Disease or Administration Comments	Clinical Comments	Therapy Alternatives
8/5/2020	**Viaskin Peanut** Generic name TBD DBV Technologies	**Peanut allergy**	Topical—transdermal patch	**Biologic product** Allergen immunotherapy Indicated for children aged 4-11	Therapy alternatives > Palforzia (oral allergen powder-dnfp), approved 1/31/2020
8/16/2020	**Zepsyre** lurbinectedin PharmaMar Jazz	**Lung Cancer** : Small cell lung cancer (SCLC) relapsed after platinum-containing therapy	IV, once every 3 weeks About 30,000 new cases of SCLC and 17,600 deaths are expected in 2020. Occurs mainly in those over age of 65, is slightly more common in men, and compared to most other cancers, carries a poorer prognosis. **FDA Designation**: Priority review, Orphan Drug	DNA minor groove binder; inhibits the growth of factors that promote tumor growth, and the production of proteins the tumor cells need to survive. SCLC incidence and death rate are both dropping due to more people quitting smoking. No new products for treatments of SCLC have been approved in more than 20 years.	**Therapy alternatives** > Topotecan
8/21/2020	**Valrox** valoctogene roxaparvovec **BioMarin**	**Hemophilia A Gene Therapy**	BioMarin Pharmaceuticals CEO Jean-Jacques Bienaimé suggested that the company is considering charging $2-3 million. Given as a single lifetime dose **FDA Designations**: Priority Review; Accelerated Approval; Breakthrough Therapy; Orphan Drug.	**Biologic product** Uses a modified, harmless virus to deliver a working copy of the gene that is mutated in hemophilia, allowing production of the missing clotting factor. Product is potentially curative: 3 years after dosing, all 7 study participants who received the highest dose had had no bleeding events, no factor infusions needed and no bleeding into joints. FDA has also accepted premarket approval application for an AAV5 total antibody assay to be used as a companion diagnostic.	**Therapy alternatives**: Symptomatic only. BioMarin estimates overall lifetime cost of care is $25 million for hemophilia patients.

Anticipated FDA Approvals *(continued)*

Expected FDA Review Date	Drug Name / Manufacturer	Indication	Disease or Administration Comments	Clinical Comments	Therapy Alternatives
8/24/2020	**Brand Name TBD** risdiplam (aka RG7916) Roche Genentech PTC Therapeutics	**Neuromuscular condition** Spinal muscular atrophy (SMA), types 1, 2 or 3.	Oral liquid If approved, risdiplam will be the only SMA treatment that does not require administration by a healthcare professional. Before Spinraza (pre-12/2016), SMA was usually fatal within 2 years after birth. **FDA Designations**: Orphan drug, Fast Track, Priority Review	Increases the number of SMN2 genes available for making normal SMN (a protein necessary for functioning nerve cells). SMN is primarily made by the SMN1 gene, but in SMA patients, SMN1 is defective. Roche plans to price risdiplam at a discount to both Zolgensma and Spinraza. Roche submitted additional data from the study that may improve access to risdiplam for a broader range of SMA patients.	**Therapy alternatives** > Spinraza (nusinersen), approved for all 4 types of SMA > Zolgensma (onasemnogene abeparvovec-xioi), approved only for type 1 SMA
8/2020	**Brand name** **TBD** cedazuridine + decitabine (aka ASTX727) Astex Otsuka	**Leukemia and sometimes-pre-cancerous bone marrow condition**: myelodysplastic syndrome, intermediate and high risk; and chronic myelomonocytic leukemia (CMML)	Oral **FDA Designation**: Orphan Drug	Antimetabolite/DNA hypomethylating agent Cedazuridine is included to allow oral administration of decitabine, by inactivating enzymes that would otherwise break it down.	**Therapy alternatives** > IV decitabine or azacitidine
8/2020	**Brand name** **TBD** satralizumab (aka SA237) Roche Chugai	**Autoimmune central nervous system disease**: Neuromyelitis optica spectrum disorder (NMOSD)	Subcutaneous; monthly dosing NMOSD is rare and debilitating, sometimes causing blindness and motor dysfunction. Often misdiagnosed as multiple sclerosis. NMOSD is more prevalent in women than men. **FDA Designations**: Breakthrough Therapy; Orphan Drug; Priority Review	**Biologic product** Interleukin 6 receptor (IL-6R) antagonist, a monoclonal antibody that reduces the inflammation of nervous tissue that causes the symptoms.	**Therapy alternatives** > Rituximab > Soliris
3Q2020	**Brand name** **TBD** filgotinib (aka GLPG0634) Galapagos Gilead	**Rheumatoid Arthritis**, moderate to severe	Oral **FDA Designation**: Priority Review	Janus kinase (JAK1) inhibitor Claimed to potentially be better than adalimumab and safer than tofacitinib and baricitinib; in a crowded market of very expensive products.	**Therapy alternatives** > Humira (adalimumab) > Rinvoq (upadacitinib) > Xeljanz (tofacitinib) > Olumiant (baricitinib)

Anticipated FDA Approvals *(continued)*

Expected FDA Review Date	Drug Name / Manufacturer	Indication	Disease or Administration Comments	Clinical Comments	Therapy Alternatives
9/30/2020	**Ryoncil** remestemcel-L Mesoblast	**Bone marrow/stem cell transplant side effect**: Graft versus host disease (GVHD) refractory to steroids Also has clearance from FDA for an Investigational New Drug application allowing expanded access compassionate use (outside of clinical trials) for respiratory distress syndrome due to COVID-19.	IV GVHD occurs when stem cells given to a patient (as a treatment) attack the patient's own cells, causing damage to numerous organs and tissues. If treatment with steroids fails, mortality rate can be up to 90%. **FDA Designation**: Fast-track	**Biologic product** Stem cell therapy created by culturing human stem cells (from healthy volunteers) in a laboratory. When given to a patient with GVHD, they act to interrupt the GVHD process. There are no safe and effective therapies for children with steroid-refractory GVHD.	**Therapy alternatives** None
11/20/2020	**Zokinvy** lonafarnib Eiger BioPharmaceuticals Merck & Co	**Viral liver disease**: Hepatitis D **Accelerated aging conditions**: Progeria and progeroid laminopathies	Oral Hepatitis D may be acute or chronic. It is uncommon in the US but exact figures are unknown. Only occurs in people who already have hepatitis B; treatment for both may be necessary. Progeria: An estimated 400 children worldwide have progeria and progeroid laminopathies. **FDA Designations**: Hepatitis D: Orphan Drug Progeria/progeroid laminopathies: Orphan Drug, Breakthrough Therapy, Priority Review, Rare Pediatric Disease	Farnesyltransferase inhibitor: In hepatitis D, it a blocks a process in humans that is needed for viral replication. In progeria and progeroid laminopathies, lonafarib prevents a step in production of abnormal proteins otherwise produced by mutated genes. Historically, children with progeria lived to an average age of 14.5 years.	**Therapy alternatives** Hepatitis D: Interferons (not curative) Progeria: None
11/20/2020	**Danyelza** naxitamab Y-mAbs Therapeutics	**Nervous system cancer**: Neuroblastoma	IV infusion Occurs most often in infants and children (rare in children older than 10 years). Often starts in nerve tissue in the abdomen; may behave in many different ways. Diagnosed in about 700 children in the US each year. **FDA designation**: Priority review, Breakthrough Therapy, Orphan Drug	**Biologic product.** Antibody that binds to tumor cells, triggering a response that kills tumor cells. New mechanism of action for treating this condition.	**Therapy alternatives** Surgery or therapy with octreotide or combination chemotherapy

Anticipated FDA Approvals *(continued)*

Expected FDA Review Date	Drug Name / Manufacturer	Indication	Disease or Administration Comments	Clinical Comments	Therapy Alternatives
11/23/2020	**Brand name TBD** pralsetinib (aka BLU-667) Blueprint Medicines	**Lung cancer**: Non-small cell lung cancer (NSCLC), RET fusion-positive	Oral RET activating gene fusions and mutations are key disease drivers in many cancer types, including NSCLC and medullary thyroid cancer. RET fusions are implicated in approximately 1 to 2 percent of patients with NSCLC. **FDA designation**: Breakthrough Therapy	Inhibits activity of cancer cell gene fusions and mutations that cause cancer symptoms. Would be the first RET-selective cancer treatment, which may mean better activity than existing agents. Also being studied for medullary thyroid cancer and other types of cancers associated with RET fusions/mutations.	**Therapy alternatives** > Alectinib > Selpercatinib
12/3/2020	**Brand name TBD** lumasiran (aka ALN-GO1) Alnylam Dicerna Pharmaceuticals	**Kidney disease**: Primary hyperoxaluria type 1 (PH1)	Subcutaneous PH1 is an ultra-rare, inherited disorder resulting from a buildup of oxalate, which combines with calcium to form kidney and bladder stones. It can lead to end-stage renal disease, which may be life threatening. 1-3 million people in North America have PH1. **FDA Designations**: Priority Review, Orphan Drug, Breakthrough Therapy, and Pediatric Rare Disease	Prevents production of oxalate by blocking an enzyme. Another product less advanced in development has potential to overshadow lumasiran with better dosing and broader indications.	**Therapy alternatives** None
12/3/2020	**Brand name TBD** berotralstat (aka bcx7353) BioCryst	**Hereditary Angioedema (HAE)**: Prevention of hereditary angioedema (HAE) attacks	Oral HAE, which affects about 1 in 50,000 people, causes recurrent episodes of severe swelling in the limbs, face, intestinal tract, and airway. Swelling in the airway can cause life-threatening airway obstruction. **FDA designations**: Through a manufacturer sponsored expanded access program, physicians may be able to request berotralstat for patients ineligible for clinical trials.	Plasma kallikrein inhibitor: inhibits uncontrolled activity of kallikrein, which otherwise causes overproduction of symptom-causing bradykinin. Does not appear to be as effective as competitor product Takhzyro, may be priced lower as a result. Untreated HAE patients have, on average, a 3-4 day attack every 1 to 2 weeks.	**Therapy alternatives** > Takhzyro > Cinryze > Haegarda

Anticipated FDA Approvals *(continued)*

Expected FDA Review Date	Drug Name / Manufacturer	Indication	Disease or Administration Comments	Clinical Comments	Therapy Alternatives
12/2020	**Brand name TBD** tanezumab Pfizer Eli Lilly	**Arthritis**: Osteoarthritis (OA) pain	Subcutaneous OA is a leading cause of disability. Patients with knee or hip OA also have a higher than usual risk of death due to cardiovascular events.	**Biologic product** Antibody that blocks a chemical, nerve growth factor, involved in transmitting osteoarthritis pain. First of this type of treatment for OA. Studies showed no risk of addiction, dependence, or misuse.	**Therapy alternatives** Combination of non-pharmacological approaches and analgesics (acetaminophen, non-steroidal anti-inflammatory drugs and opioids).
4Q2020	**Brand name TBD** viltolarsen (aka NS-065) Nippon Shinyaku NS Pharma	**Duchenne Muscular Dystrophy (DMD)** in patients with mutation amenable to exon 53 skipping	IV DMD is a fatal genetic neuromuscular disorder affecting one in 3,500 - 5,000 males worldwide. **FDA Designation**: Rare Pediatric Disease, Orphan Drug, Fast Track	Masks the mutation in the DMD gene, allowing production of a functional protein in place of the one causing DMD symptoms. Targets DMD with a specific genetic mutation that affects about 8% of DMD patients. Is not curative but may delay worsening of symptoms.	**Therapy alternatives** Vyondys 53

*CRL (Complete Response Letter) is a communication to a drug's manufacturer from the FDA indicating that the application for the drug cannot be approved in its present form.

References

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 manufacture affiliations or conflicts of interest. Approval status, dates, and WAC price are subject to variation. This document should not be exclusively used for decision-making purposes. WAC pricing data should be used for benchmarking purposes only. Prices listed above should not be used alone to set or adjudicate any prices for reimbursement or purchasing functions or considered to be an exact price for a single product and/or manufacturer.

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