

Medication	FDA Indications Note: Although every effort is made to keep this FDA indication list up to date, please consult the web link in the far right column for the most accurate information.	MSFC Specifications	Manufacturer's Prescribing Info (Hold CTRL and click on link to open)
Accutane (isotretinoin)	See Isotretinoin		
Actemra (tocilizumab)	<u>Indicated for:</u> 1. treatment of adult patients with moderately to severely active RA who have had an inadequate response to one or more DMARD(s). 2. Polyarticular Juvenile Idiopathic Arthritis (PJIA) patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis. 3. Systemic Juvenile Idiopathic Arthritis (SJIA) patients 2 years of age and older with active systemic juvenile idiopathic arthritis.	Rx by Rheumatologist	ACTREMA PI
Adcirca (tadalafil)	Indicated to treat pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability [studies establishing effectiveness included predominately patients with NYHA Functional Class II–III symptoms and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (23%)].		ADCIRCA PI
Adempas (riociguat)	<u>Indicated for:</u> 1. persistent/recurrent Chronic Thromboembolic Pulmonary Hypertension (CTEPH) (WHO Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class. 2. pulmonary Arterial Hypertension (PAH) (WHO Group 1) to improve exercise capacity, improve WHO functional class and to delay clinical worsening.	Rx by Pulmonologist or Cardiologist	ADEMPAS PI
Amitiza (lubiprostone)	<u>Indicated for:</u> 1. treatment of chronic idiopathic constipation in adults. 2. treatment of opioid-induced constipation in adults with chronic, non-cancer pain. 3. treatment of irritable bowel syndrome in women ≥ 18 years old.		AMITIZA PI
Arava (leflunomide)	Indicated for the treatment of active rheumatoid arthritis in adults.	Rx by Rheumatologist	ARAVA PI
Avinza (morphine sulfate)	Indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.	1. Cancer patients (under Oncology care) will	AVINZA PI

extended-release capsules		<p>automatically receive authorization.</p> <ol style="list-style-type: none"> 2. Chronic pain patients, i.e., rheumatoid arthritis, sickle cell anemia, RSD, diabetic neuropathy, etc. will be considered with supporting clinical information. 3. Rx by a known Pain Management Expert will automatically be authorized. 4. Pain contract is recommended. Please call for MSFC for additional monitoring resources and information. 	
Benlysta (belimumab)	Indicated for the treatment of adult patients with active, autoantibody-positive, SLE who are receiving standard therapy.	Rx by Rheumatologist	BENLYSTA PI
Beyaz (drospirenone/ethinyl estradiol/levomefolate calcium tablets and levomefolate calcium tablets)	<p><u>Indicated for:</u></p> <ol style="list-style-type: none"> 1. prevention of pregnancy. 2. treatment of symptoms of premenstrual dysphoric disorder (PMDD) for women who choose to use an oral contraceptive for contraception. 3. to treat moderate acne for women at least 14 years old only if the patient desires an oral contraceptive for birth control. 4. to raise folate levels in women who choose to use an oral contraceptive for contraception. 	<ol style="list-style-type: none"> 1. ANY OCP on prior authorization requires documentation demonstrating a compelling reason why formulary OCPs cannot be used [ex: intolerance, prior side effects, failures, etc. documented after a 3 month trial of formulary OCP(s)] 	BEYAZ PI

		2. Will not be covered as first line for treatment of acne, folate deficiency or for PMDD.	
Bosulif (bosutinib)	Indicated for the treatment of adult patients with chronic, accelerated, or blast phase Ph+ chronic myelogenous leukemia (CML) with resistance or intolerance to prior therapy.		BOSULIF PI
Botox (onabotulinumtoxin A)	<p><u>Indicated for:</u></p> <ol style="list-style-type: none"> 1. treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication. 2. treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of an anticholinergic medication. 3. prophylaxis of headaches in adult patients with chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer). 4. treatment of upper limb spasticity in adult patients. 5. treatment of cervical dystonia in adult patients, to reduce the severity of abnormal head position and neck pain. 6. treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients. 7. treatment of blepharospasm associated with dystonia in patients ≥ 12 years of age. 8. treatment of strabismus in patients ≥ 12 years of age. 	<ol style="list-style-type: none"> 1. Rx by Neurologist, Urologist, Ophthalmologist 2. Botox will NOT be approved for cosmetic purposes. 	BOTOX PI
Cometriq (cabozantinib)	Indicated for treatment of progressive, metastatic medullary thyroid cancer.	Rx by Oncologist	COMETRIQ PI
Copegus (ribavirin)	See Ribavirin		
DDAVP (desmopressin)	See Desmopressin Nasal Spray Products		
DESMOPRESSIN NASAL SPRAY PRODUCTS:	<p><u>DDAVP</u> is indicated for:</p> <ol style="list-style-type: none"> 1. treatment of central Diabetes Insipidus. 2. treatment of transient polyuria and polydipsia post head trauma or neuro-surgery. <p><u>Stimate</u> is indicated for:</p>	<ol style="list-style-type: none"> 1. STIMATE: Hemophilia A with factor VIII coagulant activity greater than 5%: <ul style="list-style-type: none"> ➤ *peri-operatively 	DDAVP FDA PI STIMATE PI

<p><u>DDAVP spray-</u> 0.01%</p> <p><u>Stimate spray-</u> 1.5 mg/mL</p>	<ol style="list-style-type: none"> 1. hemophilia A with Factor VIII coagulant activity levels greater than 5% - will stop bleeding in patients with hemophilia A with episodes of spontaneous or trauma-induced injuries such as hemarthroses, intramuscular hematomas or mucosal bleeding. 2. mild to moderate classic von Willebrand's disease (Type I) with Factor VIII levels greater than 5% - will stop bleeding in patients with episodes of spontaneous or trauma-induced injuries such as hemarthroses, intramuscular hematomas, mucosal bleeding or menorrhagia. 	<ul style="list-style-type: none"> ➤ to prevent bleeding ➤ to treat spontaneous or trauma induced bleeding <p>***Note- Patients with factor VIII levels equal to or less than 5% or patients who have factor VIII antibodies are not candidates for the drug. It is contraindicated in patients under 3 months old. It is NOT indicated for Hemophilia B.</p> <ol style="list-style-type: none"> 2. STIMATE: Patients with von Willebrand's Disease (type I) with factor VIII coagulant activity greater than 5%: <ul style="list-style-type: none"> ➤ used peri-operatively to prevent bleeding. ➤ to treat spontaneous or trauma induced bleeding. <p>***Note- The drug is NOT indicated for treatment of severe classic von Willebrand's Disease (type I) or when there is</p>	
---	--	--	--

		evidence of an abnormal molecular form of Factor VIII antigen	
Dificid (fidaxomicin)	Indicated for the treatment of <i>Clostridium difficile</i> -associated diarrhea in adults (≥ 18 years of age).	Pt must have documented failures with both metronidazole and vancomycin, or contraindication(s) to the use of these agents.	DIFICID PI
Duragesic (fentanyl transdermal system)	Indicated for the management of persistent, moderate to severe chronic pain in opioid-tolerant patients 2 years of age and older when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.	<ol style="list-style-type: none"> 1. Cancer patients (under Oncology care) will automatically receive authorization. 2. Chronic pain patients, i.e., rheumatoid arthritis, sickle cell anemia, RSD, diabetic neuropathy, etc. will be considered with supporting clinical information. 3. Rx by a known Pain Management Expert will automatically be authorized. 	DURAGESIC PI
Eligard (leuprolide SQ)	see Leuprolide		
Enbrel (etanercept)	<p>Indicated for:</p> <ol style="list-style-type: none"> 1. rheumatoid arthritis. 2. polyarticular juvenile idiopathic arthritis in patients ≥ 2 years of age. 3. psoriatic arthritis. 4. ankylosing spondylitis. 5. plaque psoriasis. 		ENBREL PI
Erwinaze	Indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of	Rx by Oncologist	ERWINAZE PI

(asparaginase <i>Erwinia chrysanthemi</i>)	patients with ALL who have developed hypersensitivity to <i>E. coli</i> -derived asparaginase.		
Firazyr (icatibant)	Indicated for the treatment of acute attacks of hereditary angioedema in adults ≥18 years of age (self-administered by the patient).	Rx by Allergist or ENT	FIRAZYR PI
FloLAN (epoprostenol sodium)	Indicated for the treatment of pulmonary arterial hypertension (WHO Group I) to improve exercise capacity [studies establishing effectiveness included predominantly patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases].	Rx by Cardiologist or Pulmonologist	FLOLAN PI
Fosrenal (lanthanum carbonate)	Indicated for the reduction of serum phosphorus levels in patients with end-stage renal disease (ESRD).	Rx by Nephrologist	FOSRENAL PI
Fulyzac (crofelemer delayed release [DR])	Indicated for the symptomatic relief of non-infectious diarrhea in adult HIV/AIDS, currently on anti-retroviral therapy.	Rx by ID, GI or HIV Specialist	FULYZAC PI
GammaGard S/D [Immune Globulin Intravenous (Human)]	<u>Indicated for:</u> <ol style="list-style-type: none"> 1. treatment of Primary Immunodeficiency (PI) in adults and pediatric patients ≥ 2 years of age. 2. prevention of bacterial infections in hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell Chronic Lymphocytic Leukemia. 3. prevention and/or control of bleeding in adult Chronic Idiopathic Thrombocytopenic Purpura (ITP) patients. 4. prevention of coronary artery aneurysms associated with Kawasaki syndrome in pediatric patients. 	Rx by ID or Hematologist/Oncologist	GAMMAGARD S/D PI
Generess FE (norethindrone and ethinyl estradiol and ferrous fumarate)	See Oral Contraceptive		GENERESS FE PI
Gilenya (fingolimod)	Indicated for the treatment of relapsing multiple sclerosis.	Rx by Neurologist	GILENYA PI
Grastek (Timothy Grass Pollen Allergen Extract)	Indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or <i>in vitro</i> testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens. GRASTEK is approved for use in persons 5 through 65 years of age.		GRASTEK PI
Growth Hormone	See Norditropin ; See Serostim		

<p>Harvoni (ledipasvir and sofosbuvir)</p> <p>SEE SPECIAL NOTE REGARDING WEEK 4 VIRAL LOAD TESTING ***** →</p>	<p>Indicated for the treatment of chronic hepatitis C genotype 1 infection in adults.</p> <p style="text-align: center;">Please note:</p> <p>The Maryland Department of Health and Mental Hygiene has <u>MANDATED</u> a test of viral load <u>after 4 weeks</u> on treatment. If this check is not completed, medication refills will NOT be authorized after week 8 of treatment. This is a DHMH requirement and as such, MSFC does not have the ability to waive this testing under any circumstances.</p>	<p>Rx by ID or GI</p> <p>Please submit: A COMPLETED PRIOR AUTHORIZATION FORM (see link below) via FAX to 410-933-2205</p> <p>PRIOR AUTHORIZATION & PRESCRIPTION FORM</p>	<p>HARVONI PI</p>
<p>Herceptin (trastuzumab)</p>	<p>Indicated for:</p> <ol style="list-style-type: none"> 1. treatment of HER2 overexpressing breast cancer. 2. treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. 	<p>Rx by Oncologist</p>	<p>HERCEPTIN PI</p>
<p>Humira (adalimumab)</p>	<p>Indicated for:</p> <ol style="list-style-type: none"> 1. treatment of moderate to severe active rheumatoid arthritis in adults. 2. treatment of moderate to severe active juvenile idiopathic arthritis in pediatric patients ≥ 4 years old. 3. treatment of active psoriatic arthritis in adults. 4. treatment of active ankylosing spondylitis in adults. 5. for treatment of moderate to severe active Crohn’s disease in adults who have had an inadequate response to conventional therapy [including those that have lost response or intolerant to Remicade (infliximab)]. 6. reduction of signs and symptoms and inducing and maintaining clinical remission in patients 6 years of age and older with moderately to severely active Crohn’s disease who have had an inadequate response to corticosteroids or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate. 7. treatment of moderate to severe active ulcerative colitis in adults with inadequate response to immunosuppressants (steroids, azothioprine, 6-MP) [effectiveness not established in pts who have lost response to or were intolerant to TNF blockers]. 		<p>HUMIRA PI</p>

	8. treatment of adults with moderate to severe chronic plaque psoriasis who are not candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate.		
Hycamtin caps (topotecan)	Indicated for treatment of patients with relapsed small cell lung cancer.	Rx by Oncologist	HYCAMTIN CAPSULES PI
Iclusig (ponatinib)	<u>Indicated for:</u> 1. treatment of adult patients with T315I-positive chronic myeloid leukemia (chronic phase, accelerated phase, or blast phase) or T315I positive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL). 2. treatment of adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia or Ph+ ALL for whom no other tyrosine kinase inhibitor (TKI) therapy is indicated.	Rx by Oncologist	INCLUSIG PI
Imbruvica (ibrutinib)	<u>Indicated for:</u> 1. treatment of patients with mantle cell lymphoma (MCL)* who have received at least one prior therapy. *Accelerated approval was granted for this indication based on overall response rate. Improvements in survival or disease-related symptoms have not been established. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trials. 2. treatment of patients with chronic lymphocytic leukemia (CLL) who have received at least one prior therapy. 3. treatment of patients with chronic lymphocytic leukemia with 17p deletion.	Rx by Oncologist	IMBRUVICA PI
Incivek (telaprevir)	Indicated <u>in combination with peg-interferon alfa and ribavirin</u> for the treatment of genotype 1 Chronic Hepatitis C in adult patients with compensated liver disease, including cirrhosis, who are treatment-naïve or who have previously been treated with interferon-based treatment, including prior null responders, partial responders, and relapsers.		INCIVEK PI
Insulin Pens	Age 0-18: Insulin pens will be provided for members ages 0-18 years of age. Age 19 and older: Lantus and Levemir pens do NOT require prior authorization and are available to all members. All other insulin pens require prior authorization.		
INTERFERON PRODUCTS: Intron A	<u>Indicated for:</u> 1. hairy cell leukemia, ≥18 years old (Intron A). 2. Kaposi's sarcoma, ≥18 years old (AIDS-related) (Intron A). 3. condylomata acuminata, ≥18 years old (Intron A).		INTRON A PI INFERGEN FDA PI

<p>(interferon alfa-2b) Infergen (interferon alfacon-1) PEG-Intron (peginterfrn alfa-2a) Pegasys (peginterferon alfa 2a)</p>	<p>4. chronic hepatitis B (Intron A (in patients 1 year of age and older), Pegasys). 5. chronic hepatitis C (Intron A, PEG-Intron, Pegasys, Infergen). 6. adjuvant to surgical treatment for malignant melanoma, ≥18 years old (Intron A only). 7. follicular (non-Hodgkins) lymphoma, ≥18 years old (Intron A only). 8. Philadelphia chromosome positive chronic myelogenous leukemia (CML) within one year of diagnosis, ≥18 years old (Intron A only).</p>		<p>PEG-INTRON PI PEGASYS PI</p>
<p>Isotretinoin</p>	<p>Indicated for treatment of severe recalcitrant nodular acne.</p>	<p>Rx by Dermatologist</p>	<p>ISOTRETINOIN FDA PI</p>
<p>Jakafi (ruxolitinib)</p>	<p>Indicated for: 1. treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis. 2. treatment of patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea.</p>	<p>Rx by Hematologist/Oncologist</p>	<p>JAKAFI PI</p>
<p>Juxtapid (lomitapide)</p>	<p>Indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia. ***ONLY available through certified pharmacies and only doctors enrolled and certified in manufacturer's program may prescribe this medication</p>	<p>Rx by Cardiology or Endocrinologist</p>	<p>JUXTAPID PI</p>
<p>Kalydeco (ivacaftor)</p>	<p>Indicated for the treatment of cystic fibrosis (CF) in patients age 6 years and older who have a <i>G551D</i> mutation in the <i>CFTR</i> gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the <i>G551D</i> mutation.</p>	<p>Rx by Pulmonologist</p>	<p>KALYDECO PI</p>
<p>Kineret (anakinra)</p>	<p>Indicated for: 1. treatment of moderate to severe, active rheumatoid arthritis in patients 18 years or older who have failed one or more disease modifying anti-rheumatic drugs (DMARDs). 2. Cryopyrin-Associated Periodic Syndromes (CAPS)- treatment of Neonatal-Onset Multisystem Inflammatory Disease.</p>	<p>Rx by Rheumatologist or Neonatologist</p>	<p>KINERET PI</p>
<p>Korlym (mifepristone)</p>	<p>Indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and</p>	<p>1. Rx by Endocrinologist 2. Medical records</p>	<p>KORLYM PI</p>

	have failed surgery or are not candidates for surgery.	submitted for review should indicate a history of a failed surgery or the reason why surgery is not a treatment option for the member.	
Krystexxa (pegloticase)	Indicated for the treatment of chronic gout in adult patients refractory to conventional therapy.	<ol style="list-style-type: none"> 1. Rx by Rheumatologist 2. failure to normalize serum uric acid or inadequately controlled signs and symptoms with xanthine oxidase inhibitors at the max appropriate dose –OR– contraindication to xanthine oxidase inhibitor 	KRYSTEXXA PI
Letairis (ambrisentan)	Indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability and delay clinical worsening [studies establishing effectiveness included predominantly patients with WHO Functional Class II-III symptoms and etiologies of idiopathic or heritable PAH (64%) or PAH associated with connective tissue diseases (32%)].	Rx by Cardiologist or Pulmonologist	LETAIRIS PI
LEUPROLIDE PRODUCTS: Eligard (leuprolide SQ) Lupron (leuprolide acetate) Lupron Depot (leuprolide acetate for	<p>Indicated for:</p> <ol style="list-style-type: none"> 1. palliative treatment for advanced prostate cancer (Eligard). 2. treatment of pediatric patients with central precocious puberty (Lupron Depot- PED). 3. treatment of endometriosis (Lupron and Lupron Depot). 4. uterine leiomyomata (fibroids) along with concurrent iron therapy in preparation for surgery [duration of treatment should be for 6 months or less (Lupron and Lupron Depot)]. 		ELIGARD PI LUPRON 3.75 mg PI LUPRON DEPOT 11.25 MG PI LUPRON DEPOT- PED PI

depot suspension) Lupron Depot-PED (leuprolide acetate for depot suspension)			
LO Loestrin Fe (norethindrone, ethinyl estradiol and ferrous fumarate)	See Oral Contraceptive		LO LOESTRIN FE PI
Lovaza (omega-3-acid ethyl esters) (historical Omacor)	Indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.		LOVAZA PI
Lupron and Lupron Depot	See Leuprolide		
Mekinist (trametinib)	Indicated as a single agent and in combination with dabrafenib for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test.		MEKINIST PI
Minastrin 24 Fe (norethindrone, ethinyl estradiol and ferrous fumarate)	See Oral Contraceptive ***CHEWABLE		MINASTRIN 24 FE PI (LIMITED INFO)
MS Contin (morphine sulfate controlled release)	Indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.	<ol style="list-style-type: none"> 1. Cancer patients (under Oncology care) will automatically receive authorization. 2. Chronic pain patients, i.e., rheumatoid arthritis, sickle cell anemia, RSD, diabetic neuropathy, etc. will be considered with 	MS CONTIN PI

		supporting clinical information. 3. Rx by a known Pain Management Expert will automatically be authorized.	
Namenda (memantine)	Indicated for treatment of moderate to severe Alzheimer’s Disease.	1. MMSE ≤ 24 2. approval for 6 months at a time only	NAMENDA PI
Natazia (estradiol valerate and estradiol valerate/dienogest)	<u>Indicated for:</u> 1. use by women to prevent pregnancy. 2. treatment of heavy menstrual bleeding in women without organic pathology who choose to use an oral contraceptive as their method of contraception.	ANY OCP on prior authorization requires documentation demonstrating a compelling reason why formulary OCPs cannot be used [ex: intolerance, prior side effects, failures, etc. documented after a 3 month trial of formulary OCP(s)]	NATAZIA PI
Norditropin (somatropin (fDNA origin) injection)	<u>Indicated for:</u> 1. treatment of children with growth failure due to growth hormone deficiency (GHD), short stature associated with Noonan syndrome, short stature associated with Turner syndrome and short stature born SGA with no catch-up growth by age 2 to 4 years. 2. treatment of adults with either adult onset or childhood onset GHD.	Rx by Endocrinologist	NORDITROPIN PI
Noxafil (posaconazole)	<u>Indicated for:</u> 1. prophylaxis of invasive <i>Aspergillus</i> and <i>Candida</i> , ≥13 years of age, who are at high risk of developing these infections due to being severely immunocompromised (such as from: stem cell transplant with GVHD or prolonged neutropenia from chemotherapy).. 2. oropharyngeal candidiasis (OPC), including infections refractory to itraconazole and/or fluconazole.		NOXAFIL PI
Olysio (simeprevir)	Indicated for the treatment of chronic hepatitis C infection as a component of a combination antiviral treatment regimen (in combination with peginterferon alfa and ribavirin) in HCV genotype 1 infected subjects with compensated liver disease (including cirrhosis).	Rx by ID or GI Patient MUST:	OLYSIO PI

<p>SEE SPECIAL NOTE REGARDING WEEK 4 VIRAL LOAD TESTING ***** →</p>	<p style="text-align: center;">Please note:</p> <p style="text-align: center;">The Maryland Department of Health and Mental Hygiene has <u>MANDATED</u> a test of viral load <u>after 4 weeks</u> on treatment. If this check is not completed, medication refills will NOT be authorized after week 8 of treatment. This is a DHMH requirement and as such, MSFC does not have the ability to waive this testing under any circumstances.</p>	<ol style="list-style-type: none"> 1. be HIV negative 2. have no h/o liver transplant 3. have testing negative for the NS3 Q80K polymorphism. <p><u>Please submit:</u> A COMPLETED PRIOR AUTHORIZATION FORM (see link below) via FAX to 410-933-2205</p> <p style="text-align: center;"><u>PRIOR AUTHORIZATION AND PRESCRIPTION FORM</u></p>	
<p>Opsumit (macitentan)</p>	<p>Indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression. Disease progression included: death, initiation of IV or subcutaneous prostanoids or clinical worsening of PAH (decreased 6-minute walk distance, worsened PAH symptoms and need for additional PAH treatment). OPSUMIT also reduced hospitalization for PAH.</p>	<p>Rx by Pulmonary or Cardiology</p>	<p><u>OPSUMIT PI</u></p>
<p>Oral Contraceptives</p>	<p>While some oral contraceptives have additional indications (ex: Beyaz for acne, PMDD, folate replacement; Estrostep Fe for acne; Safyral for folate replacement; Natazia for heavy periods), most are simply indicated for the prevention of pregnancy.</p>	<p>ANY OCP on prior authorization requires documentation demonstrating a compelling reason why formulary OCPs cannot be used [ex: intolerance, prior side effects, failures, etc. documented after a 3 month trial of formulary OCPs]</p>	
<p>Oralair (sublingual tablet of grass pollen extract)</p>	<p>Indicated for the treatment of symptoms of moderate to severe seasonal grass pollen allergic rhinitis with or without conjunctivitis in patients 5 to 50 years of age, confirmed by clinically relevant symptoms, a positive cutaneous test and a positive titre of the specific IgE to <i>Poaceae</i></p>		<p><u>ORALAIR PI</u></p>

	grass pollen, who have suffered from allergic rhinitis with or without conjunctivitis for at least two pollen seasons and have not adequately responded to, or tolerated, conventional pharmacotherapy.		
Orencia (abatacept)	<u>Indicated for:</u> 1. treatment of adults with moderately to severely active RA [can be monotherapy or concomitant with DMARDs other than TNF antagonists; should not be administered concomitantly with TNF antagonists and not recommended for use concomitantly with Kineret® (anakinra)]. 2. treatment of moderate to severe polyarticular juvenile idiopathic arthritis (JIA) as monotherapy or with methotrexate in patients ≥6 years of age.	Rx by Rheumatologist	ORENCIA PI
Pegasys (peginterferon alfa-2a)	See Interferon Products		
Pegintron (peginterferon alfa-2b)	See Interferon Products		
Prolia (denosumab)	<u>Indicated for:</u> 1. treatment of postmenopausal women with osteoporosis at high risk for fracture. 2. treatment to increase bone mass in men with osteoporosis at high risk for fracture. 3. treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. 4. treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.		PROLIA PI
Pulmozyme (dornase alfa) Inhalation solution	Indicated in the management of cystic fibrosis patients to improve pulmonary function; in patients with an FVC ≥ 40% of predicted, daily administration of Pulmozyme has also been shown to reduce the risk of respiratory tract infections requiring parenteral antibiotics.	Rx by Pulmonologist	PULMOZYME PI
Quartette (levonorgestrel/ethiny l estradiol and ethinyl estradiol)	See Oral Contraceptive		QUARTETTE PI
Ragwitek (Short Ragweed Pollen Allergen Extract)	Indicated as immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or <i>in vitro</i> testing for pollen-specific IgE antibodies for short ragweed pollen. RAGWITEK is approved for use in adults 18 through 65 years of age.		RAGWITEK PI

Rebetol (ribavirin)	See Ribavirin		
Remodulin (treprostinil) continuous subQ infusion	<u>Indicated for:</u> 1. treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to diminish symptoms associated with exercise [studies establishing effectiveness included patients with NYHA Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (58%), PAH associated with congenital systemic-to-pulmonary shunts (23%), or PAH associated with connective tissue diseases (19%)]. 2. patients who require transition from Flolan (prostaglandin vasodilator) to reduce the rate of clinical deterioration.		REMODULIN PI
Revatio (sildenafil)	Indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I) in adults to improve exercise ability and delay clinical worsening [studies establishing effectiveness were short-term (12 to 16 weeks), and included predominately patients with NYHA Functional Class II-III symptom; etiologies were idiopathic (71%) or associated with connective tissue disease (25%)].		REVATIO PI
Ribavirin (Copegus) (Rebetol)	Indicated in combination with interferon alfa-2b (pegylated and nonpegylated) for the treatment of Chronic Hepatitis C in patients 3 years of age or older with compensated liver disease. <i>***patients with the following characteristics are less likely to benefit from re-treatment after failing a course of therapy: previous nonresponse, previous pegylated interferon treatment, significant bridging fibrosis or cirrhosis and genotype 1 infection.</i>		COPEGUS PI REBETOL PI
Safyral (drospirenone/ethinyl estradiol/ levomefolate calcium tablets and levomefolate calcium tablets)	Folate containing contraceptive pill, indicated for use by women to prevent pregnancy and raise folate levels in women who choose to use an oral contraceptive for contraception.	ANY OCP on prior authorization requires documentation demonstrating a compelling reason why formulary OCPs cannot be used [ex: intolerance, prior side effects, failures, etc. documented after a 3 month trial of formulary OCP(s)]	SAFYRAL PI

Sensipar (cinacalcet)	<u>Indicated for:</u> 1. treatment of secondary hyperparathyroidism in patients with CKD on dialysis. 2. treatment of hypercalcemia in patients with parathyroid carcinoma. 3. treatment of severe hypercalcemia in patients with primary hyperparathyroidism who are unable to undergo parathyroidectomy.	Rx by Nephrologist or Endocrinologist	SENSIPAR PI
Serostim (somatropin (rDNA origin))	Indicated for the treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance.	Rx by ID or HIV Specialist	SEROSTIM PI
Sirturo (bedaquiline)	Indicated as part of combination therapy in adults with pulmonary multi-drug resistant TB. [Reserved for use when an effective treatment regimen cannot otherwise be provided; not indicated for the treatment of latent, extra pulmonary or drug-sensitive tuberculosis; should be administered by directly observed therapy].	Rx by ID	SITURO PI
Sovaldi (sofosbuvir) SEE SPECIAL NOTE REGARDING WEEK 4 VIRAL LOAD TESTING ***** →	Indicated for the treatment of chronic hepatitis C infection as a component of a combination antiviral treatment regimen. ***(efficacy has been established in subjects with HCV genotype 1, 2, 3 or 4 infection, including those with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and those with HCV/HIV-1 co-infection) Genotype 1- Sovaldi with peginterferon and ribavirin for 12 weeks Genotype 2- Sovaldi with ribavirin for 12 weeks Genotype 3- Sovaldi with ribavirin for 24 weeks Genotype 4- Sovaldi with ribavirin and peginterferon for 12 weeks For patients awaiting liver transplant- Sovaldi and ribavirin for 48 weeks or until transplant. Monthly pregnancy tests are recommended for women while on this medication and pregnancy is to be avoided (2 means of birth control are suggested) for the duration of treatment and for 6 months following the cessation of treatment for female and male patients. <p style="text-align: center;">Please note:</p> The Maryland Department of Health and Mental Hygiene has <u>MANDATED</u> a test of viral load <u>after 4 weeks</u> on treatment. If this check is not completed, medication refills will NOT be authorized after week 8 of treatment. This is a DHMH requirement and as such, MSFC does not have	Rx by ID or GI <u>Please submit:</u> A COMPLETED PRIOR AUTHORIZATION FORM (see link below) via FAX to 410-933-2205 <u>PRIOR AUTHORIZATION AND PRESCRIPTION FORM</u>	SOVALDI PI

	the ability to waive this testing under any circumstances. Viral load testing is also mandatory at 12 weeks and 24 weeks (for extended regimens).		
Stelara (ustekinumab)	Indicated for: 1. treatment of patients ≥18 years of age with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. 2. active psoriatic arthritis , alone or in combination with methotrexate.	Rx by Dermatologist or Rheumatologist	STELARA PI
Stimate nasal spray (desmopressin)	See Desmopressin Products		
Stivarga (regorafenib)	Indicated for: 1. treatment of metastatic colorectal cancer, previously treated with ALL the following therapies: a. fluoropyrimidine-based chemotherapy b. oxaliplatin-based chemotherapy c. irinotecan-based chemotherapy d. an anti-vascular endothelial growth factor (VEGF) therapy e. if Kirsten RNA Associated Rat Sarcoma 2 Virus Gene (KRAS) wild type, an anti-epidermal growth factor receptor (EGFR) therapy 2. treatment of locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST), previously treated with imatinib mesylate and sunitinib malate.	Rx by Oncologist	STIVARGA PI
Supprelin LA (histrelin acetate) subcutaneous implant	Indicated for treatment of Central Precocious Puberty in children.	Rx by Pediatric Endocrinologist	SUPPRELIN LA PI
Synagis (palivizumab)	Indicated for prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease. MedStar Family Choice uses the newest recommendations of the American Academy of Pediatrics (AAP). Recommendations were last updated in the journal Pediatrics (7/28/2014 issue): Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection	Authorization is given in accordance with the latest recommendation from the American Academy of Pediatrics (see left).	SYNAGIS PI

	The internet address for this reference is: http://pediatrics.aappublications.org/content/134/2/415.full		
Synribo (omacetaxine)	Indicated to treat adults with chronic phase (CP) or accelerated phase (AP) CML with resistance and/or intolerance to two or more TKIs.	Rx by Oncologist	SYNRIBO PI
Synvisc Synvisc-ONE (hylan G-F 20)	Indicated for the treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy and simple analgesics, e.g., acetaminophen.	Must have failed steroid joint injections or have compelling contraindication to the use of steroids.	SYNVISC PI SYNVISC ONE PI
Tafinlar (dabrafenib)	Indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test.		TAFINLAR PI
Tarceva (erlotinib)	<u>Indicated for:</u> <ol style="list-style-type: none"> 1. first-line treatment of metastatic non-small cell lung cancer (NSCLC) tumors with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test. 2. maintenance treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) where disease has not progressed after four cycles of platinum-based first-line chemotherapy. 3. treatment of locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen. 4. first-line treatment of locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine. 	Rx by Oncologist	TARCEVA PI
Tasigna (nilotinib)	<u>Indicated for:</u> <ol style="list-style-type: none"> 1. treatment of newly diagnosed adult patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. 2. treatment of Philadelphia chromosome-positive CML in adult patients in chronic phase (CML-CP) or accelerated phase (CML-AP) in patients resistant or intolerant to prior therapy, including Gleevec (imatinib). 	Rx by Oncologist	TASIGNA PI
Tecfidera (dimethyl fumarate)	Indicated for the treatment of patients with relapsing forms of multiple sclerosis.	Rx by Neurologist	TECFIDERA PI
Tykerb (lapatinib)	<u>Indicated for:</u> <ol style="list-style-type: none"> 1. the treatment of advanced or metastatic breast cancer, in combination with Xeloda (capecitabine), for patients whose tumors overexpress HER2 and who have received prior 	Rx by Oncologist	TYKERB PI

	<p>therapy including an anthracycline, a taxane, and Herceptin (trastuzumab).</p> <p>2. the treatment of postmenopausal women, in combination with letrozole , for hormone receptor positive metastatic breast cancer that overexpresses the HER2 receptor when hormonal therapy is indicated.</p>		
Tyvaso (treprostinil)	Indicated to increase walk distance in patients with World Health Organization (WHO) Group I Pulmonary Arterial Hypertension and New York Heart Association (NYHA) Class III symptoms [studies establishing effectiveness included predominately patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with connective tissue diseases (33%)].	Rx by Cardiologist or Pulmonologist	TYVASO PI
Ventavis (iloprost)	Indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve a composite endpoint consisting of exercise tolerance, symptoms (NYHA Class), and lack of deterioration [studies establishing effectiveness included predominately patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH (65%) or PAH associated with connective tissue diseases (23%)].		VENTAVIS PI
Xalkori (crizotinib)	Indicated for the treatment of locally advanced or metastatic non-small cell lung cancer that is ALK-positive (anaplastic lymphoma kinase) as detected by an FDA-approved test	Rx by Oncologist	XALKORI PI
Xgeva (denosumab)	<p><u>Indicated for:</u></p> <ol style="list-style-type: none"> 1. prevention of skeletal-related events in patients with bone metastases from solid tumors. (does not include multiple myeloma). 2. treatment of adults and skeletally mature adolescents with giant cell tumor of the bone that is unresectable or where surgical resection is like to result in severe morbidity. 3. treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy. 	Rx by Oncologist	XGEVA PI
Xolair (omalizumab)	<p><u>Indicated for:</u></p> <ol style="list-style-type: none"> 1. adults and adolescents (≥ 12 years of age) with moderate to severe persistent asthma who have a positive skin test or <i>in vitro</i> reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. 2. Chronic idiopathic urticaria in adults and adolescents (12 years of age and above) who remain symptomatic despite H1 antihistamine treatment 	<ol style="list-style-type: none"> 1. ≥ 12 years of age and ideally not >150 kg 2. moderate to severe persistent ALLERGIC asthma (confirmed by a positive skin test or RAST for ≥ 1 perennial aeroallergen) 3. IgE level of ≥ 30 and ≤ 700 IU/ml obtained <u>prior to initiation of therapy</u> in order to 	XOLAIR PI

		<p>calculate the dosage</p> <ol style="list-style-type: none"> 4. currently using an inhaled corticosteroid at maximum dose; compliance must be confirmed in the patient's Caremark profile 5. currently using a long-acting inhaled beta₂-agonist OR a leukotriene modifier; compliance must be confirmed in the patient's Caremark profile 6. Rx by Allergist or Pulmonologist 7. NOT approved for monotherapy 8. NOT approved for treating an asthma exacerbation; it is for prophylactic therapy only 	
<p>Xyrem (sodium oxybate)</p>	<p><u>Indicated for:</u></p> <ol style="list-style-type: none"> 1. treatment of cataplexy in narcolepsy. 2. treatment of excessive daytime sleepiness (EDS) in narcolepsy. <p><i>***Xyrem may only be dispensed to patients enrolled in the Xyrem Success Program</i></p>	<ol style="list-style-type: none"> 1. patient > 16 years old 2. alternative diagnoses must have been excluded 3. for cataplexy, must have failed tricyclic or SSRIs 4. for excessive daytime sleepiness, must have 	<p>XYREM PI</p>

		<p>failed at least one formulary stimulant treatment (ex: methylphenidate or dextroamphetamine)</p> <p>5. initial approval for maximum of 1-month supply with subsequent renewals for maximum approval period of 3 months at a time (Patients are to be re-evaluated by physician no less frequently than every 3 months)</p>	
Zelboraf (vemurafenib)	Indicated for the treatment of unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test. (not recommended for use in patients with wild-type BRAF melanoma).	Rx by Oncologist or Dermatologist	ZELBORAF PI
Zemaira (alpha ₁ -proteinase inhibitor [human])	Indicated for chronic augmentation and maintenance therapy in patients with A ₁ -Proteinase I deficiency and clinical evidence of emphysema.	Rx by Pulmonologist	ZEMAIRA PI
Zoladex (goserelin)	<p><u>Indicated for:</u></p> <ol style="list-style-type: none"> 1. palliative treatment of advanced carcinoma of the prostate. 2. use in combination with flutamide for the management of locally confined stage T2b-T4 (Stage B2-C) carcinoma of the prostate. 3. management of endometriosis including pain relief and reduction of endometriotic lesions for the duration of therapy [women ≥18 years of age for 6 months of treatment]. 4. palliative treatment of advanced breast cancer in pre- and peri-menopausal women. 5. use as an agent to cause endometrial thinning agent prior to endometrial ablation for dysfunctional uterine bleeding. 	Rx by Oncologist	<p>ZOLADEX 3.6 mg PI</p> <p>ZOLADEX 10.8 mg PI</p>
Zontivity (vorapaxar)	Indicated for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction (MI) or with peripheral arterial disease (PAD). **** For use with aspirin and/or clopidogrel according to their indications or standard of care. There is limited clinical experience with other antiplatelet drugs or with ZONTIVITY as the only antiplatelet agent.	Rx by Cardiology, Neurology or Vascular Surgery	ZONTIVITY PI

Zydelig (idelalisib)	<u>Indicated for:</u> <ol style="list-style-type: none">1. treatment of patients with relapsed chronic lymphocytic leukemia (CLL), in combination with rituximab, in patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities.2. treatment of patients with relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies.3. treatment of patients with relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies.	Rx by Oncologist	ZYDELIG PI
--------------------------------	--	------------------	----------------------------