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4TH QUARTER 2018
PIPELINE REPORT

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PIPELINE AT A GLANCE

Recent Approvals

- **Ajovy™ (fremanezumab-vfrm)** – Prevention of migraine headaches in adults
- **Takhzyro™ (lanadelumab-flyo)** – Prevention of hereditary angioedema attacks in patients 12 years and older
- **Lumoxiti™ (moxetumomab pasudotox-tdfk)** – Relapsed or refractory hairy cell leukemia (HCL) who have received 2 standard treatments
- **Orilissa™ (elagolix)** – Management of moderate to severe pain associated with endometriosis
- **Jivi® (damoctocog alfa pegol)** – Treatment of Hemophilia A in adults and adolescents 12 years of age and over

Anticipated FDA Approvals

- **Lorlatinib** – Treatment ALK-positive metastatic non-small cell lung cancer
- **Dacomitinib** – First-line treatment of locally advanced or metastatic non-small cell lung cancer with EGFR-activating mutations
- **Larotrectinib** – Tumors harboring a neurotrophic tyrosine receptor kinase gene fusion for adults & pediatrics
- **Gilteritinib** – Relapsed or refractory Acute Myeloid Leukemia with a FLT3 mutation as detected by an FDA-approved test
- **Talazoparib** – Advanced or metastatic inherited BRCA positive, HER-2 negative breast cancer

Anticipated Biosimilars FDA Review

- **Biosimilar to Rituxan® (rituximab)** for treatment of cancer, rheumatoid arthritis, and polyangiitis
- **Biosimilar to Herceptin® (trastuzumab)** for treatment of HER-2 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
09/17/2018	Cost projected to be comparable to Aimovig ($6,900 / AWP per year)	**Ajovy™ (fremanezumab-vfrm)** Teva	**Migraine:** A humanized monoclonal antibody indicated for the prevention of migraine headaches in adults **Anticipated Coverage: Rx** Injection: 225 mg/1.5 mL solution in a single-dose prefilled syringe	Two subcutaneous recommended dosage options: 225 mg monthly or 675 mg every 3 months (quarterly) 675mg SQ injection requires 3 x 225mg injections at the same time. Approx. 39 million Americans suffer from migraine, 3x more common in women	Offers advantage of quarterly dosing vs Aimovig which offers monthly Data suggests that women with migraine may be at increased risk of preeclampsia during pregnancy	**Preventative Treatment Options:** Aimovig, Botox, beta blockers, calcium channel blockers, tricyclic antidepressants, anti-seizure drugs PBM's will most likely place this class of drugs under prior authorization to promote lower-cost preventive therapies first
9/14/2018	Pending	**Lumoxiti™ (moxetumomab pasudotox)** MedImmune	**Blood & Bone Marrow Cancer:** Relapsed or refractory hairy cell leukemia (HCL) who have received 2 standard treatments, including treatment with a purine nucleoside analog **Anticipated Coverage: Medical**	Lumoxiti: first treatment approved for HCL patients that relapses or fail other therapy 30% of trial patients showed complete disappearance of their cancer (complete response) with few adverse effects, 75% of patients in the trial had either a partial response or complete response	First in class CD-22 inhibitor Offers treatment option to patients with shortened remissions and other therapy toxicities Promising nonchemotherapeutic treatment for HCL	Lumoxiti is a bacterial toxin–based drug, First-in-class drug **Therapy Options:** › Cladribine › Pentostatin › Rituximab
08/30/2018	Pending	**Jivi™ (damoctocog alfa pegol)** Bayer	**Hemophilia A:** 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, defined as a deficiency of Factor VIII Can be used on-demand and prophylactically	Offers an extended half-life which may result in decreased frequency of infusions for hemophilia A patients Offers ability to tailor administration frequency based on patient bleeds	**Therapy Options:** › Hemlibra › FEIBA (anti-inhibitor coagulant complex) › NovoSeven RT (coagulation factor VIIa, recombinant)
08/23/2018	$26,484 / 2 ml vial $688,584 / yr	**Takhzyro™ (lanadelumab-flyo)** 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, may extend to every 4 weeks Mechanism: Biologic plasma kallikrein inhibitor, representing a new mechanism of action and treatment option	No contraindications Less frequent dosing intervals relative to current treatment options of once or twice monthly; Poised to reduce acute attack treatment utilization Offers potential to change the HAE treatment guidelines	**Prevention Treatment Options:** › Danazol – Approx. $990 - $7,511 / year › Cinryze – Approx. $686,400 / year › Haegarda – Approx. $586,560 depending on weight-based dosing

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
7/24/2018	$36.21 per each 150 mg tablet $18.10 per each 200 mg tablet	**Orilissa™ (elagolix)** AbbVie Inc.	**Moderate to Severe Endometriosis Pain:** Management of moderate to severe pain associated with endometriosis Gonadotropin-releasing hormone receptor antagonist, resulting in decreased circulating hormone concentrations **Anticipated Coverage: Rx**	150 mg orally once daily up to 24 months or 200 mg twice daily for up to 6 months Dosage adjustment needed for moderate hepatic impairment. Orilissa should not be used in women with known osteoporosis, or who are pregnant. Approx. 4-10 million American women have endometriosis	Orilissa offers first endometriosis therapy since 1990s Poised to reduce pain Long-term effectiveness and safety unknown, however a bone density assessment is recommended in patients with a history of low-trauma fractures or other risk factors for osteoporosis or bone loss.	**Previous treatments:** › Surgical removal of tissue › Oral hormone therapy
07/20/2018	$522.30 per each 250 mg tablet $87,746 / 6 month therapy	**Tibsovo® (ivosidenib)** Agios Pharma	**Blood & Bone Marrow Cancer:** Treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test **Anticipated Coverage: Rx**	One tablet by mouth once daily with the FDA approved IDH1 mutation diagnostic test 6-10% of AML patients have the IDH1 mutation; In 2018, there were 19,520 new AML cases diagnosed, and an estimated 10,670 AML deaths	Shown to reduce need for red blood cell and platelet infusions Offers a single oral tablet treatment option where few options exist for specifically AML relapse and refractory patients with an IDH1 mutation	First drug in IDH1 inhibitor drug class First targeted therapy for patients with IDH1 genetic mutations
07/17/2018	$139.28 per each 800-150-200-10 mg tablet $50,837.20 / yr	**Symtuza™ (darunavir 800mg/ emtricitabine 200mg/ tenofovir alafenamide 10mg/ cobicistat 150mg)** Janssen	**HIV:** Treatment naive HIV-1 patients or treatment experienced patients with a viral load < 50 copies/mL on a stable antiretroviral regimen for 6 months and who have no resistance to darunavir or tenofovir Fixed-dose combination of 4 antiretroviral drugs **Anticipated Coverage: Rx**	One tablet orally once daily with food Concomitant use with several drugs is contraindicated Adverse reactions: drug-induced hepatitis, new or worsening immune reconstitution syndrome, and severe skin reactions, increased bleeding, renal toxicity, hepatomegaly, new onset or eXacerbated diabetes may occur, body fat redistribution	Combo will offer protease inhibitor based complete treatment regimen Combination Symtuza will provide another combination HIV therapy option 95% adherence needed to maintain viral suppression which may be difficult with noteworthy adverse reaction profile	**HIV Complete Treatment Oral Combo Regimen:** › Triumeq › Stribild › Atripla › Complera › Genvoya › Odefsey
06/01/2018	$82.19 per each 2 mg tablet	**Olumiant® (baricitinib)** Lilly / Incyte	**Rheumatoid Arthritis (RA):** Treatment of moderate to severe RA with an inadequate response or intolerance to 1 or more tumor necrosis factors (Enbrel, Humira, Simponi, Cimzia, Remicade) **Anticipated Coverage: Rx**	Initial dosage once daily oral 4mg Used as monotherapy or in combination with methotreXate	Olumiant is the 2rd JAK inhibitor approved for the treatment of RA. In addition to 1 other JAK inhibitor available, many other biologic therapy options are available for rheumatoid arthritis. Net cost will most likely drive preferred formulary status in each of these therapeutic classes.	**Treatment Options:** › Xeljanz - $81.91 per each 5mg tablet › Xeljanz XR 24 hr - $163.83 per each 11mg tablet

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
05/16/2018	$24.83 per each 0.18 mg tablet	**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.	Lucemyra will only lessen severity of withdrawal symptoms. 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
05/03/2018	$3,300 per 100 mg vial powder for solution	**AndexXa™ (coagulation factor Xa recombinant)** Portola Pharma	**Bleeding Reversal:** Indicated for patients treated with Xarelto (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) needs 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	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

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
9/2018	**Lorlatinib** Pfizer Inc.	**Lung Cancer:** ALK-positive metastatic non-small cell lung cancer (NSCLC) ALK inhibitors are 2nd line therapy when tumors are ALK fusion oncogene positive with previous chemotherapy	Oral tablets administered daily, inhibits ALK inhibitor therapy is usually continued until disease progression 5% of NSCLC patients are ALK-positive	Lorlatinib is poised to treat NSCLC resistant to 1st & 2nd generation ALK-targeted treatment Research continues to determine 1st line therapy for metastatic ALK-positive NSCLC (Lorlatinib vs Crizotinib)	**First-line ALK Tyrosine Kinase Inhibitors:** › Alecensa (alactinib) › Zykadia (certinib) › Xalkori (crizotinib) FDA Granted Breakthrough Therapy April 2017
9/30/2018	**Dacomitinib** Pfizer Inc.	**Lung Cancer:** First-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with EGFR-activating mutations	Once daily oral therapy Dacomitinib inhibits several receptors compared to first generation EGFR inhibitors which are limited to a single receptor Toxicity may require dose reduction	Improved efficacy over first-generation EGFR inhibitor gefitinib (Iressa), however with greater toxicity. Dacomtinib use may be limited by the more effective and better tolerate Osimertinib	**First Generation EGFR Inhibitors:** › Tarceva (erlotinib) › Iressa (gefitinib) › Gliotrif (afatinib) **Third Generation EGFR Inhibitor:** › Tagrisso (osimertinib) FDA granted a priority review in April 2018

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
11/2018	**Larotrectinib** Bayer	**Solid Tumor Cancer:** Locally advanced or metastatic solid tumors harboring a neurotrophic tyrosine receptor kinase (NTRK) gene fusion for adults & pediatrics	Once daily oral therapy Larotrectinib inhibits tropomyosin receptor kinases (TRK), resulting in reduced tumor growth when the NTRK gene fusion is present	FDA granted a priority review in May 2018 Orphan Drug, Breakthrough Therapy, Rare pediatric disease designations	Larotrectinib is the only selective TRK inhibitor in clinical development Bayer and Loxo Oncology will collaborate in development and promotion
11/2018	**Gilteritinib** Astellas Pharma	**Blood & Bone Marrow Cancer:** Relapsed or refractory (resistant to treatment) Acute Myeloid Leukemia (AML) with a FLT3 mutation as detected by an FDA-approved test	Once daily oral therapy Gilteritinib inhibits 2 types of FLT3 mutations in AML patients FLT3 mutation patients often do not respond or relapse to currently available treatments, New AML treatment options greatly needed	Gilteritinib is poised to be the only drug approved for relapsed or refractory FLT3 mutation-positive (FLT3mut+) AML 30% of AML patients have FLT3 mutations and are associated with poor survival outcomes	**First-line AML Treatment:** Non-targeted chemotherapy Rydapt (Midostaurin) inhibits tyrosine kinases and FLT3 receptor signaling w/ standard chemotherapy for newly diagnosed FLT3 mutation AML patients FDA granted a priority review in May 2018
12/2018	**Glasdegib** Pfizer Inc.	**Blood & Bone Marrow Cancer:** Previously untreated acute myeloid leukemia (AML) in combination with low-dose cytarabine (LDAC) Approximately one in four patients with AML survive longer than five years, especially for those ineligible for chemotherapy	Once daily oral therapy Glasdegib inhibits the smoothened (SMO) receptor and the hedgehog pathway, which is overexpressed in many types of cancer Combination therapy Glasdegib and low-dose cytarabine demonstrated overall AML survival improvement of 8.8 months, compared to 4.9 months on LDAC	Potential chemotherapy alternative therapy for AML patients ineligible for chemotherapy Offers greatly needed new AML treatment options for patients with limited options Shown to improve overall survival compared to low dose cytarabine therapy alone FDA granted priority review in June 2018	**First-line AML Treatment:** › Non-targeted chemotherapy **Ideal Induction Treatment:** › High dose Cytarabine/ anthracycline combination › Low dose Cytarabine alone **SMO inhibitors:** › Several under investigation › None have been approved to treat AML › SMO inhibitors treat Basal Cell Carcinoma: Odomzo (sonidegib) & Erivedge (vismodegib)
12/2018	**Talazoparib** Pfizer Inc.	**Breast Cancer:** Advanced or metastatic inherited BRCA positive, HER-2 negative breast cancer Shown to delay progression subgroups: brain metastases history, chemotherapy pretreatment, triple negative tumors, HER+ BC	Once daily oral therapy, poly ADP ribose polymerase (PARP) inhibitor Dual mechanism of action - tumor cell death by: 1) blocking PARP cancer cell repair activity, and 2) trapping PARP on DNA damage	Potential chemotherapy alternative Considered more potent compared to other PARP inhibitors due to the dual mechanism of action FDA granted priority review in June 2018	**PARP Inhibitors Currently Approved:** › Olaparib (Lynparza) – Breast cancer, HER2-negative, germline BRCA-mutated disease › Niraparib (Zejula) – Not indicated for BC › Rucaparib (Rubraca) – Not indicated for BC Current PARP inhibitors only inhibit the PARP repair enzyme and do not offer the dual action of Talazoparib

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
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 FDA designated Breakthrough Therapy	**Therapy Options:** › EGFR inhibitors - Erbitux (cetuximab), Vectibix (panitumumab), Iressa (gefitnib), Tarceva (erlotinib) › Platinum-based chemotherapy regimen (cisplatinum/bleomycin/ fluorouracil)
Q4 2018 – Q1 2019	**BaloXavir marboxil** Roche	**Flu:** Treats influenza A and influenza B	Single-dose, oral treatment would require less frequent dosing compared to existing therapy	May reduce duration of flu symptoms by about a day Advantage of single oral dose	**Treatment Options:** › Tamiflu (oseltamivir) › Relenza (zanamivir) inhaled › Rapivab (peramivir) IV
Q4 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/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

Biosimilar Pipeline

FDA Approval Date	Launch Date	Biosimilar Name	Biosimilar AWP Cost	Reference Product	Reference Product AWP Cost	Interchangeable	Disease Category
5/2018	To Be Determined	Retacrit™ (epoetin alfa-epbx)	Retacrit offers 33-57% saving over reference product Retacrit 2000u - $26.47	Epogen Procrit (Epoetin Alfa)	Retacrit 2000u - $26.47 Epogen 2000u - $39.79 Procrit 2000u- $61.74	No	**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 10/2018	To Be Determined	SB3 (trastuzumab)	TBD Upon Launch			Interchangeability is not anticipated	
10/2017	6/2019	Ogivri (trastuzumab-dkst)	TBD Upon Launch			No	

Biosimilar Pipeline *(continued)*

FDA Approval Date	Launch Date	Biosimilar Name	Biosimilar AWP Cost	Reference Product	Reference Product AWP Cost	Interchangeable	Disease Category
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:** To reduce the incidence of infection in patents receiving chemotherapy, reduce the duration and time to recovery from neutropenia caused by chemotherapy, mobilization of progenitor blood cells for collection by leukapheresis, and reducing the incidence and duration of complications due to severe neutropenia.
3/2015	9/2015	Zarxio®** (filgrastim-sndz)	$658.48 (480mcg/0.8ml)			No	
8/2013	2015	Granix®** (tbo-filgrastim)	$715.65 (480mcg/0.8ml)			No	
7/2018	To Be Determined	Nivestym™** (filgrastim-aafi)	TBD Upon Launch			No	
9/2017	7/2019	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
12/2017	To Be Determined	Ixifi™ (infliximab-qbtx)	Not anticipated to be launched due to acquisition	Remicade (infliximab)	$1,401.38 100mg Inj	No	**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
4/2017	7/2017	Renflexis® ** (infliximab-abda)	$904.07 (100mg)			No	
4/2016	11/2016	Inflectra® ** (infliximab-dyyb)	$1,135.54 (100mg/20ml)			No	
8/2017	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
9/2016	2023	Amjevita™ (adalimumab-atto)	TBD Upon Launch			No	
8/2016	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

** 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
Expected FDA Review 7/2018	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.
6/2018	7/2018	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 manufacture 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. AWP 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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