aetna[SM]

AETNA BETTER HEALTH® OF ILLINOIS Pharmacy Prior Authorization Non-Formulary and Prior Authorization Guidelines

Scroll down to see PA Criteria by drug class, or Ctrl+F to search document by drug name

Policy	Requirements	Duration of Approval if Requirements Are Met
Non-Formulary Medication Guideline	**Requests for Non-Formulary Medications that do not have specific Prior Authorization Guidelines will be reviewed based on the following:** • An appropriate diagnosis/indication for the requested medication, • An appropriate dose of medication based on age and indication, • Documented trial of at least 2 formulary agents for an adequate duration have not been effective or tolerated **OR** • All other formulary medications are contraindicated based on the patient's diagnosis, other medical conditions or other medication therapy, **OR** • There are no other medications available on the formulary to treat the patient's condition Aetna Medicaid determines patient medication trials and adherence by a review of pharmacy claims data over the preceding twelve months. Additional information may be requested on a case-by-case basis to allow for proper review.	**Initial Approval:** • Minimum of 3 months, depending on the diagnosis, to determine adherence, efficacy and patient safety monitoring **Renewal:** • Minimum of 6 months • Maintenance medications may be approved Indefinite
Medications requiring Prior Authorization	Requests for Medications requiring Prior Authorization (PA) will be reviewed based on the PA Guidelines/Criteria for that medication. Scroll down to view the PA Guidelines for specific medications. Medications that do not have a specific PA guideline will follow the Non-Formulary Medication Guideline. Additional information may be required on a case-by-case basis to allow for adequate review.	**As documented in the individual guideline**
Medications requiring Step Therapy	Medications that require Step Therapy (ST) require trial and failure of formulary agents prior to their authorization. If the prerequisite medications have been filled within the specified time frame, the prescription will automatically process at the pharmacy. Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy.	**Initial Approval:** • Indefinite
Brand Name Medication	Aetna Medicaid requires use of generic agents that are considered therapeutically equivalent	**Initial Approval:**

Policy	Requirements	Duration of Approval if Requirements Are Met
Requests	by the FDA. For authorization of a brand name medication, please submit a copy of the FDA MedWatch form detailing trial and failure of, or intolerance/adverse side effect to generic formulations made by 2 different manufacturers. The completed form should also be submitted to the FDA. The FDA MedWatch form is available at: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf	• Indefinite

Medication	Authorization Guidelines/Criteria	Duration of Approval
Acromegaly Agents[i] Last reviewed: 09/08/14 Cabergoline Octreotide Sandostatin LAR Somatuline Depot Somavert	**Cabergoline, octreotide:** • Patient must be at least 18 years of age • Documented diagnosis of acromegaly • Prescribed by or in consultation with an endocrinologist **Sandostatin LAR /Somatuline Depot:** • Patient must be at least 18 years of age • Documented diagnosis of acromegaly • Prescribed by or in consultation with an endocrinologist • Inadequate response to surgery, or surgical resection is not an option • Trial of, and positive response to octreotide immediate-release injection (for Sandostatin LAR only) • Baseline IGF-1 level above normal for age • If IGF-I levels < 2 times the upper limit of normal (ULN), then trial and failure of cabergoline x 6 months, or contraindication to cabergoline **Somavert:** • Patient must be at least 18 years of age • Documented diagnosis of acromegaly • Prescribed by or in consultation with an endocrinologist • Trial and failure of, or contraindication to Sandostatin LAR Depot or Somatuline Depot	**Initial Approval:** • 6 months **Renewal:** • Indefinite Requires decreased or normalized IGF-1 levels

Medication	Authorization Guidelines/Criteria	Duration of Approval
	• Documented baseline IGF-1 is above normal for age and normal baseline LFTs	
ADHD Medication Age Limits Last reviewed: 06/01/15 Amphetamine mixed salts IR/LA Daytrana Dextroamphetamine IR/LA methylin methylphenidate IR/CR/ER dexmethylphenidate IR/ER Vyvanse Methamphetamine	PA is required for members who are <6 years old and >18 years old. **Criteria for < 6 years old:** • Diagnosis of ADHD AND • Documentation stating that psychosocial issues and non-medical interventions are being addressed by the clinical team AND • The requested dose is NOT greater than FDA recommended maximum daily dosage **Patients who are >18 years old must have ONE of the following diagnoses:** • ADHD • Narcolepsy (for methylphenidate, amphetamine/dextroamphetamine, or dextroamphetamine) • Cancer-related fatigue (for methylphenidate) • Fatigue due MS (for methylphenidate) • Idiopathic hypersomnia (for methylphenidate, amphetamine/dextroamphetamine, or dextroamphetamine)	**Initial Approval:** 1 year **Renewal:** 1 year
Advair Last reviewed: 06/24/15	Advair Diskus will process for children 4-11 years old without PA. Prescriptions for patients outside of this age range will require a PA and documented failure or intolerance to Symbicort.	**Initial Approval:** Indefinite
Ampyra[ii] Last reviewed: 09/08/14	**For patients age 18 or older who meet all of the following criteria:** • Prescribed by, or in consultation with a neurologist • Patient is between 18 and 70 years old • Documented diagnosis of multiple sclerosis with impaired walking ability • Patient must not be wheelchair-bound • Baseline 25-ft walking test between 8 and 45 seconds • Patient must not have a history of seizures • Patient must not have moderate to severe renal impairment (Crcl < 50 ml/min) • Patient must be on disease modifying therapy for MS	**Initial Approval:** • 6 months **Renewal:** • 1 year Requires: At least 20% improvement in timed walking speeds on 25-ft walk within 4 weeks of starting medication

Medication	Authorization Guidelines/Criteria	Duration of Approval
Anticoagulants -Injectable[iii] Last reviewed: 04/01/15 Enoxaparin Fondaparinux Fragmin	**Extended courses (> 10 days of therapy) of enoxaparin and Fragmin are authorized for the following:** • DVT prophylaxis in patients undergoing hip or knee replacement or abdominal surgery • DVT/PE treatment in patients who are taking warfarin • Bridge therapy for perioperative warfarin discontinuation • Prophylaxis or treatment of thrombotic complications in a high risk pregnancy • Cancer patients with a high risk of thrombosis • Patients with restricted mobility during acute illness **For all other acceptable indications not listed above:** • Upon receipt of documentation to support the following: o The requested drug is medically necessary over formulary anticoagulants or warfarin due to a medical condition, contraindication/intolerance, or previous failure AND o There are no contraindications to therapy with the requested agent **Extended courses (>21 days of therapy) of Fondaparinux will be authorized if the following criteria are met:** • Prescribed for one of the following indications: o DVT prophylaxis in patients undergoing hip or knee replacement or abdominal surgery o DVT/PE treatment in conjunction with warfarin • Patient had therapeutic failure or intolerance to enoxaparin and Fragmin OR • Patient has contraindication to enoxaparin and Fragmin (i.e., allergic to pork, history of heparin induced thrombocytopenia)	**Initial Approval**: **DVT/PE prophylaxis (post orthopedic surgery)** • Up to 35days **DVT/PE prophylaxis (abdominal surgery); DVT/PE treatment, bridge therapy, acute illness** • 10 days or as requested **Thrombosis prophylaxis during pregnancy** • Until 6 weeks after delivery (EDC required for authorization) **Thrombosis prophylaxis in cancer patients** • 3-6 months or as requested **Contraindication/intolerance or therapeutic failure of warfarin, enoxaparin, and Fragmin** • Indefinite **Renewal:** Length of renewal authorization based on anticipated length of therapy, indication and/or recent INR if on warfarin
Anticoagulants - Oral Last reviewed: 06/01/15	Prescriptions for Eliquis and Xarelto will automatically process for up to a 45 day duration to prevent delays in therapy. A PA will be required for prescriptions filled after the initial 45 days.	**Initial Approval:** **Atrial fibrillation**

Medication	Authorization Guidelines/Criteria	Duration of Approval
Eliquis Pradaxa Xarelto	Eliquis and Xarelto may be approved for patients who are at least 18 years old for the treatment of non-valvular atrial fibrillation, DVT, and PE. Patients do NOT need a trial of warfarin. • **Pradaxa can be approved when the following are met:** o Treatment of non-valvular atrial fibrillation o Failure of, or contraindication/intolerance to warfarin (e.g. inability to achieve therapeutic INR on warfarin, concern of drug interaction with warfarin) o Prescriber preference based on RE-LY [*Randomized Evaluation of Long-term Anticoagulant Therapy*] clinical trial outcome showing lower risk of strokes and systemic embolism with Pradaxa versus warfarin.	• Indefinite **Tx of VTE (not prophy)** • 6 months **Knee replacement surgery** • Up to 12 days (does not require PA unless >45 days) **Hip replacement surgery** Up to 35 days (does not require PA unless >45 days)
Antidepressants[iv] Last reviewed: 06/15/15 Pristiq (SNRI) Brintellix (SSRI) Viibryd (SSRI) Fetzima (SNRI)	**Non-formulary antidepressants can be authorized for patients >18 years old who meet ANY of the following criteria:** • Patients with treatment resistant depression: o Documented failure or intolerance to THREE formulary agents from at least 2 different classes of antidepressants (SSRI, SNRI, bupropion, or mirtazapine) at an adequate dose and duration (at least 4 weeks). o One of these trials must be with a preferred formulary agent from the same class (SSRI or SNRI) • Patients who are currently stable on the requested non-formulary antidepressant: o Provider feels that changing to a formulary medication would incur unacceptable risk of destabilization.	**Initial approval:** Indefinite
ARBs[v] Last reviewed: 07/22/15 Benicar Edarbi Eprosartan	**Non-preferred ARBs** can be approved for members who have failed THREE formulary preferred ARBs AND meet ONE of the following: 1. Treatment of HTN with chronic kidney disease (CKD); **OR** 2. Treatment of HTN without CKD for patients who have failed a trial with a formulary agent from another class that is considered a first-line treatment per JNC8 (i.e., thiazide-type diuretic, calcium channel blocker, angiotensin-converting enzyme	**Initial Approval:** Indefinite

Medication	Authorization Guidelines/Criteria	Duration of Approval
Telmisartan	inhibitor) or require combination therapy to achieve BP goal **Preferred ARBs include:** • Losartan (or losartan/HCTZ) • Irbesartan (or irbesartan/HCTZ) • Candesartan (or candesartan/HCTZ) • Valsartan (or valsartan/HCTZ, valsartan/amlodipine, or valsartan/amlodipine/HCTZ)	
Atypical Antipsychotics less than 8 years old Last reviewed: 10/31/14 Risperidone Quetiapine Seroquel XR Clozapine Olanzapine Saphris Latuda Fanapt Ziprasidone Paliperidone Aripiprazole	1)The drug must be prescribed by a psychiatrist or neurologist or the prescriber must supply proof of a psychiatric consultation AND, 2) The recipient must have an appropriate diagnosis, as listed below: • Organic Psychiatric Conditions • Schizophrenic Disorders • Affective Psychoses (bipolar disorders) • Psychoses • Autism Spectrum Disorders • Tourette's • Reactive Adjustment Disorders • Other applicable behavioral diagnoses AND, 3) Written, informed consent for the medication must be obtained from the parent or guardian AND, 4) Formulary atypical antipsychotics must be tried prior to authorization of non-formulary agents. Risperidone ODT requires ST therapy with risperidone tablets first. Ziprasidone requires ST therapy with both risperidone and quetiapine.	Initial approval: 6 months Renewal: 6 months
Atypical Antipsychotics 8-17 years old Last reviewed: 10/31/14	1) An appropriate indication/diagnosis for the medication based on FDA approval, nationally established/recognized guidelines, peer-reviewed medical literature or clinical studies AND,	Initial approval: 6 months Renewal: 1 year

Medication	Authorization Guidelines/Criteria	Duration of Approval
Risperidone Quetiapine Seroquel XR Clozapine Olanzapine Saphris Latuda Fanapt Ziprasidone Paliperidone Aripiprazole	2) Age of member is within FDA-approved age limits for medication prescribed or based on nationally established/recognized guidelines, peer-reviewed medical literature or clinical studies, AND, 3) Dose is appropriate for age and indication based on FDA approval, nationally established/recognized guidelines, peer-reviewed medical literature or clinical studies AND, 4) Written, informed consent for the medication must be obtained from the parent or guardian AND, 5) Formulary antipsychotics must be tried prior to authorization of non-formulary agents. Covered for psychiatrists and neurologists Risperidone ODT requires ST therapy with risperidone tablets first. Ziprasidone requires ST therapy with both risperidone and quetiapine.	

Long-Acting Injectable Atypical Antipsychotics[vi]
Last reviewed: 6/1/15
 	
Invega Sustenna
Invega Trinza
Risperdal Consta
Abilify Maintena
Zyprexa Relprevv
	Invega Sustenna, Invega Trinza, and Risperdal Consta are the formulary preferred agents and are also available without prior authorization for members residing in LTC facilities. Non-preferred agents require trial and failure of preferred agents.
	
	Approval is authorized when the following criteria are met:
	• Patient is at least 18 years of age
	• Prescribed by or in consultation with a psychiatrist
	• Have received the recommended oral dosage (per FDA approved labeling) to confirm tolerability and efficacy prior to receiving the long-acting injectable medication
	• Will not receive concomitant oral antipsychotics after the initial overlap period (per FDA approved labeling)
	• Are not taking a CYP3A4 inducer (Abilify only)
	• Have an FDA approved indication:
	  ○ Invega Sustenna/Trinza: schizophrenia or schizoaffective disorder
	  ○ Risperdal Consta: schizophrenia or bipolar I
	  ○ Abilify Maintena: schizophrenia
	  ○ Zyprexa Relprevv: schizophrenia
	• Non-adherence to oral antipsychotic medications which places the patient at risk for
		Approval Duration:
		Indefinite

Medication	Authorization Guidelines/Criteria	Duration of Approval
	poor outcomes • For Invega Trinza only: patient must be stable on the same dose of Invega Sustenna for 4 consecutive months	

Botulinum Toxins[vii]
Last reviewed: 09/08/14
 	
Botox
Myobloc
Dysport
Xeomin
	For Patients who meet the following:
	• Medically accepted use (Not covered when used for cosmetic purposes)
	• Prescribed by an appropriate specialist based on indication
	• FDA-approved indication for the requested agent (or other indication with supporting peer-reviewed medical literature)
	• Additional criteria based on diagnosis:
	  • Cervical dystonia *(Botox, Dysport, Myobloc, Xeomin)*
	  o Documented diagnosis
	  o Age restriction: must be at least 16 years of age
	  • Blepharospasm *(Botox, Dysport, Xeomin)*
	  o Documented diagnosis
	  o For Xeomin: patient must be previously treated with onabotulinumtoxinA (Botox)
	  o Age restriction: must be at least 16 years of age
	  • Strabismus *(Botox, Dysport)*
	  o Documented diagnosis
	  o Age restriction: must be at least 12 years of age
	  • Upper or lower limb spasticity *(Botox, Dysport)*
	  o Trial and failure of at least 2 formulary muscle relaxants, including baclofen and tizanidine
	  o Age restriction: must be at least 18 years old
	  • Severe primary axillary hyperhidrosis *(Botox, Dysport)*
	  o Medical complications from hyperhidrosis are present such as skin maceration with secondary skin infections
	  o Trial and failure of a 2 month trial of topical aluminum chloride 20%
	  o Age restriction: must be at least 18 years old
		Initial Approval:
		1 treatment/12 weeks x 1 yr
		
		Renewal:
		1 treatment/12 weeks x 1 yr

Medication	Authorization Guidelines/Criteria	Duration of Approval
	○ Migraine Prophylaxis *(Botox)* ○ Documented frequency of more than 15 migraine headaches in a 30-day period with each headache lasting 4 hours or longer **and** ○ Documented failure or intolerance to 2 different classes of formulary medications used for migraine prophylaxis: beta-blocker (propranolol, metoprolol, timolol, atenolol, nadolol), anticonvulsant (divalproex, valproate, topiramate), antidepressants (amitriptyline, venlafaxine) ○ Age restriction: must be at least 18 years old • Neurogenic bladder *(Botox)* ○ Trial and failure of 2 first-line agents, such as oxybutynin and trospium ○ Age restriction: must be at least 18 years old • Sialorrhea (excessive drooling) associated with neurological disorders (i.e., Parkinson's disease, amyotrophic lateral sclerosis, cerebral palsy) *(Botox, Myobloc)* ○ Trial and failure of glycopyrrolate and benztropine ○ Age restriction: must be at least 4 years old • Hemifacial spasm *(Botox, Dysport)* ○ Trial and failure of 2 formulary muscle relaxants such as baclofen and tizanidine ○ Age restriction: must be at least 18 years old • Achalasia *(Botox)* ○ Documented diagnosis ○ Age restriction: must be at least 18 years old • Chronic anal fissures *(Botox)* ○ Trial and failure of conservative therapy (e.g., nitroglycerin ointment, topical diltiazem cream) ○ Age restriction: must be at least 18 years old • Cerebral palsy with chronic focal spasticity and equinus gait (tiptoeing) *(Botox, Dysport)* ○ Documented diagnosis ○ Age restriction: pediatric patient (2-18 years of age)	

Medication	Authorization Guidelines/Criteria	Duration of Approval
	Note: Additional information may be required on a case-by-case basis to allow for adequate review	
Cambia[viii] Last reviewed: 09/08/14	**For patients who meet the following:** • Patient has a diagnosis of migraine headaches • Patient is 18 years of age or older • Patient must also be taking oral daily prevention medication • Patient has tried and failed at least 2 formulary triptans (e.g., sumatriptan, Relpax) • Patient is not taking Cambia chronically everyday • Limit of 9 packets (1 box per month)	**Initial Approval:** Indefinite
Celecoxib [ix] Last reviewed: 09/08/14	**For patients who meet the following:** • Trial and failure of 2 formulary NSAIDs OR • If member is at a high-risk for adverse GI events (e.g., 65 years of age, or older, history of GI bleed, PUD, GERD, or gastritis, or concomitant corticosteroid or anticoagulant use) AND • Requested dose does not exceed FDA recommended maximum for indication o OA, JRA = 200 mg/day o RA, acute moderate pain, dysmenorrhea, moderate to severe pain associated with orthopedic surgery, ankylosing spondylitis = 400 mg/day • Age restriction (juvenile rheumatoid arthritis): must be at least 2 years old and weigh at least 55 lbs. (25 kg) • Age restriction (all other indications): must be at least 18 years old	**Initial Approval:** Indefinite
Cimzia[x] Last reviewed: 04/01/15	**For patients who meet all of the following:** • Prescribed by, or in consultation with a rheumatologist, dermatologist, or gastroenterologist (based on indication) • Not concurrently receiving live vaccines, other TNF-inhibitors or Kineret • 18 years of age, or older **In addition, for treatment of active ankylosing spondylitis:** • Failure of, or contraindication/intolerance to all of the following:	**Initial Approval:** Indefinite

Medication	Authorization Guidelines/Criteria	Duration of Approval
	○ Failure of a compliant regimen of two different NSAIDs (or contraindication or intolerance to NSAIDs) ○ Failure of at least 2 of the following: Enbrel, Humira or Remicade for three consecutive months (or contraindication or intolerance to Enbrel, Humira, and Remicade) **In addition, for treatment of moderate to severe active Crohn's disease:** • Failure of, or contraindication/intolerance to all of the following: ○ Oral or IV corticosteroids for one month ○ Azathioprine OR mercaptopurine for three consecutive months ○ Parenteral methotrexate for three consecutive months ○ Humira and Remicade for three consecutive months **In addition, for treatment of active psoriatic arthritis:** • Failure of, or contraindication/intolerance to all of the following: ○ Methotrexate for at least three months ○ At least 2 of the following: Enbrel, Humira, or Remicade for three months **In addition, for treatment of moderate to severe rheumatoid arthritis:** • Failure of, or contraindication/intolerance to all of the following: ○ Methotrexate AND at least 1 other oral DMARD (sulfasalazine, hydroxychloroquine or leflunomide) for at least 3 months (in combination or each as monotherapy) • At least 2 of the following: Enbrel, Humira, or Remicade for three consecutive months	
Colony-Stimulating Factors (CSF)[xi] Last reviewed: 08/14/14 Neupogen Neulasta Neumega Leukine	**For Patients who meet the following:** • Prescribed for a medically accepted indication/diagnosis • Prescribed by hematologist and/or oncologist, or other specialist per associated diagnosis/indication **In addition, for Neupogen:** • Chemotherapy-induced neutropenia ○ Chemotherapy regimen has approximately ≥ 20% risk of febrile neutropenia OR	**Initial Approval:** **Neupogen** • 14 day course per chemotherapy cycle • Refills if indicated **Neulasta** • 1 dose per 21 days • Refills as indicated

Medication	Authorization Guidelines/Criteria	Duration of Approval
	○ Member is at high-risk for neutropenic complications (e.g., age > 65, pre-existing neutropenia or tumor involvement in the bone marrow, infection, renal or liver impairment, other serious co-morbidities) ○ Administered 24 – 72 hours after completion of chemotherapy ○ Patient is not receiving concurrent chemotherapy and radiation therapy • <u>Treatment of neutropenia</u> ○ Severe chronic congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia ○ HIV-induced or drug-induced neutropenia in immunosuppressed patients ▪ Patient has evidence of inadequate bone marrow reserve (e.g., recurrent fevers, splenomegaly, mucosal ulcers, abdominal pain) OR ▪ Patient is at high risk for the development of serious bacterial infection (e.g., primarily severe neutropenia, indwelling venous catheters, prior serious infections) OR ▪ Patient has a documented bacterial infection ○ Myeloid reconstitution after autologous or allogenic or autologous bone marrow transplant ▪ Patient has a non-myeloid malignancy ○ Following reinfusion of peripheral blood stem cells (PBSCs) • <u>Peripheral blood stem cell (PBSC) mobilization</u> ○ Prior to and during leukapheresis in cancer patients preparing to undergo bone marrow ablation **In addition, for Neulasta:** • <u>Chemotherapy-induced neutropenia</u> ○ Chemotherapy regimen has approximately ≥ 20% risk of febrile neutropenia OR ○ Member is at high-risk for neutropenic complications (e.g., age > 65, pre-existing neutropenia or tumor involvement in the bone marrow, infection, renal or liver impairment, other serious co-morbidities) ○ Chemotherapy cycle is at least 14 days	**Neumega** • Up to 21 days' supply • Refills if number of cycles provided **Leukine** • AML, bone marrow transplant: up to 42 days • All other indications: 30 days **<u>Renewal:</u>** • Recent ANC (or platelet count for Neumega) • Approval up to 1 year (depending on indication)

Medication	Authorization Guidelines/Criteria	Duration of Approval
	○ Neulasta will NOT be administered in the following situations: ▪ In the period between 14 days before and 24 hours after completion of chemotherapy ▪ Concurrently with radiation therapy ▪ Concurrently with mitomycin C ▪ Concurrently with antimetabloites (e.g., 5-FU, cytarabine) ▪ Concurrently with agents that have a delayed myelosuppressive effect (e.g., nitrosureas) **In addition for Neumega:** • Chemotherapy-induced thrombocytopenia ○ Patient is at least 12 years old ○ Patient has a non-myeloid malignancy ○ Patient is at high risk of severe thrombocytopenia or has experienced severe thrombocytopenia with a previous chemotherapy cycle ○ Patient is receiving myelosuppressive chemotherapy ○ Not being used in the following situations: ▪ After myeloablative therapy ▪ Chemotherapy regimen longer than 5 days ▪ Concurrently with agents associated with delayed myelosuppression (e.g., nitrosoureas, mitomycin C) ▪ Patients with myeloid malignancy (e.g., leukemia, multiple myeloma) ○ Administered 6 – 24 hours after the completion of chemotherapy **In addition, for Leukine:** • Chemotherapy-induced neutropenia ○ AML ▪ Patient must be at least 55 years old ▪ Bone marrow is hypoplastic with < 5% blasts *(contraindicated in patients with excessive leukemic blasts (≥ 10%) in the bone marrow or peripheral blood)* ▪ Administered on day 11 (or 4 days after the completion) of induction therapy	

Medication	Authorization Guidelines/Criteria	Duration of Approval
	○ All other malignancies ▪ Administered at least 24 hours after the completion of chemotherapy • Treatment of neutropenia ○ Bone marrow transplant failure or engraftment delay ○ Myeloid reconstitution after allogenic or autologous bone marrow transplant ▪ Patient has Hodgkin's disease, non-Hodgkin's lymphoma, or acute lymphocytic leukemia ○ Before and after peripheral blood stem cell transplantation ○ Following reinfusion of peripheral blood stem cells (PBSCs) ○ HIV-induced or drug-induced neutropenia in immunosuppressed patients ▪ Patient has evidence of inadequate bone marrow reserve (e.g., recurrent fevers, splenomegaly, mucosal ulcers, abdominal pain) OR ▪ Patient is at high risk for the development of serious bacterial infection (e.g., primarily severe neutropenia, indwelling venous catheters, prior serious infections) OR ▪ Patient has a documented bacterial infection • Peripheral blood stem cell (PBSC) mobilization ○ Prior to and during leukapheresis in cancer patients preparing to undergo bone marrow ablation • Patient is not a neonate • Patient is not receiving concurrent chemotherapy and radiation CSFs for non-FDA approved indications require medical literature/clinical studies from peer-reviewed journals with safety, efficacy and dosing information for the intended use.	
Cystic Fibrosis (pulmonary) Medications[xii] Last reviewed: 4/22/15 Pulmozyme Tobramycin inh Tobi Podhaler	**Pulmozyme:** • Age >/= 5 years (Per label: Pulmozyme was studied in patients 3 months to 5 years of age; while clinical trial data are limited in patients <5 years, the use of Pulmozyme should be considered for pediatric patients with CF who may experience potential benefit in pulmonary function or who may be at risk of respiratory tract infection. • Diagnosis of moderate to severe cystic fibrosis **OR**	**Initial Approval:** Orkambi: 3 months All others: Indefinite **Renewal:** 6 months

Medication	Authorization Guidelines/Criteria	Duration of Approval
Bethkis Cayston Kalydeco Orkambi	• Diagnosis of mild cystic fibrosis after failure of inhaled hypertonic saline **Tobramycin inhalation solution (generic for Tobi):** • Diagnosis of cystic fibrosis • Age >/= 6 years • FEV_1 between 25-80% predicted • Sputum cultures positive for *P.aeruginosa* • NOT colonized with *Burkholderia cepacia* **Tobi Podhaler or Bethkis:** • Must meet criteria listed above for tobramycin inhalation solution, **PLUS** patient must have contraindication/intolerance to or failure of tobramycin nebulizer solution (generic) **Cayston will be authorized for patients that meet the following:** • Diagnosis of cystic fibrosis • Age >/= 7 years • FEV_1 between 25-75% predicted • Sputum cultures positive for *P.aeruginosa* • NOT colonized with *Burkholderia cepacia* • Contraindication/intolerance to tobramycin **Kalydeco can be recommended for approval for patients who meet the following:** • Diagnosis of cystic fibrosis with one of the following *CFTR* gene mutations: *G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, or R117H* • NOT homozygous for the *F508del* mutation in the *CFTR* gene • Prescribed by a pulmonologist • Age >/=2 years • Note: all reviews must be sent to MDR for final decision **Orkambi can be recommended for approval for patients who meet the following:**	(requires documentation to support response to therapy including current lab results to support normal ALT/AST and bilirubin levels)

Medication	Authorization Guidelines/Criteria	Duration of Approval
	• Prescribed by a pulmonologist • Member is at least 12 years old • Diagnosis of Cystic Fibrosis and lab results to support homozygous F508Del at the CFTR gene. (If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the *F508del* mutation on both alleles of the *CFTR* gene) • Liver function tests and bilirubin are within normal limits • Patient is NOT taking a strong CYP3A inducer such as rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John's wort • NOTE: Patients should be on other CF agents to manage and control symptoms (i.e., dornase alpha, tobramycin, hypertonic saline, or Cayston) • Note: all reviews must be sent to MDR for final decision	

Daraprim[xiii]
Last reviewed: 09/25/2015
	Daraprim may be authorized for the treatment and secondary prevention of Toxoplasmosis in patients with HIV.
	• Dose for initial treatment of Toxoplasmosis is 50-75mg per day for 6 weeks
	• Dose for secondary prophylaxis after completing initial 6-week treatment is 25-50mg per day to prevent relapse.
	• Secondary prophylaxis may be discontinued when the following apply:
	  ○ Patient is asymptomatic
	  ○ Patient is receiving antiretroviral therapy (ART)
	  ○ Patient has a suppressed HIV viral load
	  ○ Patient has maintained a CD4 count >200 cells/microL for at least six months
	• Maintenance therapy may be reinitiated if the CD4 cell count declines to <200 cells/microL
	
	Daraprim may also be authorized for Pneumocystis Pneumonia (PCP) when the following criteria are met:
	• Patient is allergic to sulfa or has another contraindication to TMP/SMX use
	• For PCP prophylaxis in patients with HIV:
	  ○ Patient has ONE of the following:
	  ▪ CD4 count <200 cells/microL
		<u>Initial Approval:</u>
		Acute Toxoplasmosis:
		• 6 weeks
		
		Acute PCP:
		• 21 days
		
		PCP prophylaxis:
		• 3 months
		
		<u>Renewals:</u>
		Secondary Prophylaxis after Acute Toxoplasmosis treatment:
		• 6 months
		
		PCP prophylaxis:
		• 3 months
		• If CD4 count is <200 or

Medication	Authorization Guidelines/Criteria	Duration of Approval
	▪ Oropharyngeal candidiasis ▪ CD4 count percentage <14 percent ▪ CD4 cell count between 200 and 250 cells/microL when frequent monitoring (eg, every three months) of CD4 cell counts is not possible ○ Patient has a trial and failure or contraindication to atovaquone AND dapsone • **For PCP treatment:** ○ **Patient is diagnosed PCP infection** ○ Patient has a trial and failure or contraindication to atovaquone **Daraprim is not covered for treatment or prevention of malaria:** • Daraprim is no longer recommended for malaria treatment or prophylaxis. • Treatment of malaria is VERY individualized. • Refer to the CDC website for recommendations for acute treatment of malaria. ○ http://www.cdc.gov/malaria/resources/pdf/algorithm.pdf ○ http://www.cdc.gov/malaria/diagnosis_treatment/treatment.html http://www.cdc.gov/malaria/resources/pdf/treatmenttable.pdf. • Refer to the CDC website for recommendations for prevention of malaria ○ http://www.cdc.gov/malaria/travelers/country_table/a.html	CD4 count % is <14%
Daliresp[xiv] Last reviewed: 06/15/15	**For patients who meet all of the following:** • Adult 40 years of age or older • Prescribed by or in consultation with a pulmonologist • Diagnosis of severe COPD with chronic bronchitis with FEV1<50% predicted based on post-bronchodilator FEV1 • Documented symptomatic exacerbations within the last year while compliant with dual long-acting bronchodilator treatment [long-acting beta-agonist (LABA) plus long-acting muscarinic antagonist (LAMA)] for at least 3 months • Daliresp will be used in conjunction with a LABA and LAMA unless contraindicated/intolerant • Will not be used in combination with theophylline	**Initial Approval:** 6 months **Renewals:** Indefinite; requires improvement in the number of COPD exacerbations
Non-Formulary Diabetic Supplies	**Diabetic Test Strip and Glucometer Quantity Limits:** • All diabetic test strips are limited to 150ct/30 days	**Initial Approval:**

Medication	Authorization Guidelines/Criteria	Duration of Approval

Last reviewed: 05/01/15	• Glucometers are limited to 1 glucometer/12 months
	
	Criteria to Receive Non-Formulary Diabetic Supplies
	• Member with hematocrit level that is chronically less than 30% or greater than 55%
	  ○ Accu-Chek Aviva Plus and Nano SmartView are accurate for Hct 10-65%
	  ○ One Touch Verio IQ is accurate for Hct 20-60%
	• Member with physical limitation (manual dexterity or visual impairment) that limits utilization of formulary product
	• Member with an insulin pump that requires a specific test strip
	
	Criteria to Receive >150 Test Strips Per Month
	• Members newly diagnosed with diabetes or with gestational diabetes
	• Children with diabetes (age ≤ 12)
	• Members on insulin pump
	• Members on high intensity insulin therapy with documentation of need to routinely test more than 4-5 times daily
	
	Criteria to Receive >1 Glucometer Per Year
	• Current glucometer is unsafe, inaccurate, or no longer appropriate based on patients medical condition
	• Current glucometer no longer functions properly, has been damaged, or was lost or stolen.
		1 year

Direct Renin Inhibitors[xv]
Last reviewed: 06/15/15
Tekturna
Tekturna HCT
Tekamlo
Amturnide
	For patients that meet the following:
	• Treatment of HTN
	• At least 18 years old
	• Inadequate response or inability to tolerate a trial of a formulary ARB and ACE inhibitor and at least one other formulary antihypertensive agent from a different class:
	  ○ Thiazide-type diuretic
	  ○ Calcium channel blocker
	  ○ Beta-blocker
		Initial Approval:
		Indefinite

Medication	Authorization Guidelines/Criteria	Duration of Approval
	• Will not be used in combination with an ACE inhibitor or an ARB Note: The long-term benefit on major cardiovascular or renal outcomes with direct renin inhibitors in the treatment of HTN has not been established, therefore it is recommended to use medications from other classes first.	

Duavee[xvi]
Last reviewed: 4/22/15
	Duavee can be approved for adult women who have an intact uterus and who meet ONE of the following:
	• Treatment of vasomotor symptoms associated with menopause (VMS):
	  ○ Patient has failed or has an intolerance to at least 2 formulary estrogen/progestin products (e.g., estradiol tablets/patch, Prempro, Estrace)
	• Prevention of postmenopausal osteoporosis:
	  ○ Patient is at significant risk of osteoporosis
	  ○ Patient has tried and failed (or has contraindication/intolerance to) raloxifene and alendronate (non-estrogen medication is preferred)
		Initial Approval:
		
		5 years

Topical Calcineurin Inhibitors[i]
Last reviewed: 09/22/2015
 	
Elidel
Tacrolimus
	Elidel and tacrolimus are covered for patients between 2 and 10 years of age.
	For other age groups, Elidel and tacrolimus require step therapy with topical corticosteroids.
	• If patient has filled 2 topical corticosteroids in the last 60 days, the prescription will automatically process at the pharmacy.
	• **Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy.** In those cases, Elidel and tacrolimus will be reviewed for the treatment of eczema or atopic dermatitis based upon the affected area being treated:
	  ○ Body/extremities – authorized after trial and failure or intolerance to at least 2 different formulary topical corticosteroids.
	  ○ Face – authorized after trial and failure of one formulary low-potency topical corticosteroid
	  ○ Eyelid or other sensitive area – authorized without trial and failure of topical corticosteroids
		Initial Approval:
		Indefinite

Emend[xvii] Last reviewed: 04/07/2015	**For patients who meet the following:** • Diagnosis of post-operative nausea/vomiting OR nausea related to cancer • Failure or contraindication/intolerance to formulary selective serotonin-receptor (5-HT3)	**Initial Approval:** **Oncology diagnosis:** 3 months **Post-op N/V:** 1, 40 mg dose

Medication	Authorization Guidelines/Criteria	Duration of Approval
	antagonists: ondansetron and granisetron	**Renewal:** **Oncology diagnosis:** 3 months
Enbrel/Humira/ Cosyntyx[xviii] Last reviewed: 09/08/14	**For patients who meet the following:** • Prescribed by, or in consultation with a specialist, based on indication (rheumatologist, dermatologist, gastroenterologist) • Additional criteria based on the diagnosis (unless contraindications are documented): ○ Ankylosing Spondylitis (Enbrel or Humira): ▪ Trial and failure of 2 different NSAIDs within the last 60-days ▪ Age restriction: must be at least 18 years old ○ Plaque Psoriasis [Enbrel or Humira]: ▪ Trial and failure of UVB or PUVA therapy or contraindication to therapy ▪ Trial and failure of methotrexate for at least 3 consecutive months or contraindication/intolerance to methotrexate ○ Psoriatic Arthritis: ▪ Trial and failure of methotrexate for at least 3 months ▪ Age restriction: must be at least 18 years old ○ Rheumatoid Arthritis (Adults): ▪ Trial and failure of methotrexate and at least 1 other oral DMARD (sulfasalazine, hydroxychloroquine or leflunomide) as sequential monotherapy for 3 months each or in combination for at least 3 months (or contraindication/intolerance to methotrexate and other DMARDs) ○ JIA (age ≥ 2 years for Enbrel, ≥ 4 years for Humira): ▪ Trial and failure of at least 3 consecutive months of methotrexate or contraindication/intolerance to methotrexate ○ Crohn's Disease (Humira only): ▪ Trial and failure of oral or intravenous corticosteroids for at least one month or contraindication/intolerance to corticosteroids ▪ Trial and failure of azathioprine or mercaptopurine for 3 months or contraindication ▪ Trial and failure of parenteral methotrexate for 3 months or contraindication/intolerance to methotrexate	**Initial Approval:** **Plaque psoriasis:** • Enbrel 50mg twice weekly : 3 months • Humira or Cosentyx: indefinite **Ulcerative Colitis (Humira):** • 3 months (discontinue Humira if remission is not seen by week 8) **Other indications:** • Indefinite **Renewal:** • Indefinite Requires a response to therapy. Enbrel dose for plaque psoriasis should be reduced to 50mg per week after the initial 3 month approval.

Medication	Authorization Guidelines/Criteria	Duration of Approval
	OR ▪ Trial and failure of Remicade ▪ Age restriction: must be at least 6 years old ○ Ulcerative Colitis (Humira only): ▪ Trial and failure of oral or rectal aminosalicylates (e.g., mesalamine, sulfasalazine) for 2 consecutive months or contraindication/intolerance to aminosalicylates ▪ Trial and failure of oral or intravenous corticosteroids for at least one month ▪ Trial and failure of azathioprine or mercaptopurine for 3 months or contraindication/intolerance to azathioprine and mercaptopurine ▪ Age restriction: must be at least 18 years old Note: Additional information may be required on a case-by-case basis to allow for adequate review	
Entyvio[xix] Last reviewed: 4/22/15	**For patients that meet all of the following:** • At least 18 years old • Prescribed by, or in consultation with a gastroenterologist • Recommended immunizations are current before initiating treatment **In addition, for moderate to severe active Crohn's disease:** • Patient has tried and failed corticosteroids (oral or IV) for 1 month • Patient has failed a 3-consecutive month trial of azathioprine or mercaptopurine • Patient has failed a 3-consecutive month trial of Humira or Remicade ○ If patient has contraindication/intolerance to any of these medications, that requirement will be waived **In addition, for moderate to severe active ulcerative colitis:** • Patient has failed a 2-consecutive month trial of oral or rectal aminosalicylates (i.e., mesalamine, sulfasalazine) • Patient has failed a one month trial and failure of corticosteroids (oral or IV) • Patient has failed a 3-consecutive month trial of azathioprine or mercaptopurine	**Initial Approval:** 4 months **Renewal:** 1 year Requires: Response to treatment

Medication	Authorization Guidelines/Criteria	Duration of Approval
	• Patient has failed a 2-consecutive month trial and failure of Humira or Remicade ○ If patient has contraindication/intolerance to any of these medications, that requirement will be waived	
Erythropoiesis-Stimulating Agents[xx] Last reviewed: 09/08/14 Epogen Procrit Aranesp **(Detailed Document)**	**For all indications and agents:** • Iron studies showing member has adequate iron stores to support erythropoiesis (e.g., ferritin >100, transferrin saturation >20%) • Age restriction: Safety and efficacy in neonates has not been established. **Anemia Due to CKD** *(Epogen, Procrit, Aranesp)* • Hemoglobin < 10 g/dL within the last 2 weeks **Anemia Due to Peg-Interferon and Ribavirin Treatment for Hepatitis C** *(Epogen, Procrit, Aranesp)* • Recent (within the last 2 weeks) hemoglobin 8.5-10 g/dL (if hemoglobin < 8.5, hep C treatment should be discontinued) AND • Member was unresponsive to ribavirin dosage reduction OR • Member has HIV co-infection, cirrhosis, or liver transplant **Reduction of Allogeneic Red Blood Cell Transfusions in Patients Undergoing Elective, Noncardiac, Nonvascular Surgery** (*Epogen, Procrit)* • Patient will be undergoing elective, noncardiac, nonvascular surgery • Hemoglobin level >10 and < 13 g/dL within 30 days prior to the planned surgery date **Anemia Due to Zidovudine in HIV-infected Patients** *(Epogen, Procrit)* • Patient is receiving treatment with zidovudine at a dose < 4200 mg/week • Patient meets both of the following: ○ Endogenous erythropoietin levels < 500 mUnits/mL.	**<u>Initial Approval:</u>** **CKD on dialysis (not enrolled with Medicare Part B):** • 4 months to allow time for enrollment with Medicare Part B for dialysis coverage **Reduction of perioperative RBC infusion:** • Up to 21 days of therapy per surgery **Anemia Due to Pegylated Interferon and Ribavirin Treatment for Hepatitis C** • 1 month **All other indications:** • 3 months **<u>Renewal:</u>** • 1 month (for HCV) • 3 months (for all others) Requires 1. Hb < 11 g/dL within the last 2 weeks 2. Follow up iron studies

Medication	Authorization Guidelines/Criteria	Duration of Approval
	○ Hemoglobin < 10 g/dL within the last two weeks **Anemia associated with myelodysplastic syndrome** *(Epogen, Procrit)* • Patient meets all of the following: ○ Hemoglobin < 10 g/dL within 2 weeks prior to initiating therapy ○ Recent erythropoietin level < 500 mU/mL **Anemia due to Chemotherapy in Patients with Cancer** *(Epogen, Procrit, Aranesp)* • Patient is currently receiving chemotherapy • Patient meets all of the following: ○ Hemoglobin < 10 g/dL within the 2 weeks prior to starting therapy ○ Documentation to support anemia is due to concomitant myelosuppressive chemotherapy ○ Diagnosis of non-myeloid malignancy (e.g., solid tumor) ○ Patient has a minimum of 2 additional months of planned chemotherapy upon initiation of therapy Additional information may be required on a case-by-case basis to allow for adequate review.	showing member has adequate iron to support erythropoiesis
Forteo Last reviewed: 09/08/14	**For patients who meet all of the following:** • Adult > 18 years of age • **Black box warning** – due to the potential risk of osteosarcoma, Forteo should not be used in patients at increased baseline risk for osteosarcoma (e.g., Paget's disease of bone or unexplained elevations of alkaline phosphatase, open epiphyses, or prior external beam or implant radiation therapy involving the skeleton). Forteo should only be prescribed for patients whom potential benefits outweigh potential risk. **For the treatment of osteoporosis in men and women who meet the following criteria:** • Intolerance or contraindication to at least one formulary oral bisphosphonate (e.g., alendronate) OR	**Initial Approval:** **Osteoporosis** • 2 years **Hypoparathyroidism** • 3 months **Renewal:** • 1 year Requires PTH level (hypoparathyroidism)

Medication	Authorization Guidelines/Criteria	Duration of Approval

	• Documented failure of consecutive 6 month regimen of formulary oral bisphosphonate:
	  ○ Decrease in T-score in comparison with baseline T-score from DEXA scan
	  OR
	  ○ New fracture
	
	Treatment of corticosteroid-induced osteoporosis for those who meet one of the following criteria:
	• Baseline T-score ≤ -1.0
	  OR
	• Documented failure of consecutive 6 month regimen of at least one formulary bisphosphonate or intolerance/contraindication to at least one formulary bisphosphonate (for any length of time)
	
	Treatment of hypoparathyroidism for those who meet the following:
	• PTH level drawn within the last 30 days
	  AND
	• Trial of a compliant regimen of at least one formulary medication used to treat hypoparathyroidism (Calcijex/Rocaltrol, ergocalciferol)
	  OR
	• Intolerance or contraindication to at least one formulary medications (for any length of time)
		Note: Not recommended for use beyond 2 years/lifetime

Gleevec[xxi]
Last reviewed: 10/01/14
	Can be authorized for patients who meet the following:
	• Prescribed by an oncologist
	• Prescribed to treat one of the following FDA-approved or NCCN compendium-listed indications:
	  ○ FDA Approved Indications
	  ▪ Adult: Newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase, accelerated phase, or blast phase
	  ▪ Ph+ CML in chronic phase, accelerated phase, or blast phase after failure of a prior therapy (prior interferon-alpha or prior tyrosine kinase inhibitor
		GIST, CML, ASM, or HES/CEL:
		Yearly
		In the presence of disease progression or a demonstrated insufficient response to therapy, a dose increase may be considered in the absence of severe adverse reactions and/or cytopenias**.**

Medication	Authorization Guidelines/Criteria	Duration of Approval
	therapy) ▪ Pediatric: Ph+ CML in chronic phase who are newly diagnosed or whose disease has recurred after stem cell transplant or who are resistant to interferon-alpha therapy. There are no controlled trials in pediatric patients demonstrating a clinical benefit, such as improvement in disease-related symptoms or increased survival ▪ Adult: Relapsed or refractory Ph+ acute lymphoblastic leukemia (Ph+ ALL) ▪ Pediatric: Newly diagnosed Ph+ALL in combination with chemotherapy and corticosteroids ▪ Adult: Myelodysplastic/ myeloproliferative diseases (MDS/MPD) associated with PDGFR (platelet-derived growth factor receptor) gene rearrangements ▪ Adult: Aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown ▪ Adult: Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) who have the FIP1L1-PDGFRα fusion kinase (mutational analysis or FISH demonstration of CHIC2 allele deletion) and for patients with HES and/or CEL who are FIP1L1-PDGFRα fusion kinase negative or unknown ▪ Adult: Unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP) ▪ Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST) ▪ Adult: Adjuvant treatment following resection of Kit (CD117) positive GIST o NCCN listed indications ▪ Primary treatment of newly diagnosed CML (Philadelphia chromosome or BCR-ABL positive (level of evidence: 1) ▪ De novo Ph+ ALL in combination with chemotherapy (level of evidence: 2A) ▪ Induction or reinduction therapy for Ph+, stage I-IV disease as a component of HyperCVAD (cyclophosphamide, vincristine, doxorubicin, and dexamethasone alternating with high-dose methotrexate and	**Indications other than GIST, CML, ASM, or HES/CEL:** Yearly as long as there is no evidence of progressive disease or unacceptable toxicity.

Medication	Authorization Guidelines/Criteria	Duration of Approval
	cytarabine) regimen with rituximab in CD20-positive disease (level of evidence: 2A) ▪ Soft tissue sarcoma – Desmoid tumors: Treatment for gross residual disease following surgery or for unresectable disease as an initial treatment or for recurrence (level of evidence: 2A) ▪ Recurrent bone cancer- chordoma: used as a single-agent therapy or in combination with cisplatin or sirolimus (level of evidence: 2A) ▪ Primary treatment for GIST (resectable, unresectable, recurrent, or metastatic disease) (level of evidence: 2A) **This list is not inclusive. All off-label use will be reviewed in nationally recognized compendia for the determination of medically-accepted indications.*	
GnRH Analogs[xxii] Last reviewed: 7/1/15 Leuprolide acetate Lupron Depot Lupron Depot-PED Eligard Trelstar Vantas Synarel Supprelin LA Zoladex	**For patients who meet the following based on diagnosis:** **<u>Endometriosis</u>** *<u>(Lupron Depot, Synarel, Zoladex [3.6 mg dose only])</u>* • Prescribed by or in consultation with a gynecologist or obstetrician • 18 years of age or older • Trial and failure of at least one formulary hormonal cycle control agent (such as Portia, Ocella, Previfem), medroxyprogesterone, or Danazol • Patient is not pregnant or breastfeeding **<u>Uterine Leiomyoma (fibroids)</u>** *<u>(Lupron Depot, Synarel, Zoladex [3.6 mg dose only])</u>* • Prescribed by or in consultation with a gynecologist or obstetrician • 18 years of age or older • Prescribed to improve anemia and/or reduce uterine size for 3-6 months prior to planned surgical intervention • Patient is not pregnant or breastfeeding **<u>Dysfunctional Uterine Bleeding</u>** *<u>(Zoladex [3.6mg dose only])</u>*	**<u>Initial Approval:</u>** **Central Precocious Puberty** • Supprelin LA: 12 months • All others: 6 months **Endometriosis** • 6 months **Uterine Leiomyoma (fibroids)** • 6 months **Dysfunctional uterine bleeding** • 2 months **Prostate/Breast Cancer** • 2 years **<u>Renewal:</u>** **Central Precocious Puberty** • 6 months - 1 year (up to

Medication	Authorization Guidelines/Criteria	Duration of Approval
	• Prescribed by or in consultation with a gynecologist or obstetrician • 18 years of age or older • Prescribed to thin endometrium prior to planned endometrial ablation or hysterectomy within the next 4-8 weeks • Patient is not pregnant or breastfeeding **Central Precocious Puberty (CPP)** *(Lupron Depot-PED, leuprolide acetate solution, Synarel, Supprelin LA)* • Prescribed by, or in consultation with an Endocrinologist • MRI or CT Scan has been performed to rule out lesions • Onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males • Response to a GnRH stimulation test (or if not available, other labs to support CPP such as luteinizing hormone levels, estradiol and testosterone level) • Bone age advanced 1 year beyond the chronological age • Baseline height and weight • Age restriction (leuprolide acetate solution for injection [once daily regimen]): must be at least 1 year old • Age restriction (Lupron Depot-Ped [1-month or 3-month regimen]): must be at least 2 years old **Advanced Prostate Cancer** (*Lupron Depot, Leuprolide acetate solution*, *Eligard, Zoladex,Vantas Trelstar*) • Prescribed by, or in consultation with oncologist or urologist • Age restriction: must be at least 18 years old **Advanced Breast Cancer** *(Zoladex [3.6mg dose only])* • Prescribed by, or in consultation with oncologist • Age restriction: must be at least 18 years old	age 11 for females and age 12 for males) • Requires clinical response to treatment (i.e., pubertal slowing or decline, height velocity, bone age, LH, or estradiol and testosterone level) **Endometriosis Retreatment** • Lupron only (treatment with Synarel and Zoladex not recommended beyond 6 months): 6 months • Requires: ○ Bone mineral density within normal limits ○ Use in combination with norethindrone acetate **Uterine Leiomyoma (fibroids) or Dysfunctional Uterine Bleeding** • Long-term use is not recommended • Retreatment may be considered on a case by case basis

Medication	Authorization Guidelines/Criteria	Duration of Approval
Growth Hormone and related agents[xxiii] Last reviewed: 09/08/2014 (Detailed Document) Genotropin Humatrope Norditropin Nutropin Omnitrope Saizen Tev-Tropin Zorbtive	**For patients who meet the following:** • Prescribed by a specialist based on the condition treated (e.g., endocrinologist (for adults) or pediatric endocrinologist (for children), HIV specialist, nephrologist) **Neonates/Infants:** • Random GH level <20ng/ml (by RIA test). • Abnormal IGFBP-3 (in infants) • Other causes have been ruled out or treated (hypothyroidism, metabolic disorders) **Children:** • Not used for idiopathic short stature (not considered medically necessary) • Not used for growth promotion in pediatric patients with epiphyseal closure (linear growth can no longer occur. i.e., bone age>14 yrs old). The potential for achieving additional growth after Tanner 4-5 (full maturity) is small as this correlates with epiphyseal closure. • Other factors contributing to growth failure have been ruled out, or are being treated (e.g., inadequate caloric intake/malnutrition/eating disorder, untreated hypothyroidism – patients need normal TSH, T4) • Recent (within the last 3 months) height more than 2 SDS below the mean (<3rd percentile) for age and sex • Recent (within the last 3 months) weight • Pretreatment growth velocity below normal for age and sex **Additional information required (based on diagnosis):** **Child - Growth Hormone Deficiency (GHD):** *(Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Tev-Tropin)* • Fasting Growth Hormone Stimulation testing with arginine (ARG), clonidine, glucagon, insulin tolerance test (ITT) and/or levodopa • Peak levels < 10 mcg/L from 2 different agents are required if the cause of growth failure is unknown • If cause of GHD is known, only 1 peak level < 10 mcg/L will be required:	**Initial Approval:** **Pediatric Indications** • 6 months **Adult Indications:** **Adult GHD** • 6 months **Adults with wasting due to HIV** • 3 months **Adults with SBS**: • One 4-week course **Adults with excess abdominal fat in HIV-infected patients with lipodystrophy** *(Egrifta®)* • 3 months **Renewal:** **Pediatric Indications** • 6 months Requires: 1. Documentation to support final height has not been achieved 2. No evidence of epiphyseal closure AND 3. Growth velocity is > 5cm/year on current dose or < 5 cm/year with intended

Medication	Authorization Guidelines/Criteria	Duration of Approval
	○ Structural or developmental abnormalities: e.g. anencephaly, pituitary aplasia ○ Genetic disorders: e.g., *PROP1* and *PIT1* mutations, septo-optic dysplasia ○ Acquired causes: e.g., craniopharyngeomas*, cranial irradiation, brain surgery, head trauma, CNS infections **Child - Turner Syndrome, Prader-Willi Syndrome, SHOX deficiency or Noonan Syndrome:** *(Prader-Willi Syndrome: Genotropin, Tev-Tropin, Omnitrope) (Turner Syndrome: Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope) (SHOX: Humatrope) (Noonan Syndrome: Norditropin)* • Documentation to support the diagnosis (e.g., Turner Syndrome confirmed by karyotype studies, Prader-Willi Syndrome confirmed by genetic testing) **Child - Chronic Renal Insufficiency (CRI):** *(Nutropin)* • Documented diagnosis of CRI • Patient has not received a renal transplant • Existing metabolic abnormalities (e.g., malnutrition, acidosis, secondary hyperparathyroidism and hyperphosphatemia - correct phosphorus to < 1.5 times the upper limit for age) have been corrected **Child - Small for Gestational Age (SGA) with failure to catch-up by 2 years of age :** *(Genotropin, Humatrope, Norditropin, Omnitrope)* • At least 2 years of age • Birth length or weight < 3rd percentile for gestational age, or • Birth weight < 2500 grams at a gestational age of more than 37 weeks **Adult Idiopathic GH deficiency (Childhood-onset):** *(Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen)* • Documented diagnosis of idiopathic childhood-onset GHD • Growth hormone must not be taken for 1-3 months before repeat GH stimulation test and IGF-1 were drawn • Growth hormone stimulation testing:	dose increase (Note: Growth velocity will typically decrease as final height is approached (growth velocity <2 cm/year). 4. *For Chronic Renal Insufficiency:* there is insufficient data regarding the benefit of treatment beyond three years. **Adult Indications:** **Adults with GHD:** • 6 months if IGF-1 is low but dose is being increased or 1 year if IGF-1 is at a stable range **Adults with wasting due to HIV:** (*Serostim*) • 12 weeks (maximum 48 weeks) • Requires: documentation to support response to therapy **Adults with SBS**: (*Zorbtive*) Approve 4 weeks, No renewals **Adults with excessive abdominal fat in HIV-infected patients with lipodystrophy** : (*Egrifta*) • Initial Renewal:6 months

Medication	Authorization Guidelines/Criteria	Duration of Approval
	○ **Insulin Tolerance Test (ITT):** ▪ Considered Gold standard test ▪ Peak ≤ 5 mcg/L indicative of GHD ○ **Glucagon (for patients who are unable to take ITT):** ▪ Alternative test if recombinant GHRH is unavailable or if ITT is contraindicated (seizures, CVD, or cerebrovascular disease) ▪ Peak ≤ 3 mcg/L indicative of GHD ○ Note: Levodopa and clonidine tests are not recommended • Baseline serum IGF-1 **Adult – GH deficiency due to a known cause (Childhood-onset):** *(Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen)* • Documented diagnosis of childhood-onset GHD due to a known cause (structural lesions, genetic disorders, acquired causes) • Baseline serum IGF-1 • Note: for conditions other than GHD, such as Turner Syndrome and small for gestational age, there is no proven benefit to continuing GH treatment into adulthood once final height is achieved. **Adult-onset GH deficiency:** *(Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen)* • Documented diagnosis of GHD acquired as an adult due to a known cause (e.g., surgery, cranial irradiation, panhypopituitarism) • Baseline IGF-1 • Growth hormone stimulation test: ○ **Insulin Tolerance Test (ITT):** ▪ Considered Gold standard test ▪ Peak ≤ 5 mcg/L indicative of GHD ○ **Glucagon (for patients who are unable to take ITT):** ▪ Alternative test if recombinant GHRH is unavailable or if ITT is contraindicated (seizures, CVD, or cerebrovascular disease) ▪ Peak ≤ 3 mcg/L indicative of GHD	• Requires: documentation to support response to therapy, decrease in baseline waist circumference, and documentation that IGF-1, and A1C is being monitored • Subsequent renewals: indefinite

Medication	Authorization Guidelines/Criteria	Duration of Approval
	○ Note: Levodopa and clonidine tests are not recommended • If GH deficiency is due to traumatic brain injury and aneurysmal subarachnoid hemorrhage, GHD may be transient; therefore, GH stimulation testing should be performed at least 12 months after the event **Adult HIV Wasting/cachexia** *(Serostim)* • Documented height, weight, and ideal body weight • Patient had progressive weight loss below IBW over the last year which cannot be explained by a concurrent illness other than HIV infection • Documented adequate caloric intake • Failure of megestrol and dronabinol • On antiretroviral therapy **Adults Short Bowel Syndrome** *(Zorbtive)* • Age > 18 years of age • Patient is receiving specialized nutrition (e.g. TPN or PPN) **Treatment of excess abdominal fat in HIV-infected patients with lipodystrophy** *(Egrifta)* • 18-65 years of age • **Men:** waist circumference ≥ 95 cm (37.4”) and waist-to-hip ratio ≥ 0.94 • **Women:** ≥ 94 cm (37.0”) and waist-to-hip ratio ≥ 0.88 • On antiretroviral therapy • Patient is at risk for medical complications due to excess abdominal fat • Contraindications: No disruption of the hypothalamic-pituitary axis (e.g. hypothalamic-pituitary-adrenal (HPA) suppression) due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, radiation therapy of the head or head trauma, active malignancy, known hypersensitivity to tesamorelin and/or mannitol, and pregnancy • Not using Egrifta for weight loss (cosmetic use)	
Hemophilia[xxiv] Factor VIIa Factor VIII	**Hemophilia Factor Replacement Products:** • Factor VIIa: Novoseven RT • Factor VIII: Advate, Bioclate, Eloctate, Genarc, Helixate FS, Kogenate FS, Recombinate, ReFacto, Xyntha, Alphanate, Hemofil M, Monarc-M, Koate-DVI, Monoclate-P, Humate-	**Initial Approval**: 3 months **Renewal:** 1 year

Medication	Authorization Guidelines/Criteria	Duration of Approval

Factor IX	P
	• Factor IX: Alphanine SD, Mononine, Bebulin VH, Proplex T, Profilnine SD, Benefix
	
	Hemophilia A is a deficiency in factor VIII
	Hemophilia B is a deficiency in factor IX
	Von Willebrand's is a dysfunction in VWF and deficiency in factor VIII
	
	Factor VIII and IX is authorized for Members who meet ONE of the following criteria:
	• Treatment of hemorrhagic complications in patients with hemophilia A, hemophilia B or von Willebrand's disease, **OR**
	• Prevention of bleeding in surgical or invasive procedures in patients with hemophilia A, hemophilia B or von Willebrand's disease, **OR**
	• Primary prophylactic therapy for patients with severe hemophilia A or hemophilia B (less than 1% of normal factor (less than 0.01 IU/ml)), **OR**
	• Secondary prophylactic therapy for patients with hemophilia A or hemophilia B (regardless of normal factor levels) and has documented history of two or more episodes of spontaneous bleeding into joints.
	
	Novoseven (factor VIIa) is authorized for members who meet ONE of the following:
	• Treatment of hemorrhagic complications OR prevention of bleeding in surgical or invasive procedures in a patient with one of the following indications:
	  • Hemophilia A or hemophilia B with inhibitors
	  • Congenital factor VII (FVII) deficiency
	  • Glanzmann's thrombasthenia with refractoriness to platelet transfusions
	  • Acquired hemophilia
		Factor VIII and IX should be discontinued upon development of a Factor inhibitor resulting in lack of response to factor VIII or IX

Medication	Authorization Guidelines/Criteria	Duration of Approval
Hepatitis C Agents Sovaldi Harvoni Olysio Viekira Pak	**Follow IL state guidelines:** HFS.HepatitisC_General_Criteria.pdf HFS.Harvoni_Criteria.pdf HFS.sovaldi_criteria.pdf HFS.ViekiraPak_Criteria.pdf **HCV RNA must be received within 3 months of prior authorization request.**	**Note:** Duration of therapy for all agents should be based on the FDA approved regimens. Pharmacists should indicate in the PA notes if a requested regimen is not FDA approved and is based on most recent AASLD Guidelines.
Hetlioz[xxv] Last reviewed: 4/22/15	**For patients that meet all of the following:** • At least 18 years old • Diagnosis of non-24 sleep-wake disorder • Completely blind with NO light perception • History of at least 3 months of difficulty initiating sleep, difficulty awakening in the morning, or excessive daytime sleepiness • No other concomitant sleep disorder (i.e., sleep apnea, insomnia)	**Initial Approval** Indefinite
Hyaluronic Acid Agents (Topical)[ii] Last reviewed: 09/22/2015 <u>Topical:</u> Bionect HyGel Hylira XClair	**When used for treatment of burns, dermal ulcers, wounds, radiation dermatitis:** • Prescriber must be a dermatologist • Patient must be at least 18 years old **When used for treatment of xerosis:** • Prescriber must be a dermatologist • Trial and failure of ammonium lactate or a topical corticosteroid Patient must be at least 18 years old Viscosupplements.docx	**<u>Intial Approval:</u>** **Burns or dermatitis:** • 3 fills of generic agent **Xerosis:** • Up to 1,000 grams of equivalent generic agent per 30 days for three months **<u>Renewal:</u>** 3 months
Hyperlipidemia Medications[xxvi]	**Crestor can be approved when the following criteria are met:** • Patient is at least 10 years old; **AND**	**<u>Initial Approval:</u>** PSCK9 inhibitors: 3 months

Medication	Authorization Guidelines/Criteria	Duration of Approval
Last reviewed: 6/15/15 Crestor Zetia Lovaza Vascepa Epanova Repatha Praluent Juxtapid Kynamro	• Patient has failed to achieve LDL goal on a compliant regimen of maximum tolerated dose of atorvastatin; **OR** • Patient requires a high intensity statin (i.e., diagnosis of familial hypercholesterolemia or high ASCVD risk per provider evaluation) AND patient had a trial and failure of atorvastatin **Zetia requires step therapy:** • **If member has filled 2 prescriptions for 2 different statins (specifically atorvastatin, simvastatin or Crestor) within the last 130-days, the prescription will automatically process at the pharmacy.** • **Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy.** • In those cases, Zetia will be authorized upon receipt of documentation to support the diagnosis of hyperlipidemia and failure of, or contraindication to atorvastatin, simvastatin, and Crestor**.** **Non-formulary medications for hypertriglyceridemia (Lovaza, Vascepa, and Epanova) can be approved when the following criteria are met:** • Patient is at least 18 years old • Drug will be used as an add-on to lifestyle interventions to include diet and exercise • Treatment of severe hypertriglyceridemia (triglyceride level greater than or equal to 500 mg/dL) • Trial and failure of OTC fish oil and at least ONE other formulary medication such as fenofibrate, fenofibric acid, gemfibrozil, or niacin or contraindication to all formulary agents **PCSK9 Inhibitors (Repatha and Praluent) can be approved when ALL of the following criteria are met:** • Lab results support an LDL ≥300 mg/dL (within the past 90 days) • Failure of a compliant, 60 day trial of 2 different high potency statins* (atorvastatin and Crestor) at maximum tolerated doses used in combination with Zetia, niacin, or a	Juxtapid, Kynamro: 3 months All others: 6 months **Renewal:** PSCK9 inhibitors: 6 months Juxtapid, Kynamro: 6 months All others: indefinite Renewals require improvement in fasting lipids and documentation of recommended safety monitoring parameters (such as liver enzymes)

Medication	Authorization Guidelines/Criteria	Duration of Approval

	bile acid sequestrant
	• The PCSK9 will be used in combination with maximum tolerated doses of a statin* in combination with Zetia, niacin, or a bile acid sequestrant
	• <u>In addition for diagnosis of Familial Hypercholesterolemia (FH):</u>
	  o Patient has tried and failed or is not a candidate for LDL apheresis
	• <u>In addition for diagnosis of Primary Hypercholesterolemia non FH:</u>
	  o Chart notes support evidence of ASCVD or high CVD risk (i.e., history of AMI, MI, PCI, or CABG)
	• NOTE: All requests must be forwarded to MDR for final approval
	
	Juxtapid and Kynamro can be approved when ALL of the following criteria are met:
	• Diagnosis of homozygous familial hypercholesterolemia with a documented LDL of <u>≥</u>300 mg/dl (within the past 90 days)
	• Failure of a compliant, 60 day trial of 2 different high potency statins* (atorvastatin and Crestor) at maximum tolerated doses used in combination with Zetia, niacin, or a bile acid sequestrant
	• Juxtapid or Kynamro will be used in combination with maximum tolerated doses of a statin* in combination with Zetia, niacin, or a bile acid sequestrant AND lifestyle interventions to include diet and exercise (low-fat diet recommended, <20% of calories from fat)
	• Patient has tried and failed or is not a candidate for LDL apheresis
	• Patient is at least 18 years old
	• Recommended baseline labs are submitted: Fasting lipid panel, ALT, AST, alk phos, total bili, and negative pregnancy test (if applicable)
	• Patient does not have moderate to severe hepatic impairment (Child-Pugh B or C) or active liver disease
	• NOTE: All requests must be forwarded to MDR for final approval
	
	* Exception to statin therapy trials requires documentation of intolerance to at least 2 statins (at least one trial being a moderate to high potency statin). Documentation will include chart notes supporting skeletal muscle related symptoms that resolved when statin therapy was	

Medication	Authorization Guidelines/Criteria	Duration of Approval
	discontinued; and documentation the member has been rechallenged at a lower dose or with a different statin.	

Idiopathic Pulmonary Fibrosis Agents[xxvii]
Last reviewed: 06/16/15
 	
Esbriet
Ofev
	Non-formulary use of Esbriet or Ofev can be approved when the following are met:
	• Diagnosis of mild to moderate idiopathic pulmonary fibrosis
	  ○ Confirmed by high resolution computed tomography (HRCT), lung biopsy, or bronchoscopy
	  ○ Interstitial lung disease cannot be attributed to another cause (i.e., rheumatoid arthritis, lupus, systemic sclerosis, asbestos exposure, or hypersensitivity pneumonitis)
	  ○ Forced vital capacity (FVC) between 50 and 80% predicted
	• Documentation of baseline liver function tests (LFT's) prior to initiating treatment
	• Patient age must be 18 years or greater
	• Patient is not a current smoker
	• Prescribed by, or in consultation with, a pulmonologist
	
	Note: There is no conclusive evidence to support the use of any drugs to increase the survival of people with idiopathic pulmonary fibrosis.
		Initial Approval: 3 months
		
		Renewal: 6 months
		
		Criteria for renewal:
		• Documentation of stable FVC (recommended to discontinue if there is a >10% decline in FVC over a 12 month period)
		• Attestation that LFT's are being monitored

Increlex
Last reviewed: 4/22/15
	For patients that meet the following:
	• Prescribed by or in consultation with pediatric endocrinologist
	• Patient is ≥ 2 years old
	• No evidence of epiphyseal closure
	• No evidence of neoplastic disease
	• Documentation supports a diagnosis of Severe, Primary IGF-1 deficiency
	  ○ Height standard deviation score less than or equal to −3
	  ○ Basal IGF-1 standard deviation score less than or equal to −3
	  ○ Normal or elevated growth hormone levels
	  ○ No evidence of secondary forms of IGF-1 deficiency, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of corticosteroids.
	OR
		Initial Approval:
		6 months
		
		Renewal:
		• 6 months if at least doubling of pretreatment growth velocity
		• 1 year if growth velocity ≥ 2.5 cm/yr and epiphyses are open

Medication	Authorization Guidelines/Criteria	Duration of Approval
	• Documentation supports diagnosis of Growth hormone (GH) gene deletion and development of neutralizing antibodies to GH	

Injectable Osteoporosis Agents
Last reviewed: 09/08/14
 	
Prolia
Reclast
Boniva
	For patients who meet all of the following:
	• Adult > 18 years of age
	For the treatment of osteoporosis in members who meet the following criteria: *(Boniva, Reclast, Prolia)*
	• Intolerance or contraindication to at least one formulary oral bisphosphonate (e.g., alendronate)
	• Failure of a 6 month trial of a formulary oral bisphosphonate
	  ○ Documentation supporting failure OR
	  ○ Decrease in T-score in comparison with baseline T-score from DEXA scan OR
	  ○ New fracture
	• Boniva only: must be female
	
	Treatment of corticosteroid-induced osteoporosis for those who meet the following criteria: *(Reclast)*
	• Treatment with 7.5 mg/day oral prednisone (or equivalent) for a planned duration of at least 3 months
	• Baseline T-score < -1.0, with DEXA scan
	• Failure of consecutive 6 month regimen of at least one formulary bisphosphonate OR intolerance/contraindication to at least one formulary bisphosphonate per medical records (for any length of time)
	
	For the treatment of Paget's disease of bone in men and women who meet the following criteria: *(Reclast)*
	• Failure of consecutive 6 month regimen of at least one formulary bisphosphonate OR intolerance/contraindication to at least one formulary bisphosphonate per medical records (for any length of time)
		Initial Approval:
		• Osteoporosis – Indefinite
		• Paget's Disease: 1 time

Insulin Pens Last reviewed: 04/01/15 Humulin N Pen	**For patients who meet the following:** • Patient is a school-aged child requiring multiple daily injections of insulin OR • Patient is unable to effectively use insulin vials and syringes to self-administer insulin	**Initial Approval:** • Adults: Indefinite • Children: through 18 years of age

Medication	Authorization Guidelines/Criteria	Duration of Approval
Humulin 70/30 Pen Novolog Flexpen Humalog Kwikpen Lantus Solostar Levemir Flexpen Levemir Flextouch Apidra Solostar	due to <u>at least one</u> of the following: o Member has uncorrectable visual disturbances (e.g., macular degeneration, retinopathy, vision uncorrectable by prescription glasses) OR o Member has a physical disability or dexterity problems due to stroke, peripheral neuropathy, trauma, or other physical condition AND o Member does not have a caregiver who can administer insulin using vials and syringes.	
Interferons[xxviii] Last reviewed: 09/08/14 ***α-Interferon*** Infergen Intron A Pegasys Pegintron Sylatron ***β-Interferon*** See Multiple Sclerosis Agents ***γ-Interferon*** Actimmune **(Detailed Document)**	**<u>Chronic Hepatits B Infection:</u>** *(Intron A, Pegasys)* **Patients with HBeAg-positive or HBeAg-negative chronic hepatitis B** • Prescribed by, or in consultation with an infectious disease physician, HIV specialist, gastroenterologist, hepatologist, or transplant physician • HBeAg-positive or HBeAg-negative **AND** • Compensated liver disease (e.g., normal bilirubin, albumin within normal limits, no cytopenias) **AND** • Evidence of viral replication (e.g., HBV DNA > 20,000 IU/ml) **AND** • Evidence of liver inflammation (e.g., ALT > 2 times the upper limit of normal, inflammation or fibrosis on liver biopsy) • Age restriction (*Pegasys*): Must be at least 18 years old • Age restriction (*Intron A*): Must be at least 1 year old **<u>AIDS-related Kaposi's sarcoma:</u>** *(Intron A [powder for solution ONLY])* • Prescribed by, or in consultation with an infectious disease physician or HIV specialist • Not being used for the treatment of visceral AIDS-related Kaposi's sarcoma associated with rapidly progressive disease	**<u>Initial Approval:</u>** **Hepatitis B** Intron A – 16 weeks Pegasys – 48 weeks **Malignant Melanoma:** Intron A: 1 year Sylatron: up to 5 years **Osteopetrosis, CGD, Kaposi's sarcoma:** 6 months **Hairy cell leukemia:** 6 months **<u>Renewal:</u>** **Osteopetrosis:** 1 year if no evidence of disease progression **CGD:** 1 year if number and/or severity of infections has

Medication	Authorization Guidelines/Criteria	Duration of Approval
	• Patient must be at least 18 years old **Hairy-cell Leukemia:** *(Intron A)* • Prescribed by, or in consultation with a hematologist/oncologist • Patient has demonstrated less than complete response to cladribine or pentostatin OR • Patient has relapsed within 1 year of demonstrating a complete response to cladribine or pentostatin • Patient has indications for treatment such as: o Systemic symptoms – fatigue, weakness, weight loss, fever, night sweats o Symptomatic splenomegaly or adenopathy o Significant cytopenias – hemoglobin < 12 g/dL, platelet count < 100,000/mcL, or ANC < 1000/mcL • Patient is at least 18 years old **Malignant Melanoma:** *(Intron A, Sylatron)* • Prescribed by, or in consultation with a hematologist/oncologist • Patient has undergone surgical resection AND is at high risk for recurrence (e.g., primary tumor > 4 mm thick, presence of ulceration, lymph node involvement) • Patient is at least 18 years old **Chronic Granulomatous Disease:** *(Actimmune)* • Prescribed by, or in consultation with an immunologist • Patient is also receiving prophylactic antimicrobials (such as itraconazole and trimethoprim/sulfamethoxazole) **Malignant Osteopetrosis:** *(Actimmune)* • Prescribed by, or in consultation with a hematologist/oncologist	decreased **Kaposi's sarcoma:** 1 year **Hairy cell leukemia:** 6 months

Medication	Authorization Guidelines/Criteria	Duration of Approval
	• Prescribed for the treatment of severe, malignant osteopetrosis	
Intravaginal Progesterone Products[xxix] Last reviewed: 4/22/15 Progesterone capsules Crinone First-progresterone suppositories	**For patients that meet the following:** • Prescribed by a provider of obstetrical care • Patient is not on Makena (17-hydroxyprogesterone) • Patient is pregnant and has 1 of the following: o Patient has a short cervix OR o Patient is at high risk for pregnancy loss based on other risk factors	**Initial Approval:** Approve as requested until 37 weeks gestation
Lidocaine Patch[xxx] Last reviewed: 06/15/15	**Lidocaine patch is covered for the following:** • Member is ≥ 65; OR • Member has a diagnosis of post herpetic neuralgia; OR • Member has diabetic peripheral neuropathy (DPN) AND has failed a trial of duloxetine and at least one other formulary medication such as; tricyclic antidepressants, gabapentin, topical capsaicin, or tramadol; OR • Member has other neuropathic pain including pain associated with spinal cord injury AND has failed a trial of two formulary medications (e.g., topical capsaicin, tricyclic antidepressants, tramadol, or gabapentin)	**Initial Approval:** • Indefinite
Long-Acting Beta-2 Agonists (LABA) Last reviewed: 07/22/15 Brovana Foradil Perforomist Serevent	**Arcapta Neohaler and Striverdi Respimat** are the formulary preferred LABA inhalers and do not require PA. These agents are only approved for COPD and NOT approved for asthma. Patients with asthma who require a LABA in addition to an inhaled corticosteroid (ICS) should use a formulary combination inhaler (i.e., Symbicort). **Foradil** for the treatment of COPD requires ST therapy and will process at the point of sale if there are fills of BOTH Arcapta and Stiverdi within the previous 130 days. **Foradil and Serevent** for the treatment of asthma requires trial and failure of BOTH Symbicort and Advair. Please note, Advair requires a PA for patients who are not age 4-11. Patients outside of that age require a trial and failure of Symbicort before Advair. Foradil and Serevent should only be used in combination with an ICS.	**Initial Approval:** Indefinite

Medication	Authorization Guidelines/Criteria	Duration of Approval
	Brovana, Perforomist, and Serevent are NF and require trial and failure of both Arcapta and Striverdi for the treatment of COPD.	

Long-Acting Muscarinic Antagonists (LAMA)
Last reviewed: 07/22/15
 	
Spiriva HandiHaler
Spiriva Respimat
	Tudorza Pressair and Incruse Ellipta are the formulary preferred agents for the treatment of COPD and do not require PA.
	
	Spiriva for COPD requires ST therapy and will pay at the point of sale if there is at least one fill of either Tudorza or Incruse.
	
	Criteria for the use of Spiriva Respimat for Asthma:
	• Patient is at least 12 years old
	• Patient is currently taking an inhaled corticosteroid (ICS) and will continue an ICS when Spiriva is initiated
	• Patient has had a trial and failure to at least 2 formulary agents:
	  ○ Inhaled corticosteroid
	  ○ Inhaled corticosteroid with a long-acting beta-2 agonist
	  ○ Montelukast or zafirlukast (zafirlukast requires ST)
	• NOTE: Spiriva HandiHaler, Tudorza, and Incruse are NOT FDA-approved for asthma
		Initial Approval:
		Indefinite

Long Acting Opioids Last reviewed: 5/13/15 Oxycontin Butrans Patch Exalgo Oxymorphone ER Zohydro ER	**Criteria for ALL long-acting opioids (formulary and non-formulary):** • NOTE: Patients with cancer-related pain or pain from sickle cell anemia are EXEMPT from this section • Patient has a treatment plan that includes the diagnosis and goals of therapy • Prescriber has completed an addiction risk assessment for the specific therapy • Prescriber has recently reviewed the state Prescription Monitoring Program (PMP) database • Patient has a pain management contract that addresses the following:	**Initial Approval:** • 1 year **Renewal:** • 1 year NOTE: QL's may exist

Medication	Authorization Guidelines/Criteria	Duration of Approval
Xartemis XR Nucynta ER Morphine Sulfate ER Fentanyl Patch Methadone	○ Consequences of unexplained loss or shortage of medications ○ Consequences of obtaining similar prescription medications from other prescribers ○ An agreement with the member to only use one pharmacy **In Addition, STEP criteria for Oxymorphone ER:** • Treatment of chronic pain • At least 18 years old • Failed a minimum of 2 week trials of maximum tolerated doses of at least TWO formulary long-acting opioids (i.e., fentanyl patch, morphine sulfate ER, methadone) OR have contraindications to all formulary agents. **In Addition, Criteria for Oxycontin and Non-Formulary Long-Acting Opioids:** • **Treatment of malignant pain and pain due to sickle cell anemia (Oxycontin)** OR • **Treatment of chronic non-malignant pain:** ○ At least 18 years old ○ Failed a minimum of 2 week trials of maximum tolerated doses of at least THREE formulary long-acting agents (i.e., fentanyl patch, morphine sulfate ER, methadone, oxymorphone ER) one of which must be oxymorphone ER OR ○ Contraindication to all formulary long-acting agents OR • **Treatment of diabetic peripheral neuropathy (Nucynta ER only):** ○ At least 18 years old ○ Failed an adequate trial (at least 4 weeks at maximum tolerated doses) of duloxetine and tramadol and at least ONE additional formulary medication (i.e., gabapentin, amitriptyline, nortriptyline, or topical capsaicin) OR ○ Contraindications to all formulary agents METHADONE IS ONLY AUTHORIZED FOR THE TREATMENT OF PAIN	
Lyrica[xxxi]	Lyrica is authorized for members who are 18 years of age or older with a diagnosis of post	**Initial Approval:**

Medication	Authorization Guidelines/Criteria	Duration of Approval
Last reviewed: 09/08/14	herpetic neuralgia and partial onset seizures. **For the diagnosis of fibromyalgia:** • Patient is 18 years of age or older • Trial and failure of duloxetine **For the diagnosis of neuropathic pain associated with diabetic peripheral neuropathy, spinal cord injury, or cancer-related neuropathic pain:** • Trial and failure of duloxetine AND at least 1 other generic formulary agent such as topical capsaicin, tricyclic antidepressants, tramadol, venlafaxine, or gabapentin • Patient must be at least 18 years old	Indefinite
Modafinil/Nuvigil[xxxii] Last reviewed: 09/08/14	• **Narcolepsy:** o For patient 17 years of age or older after trial and failure of, or documented contraindication to 2 formulary CNS stimulants (amphetamine/dextroamphetamine, dextroamphetamine, or methylphenidate) • **Obstructive Sleep Apnea:** o For patients 17 years of age or older after trial and failure of, or despite use of CPAP • **Circadian rhythm disruption (i.e., shift-work sleep disorder):** o For patients 17 years of age or older with documentation to support the diagnosis (e.g., other causes of hypersomnolence have been ruled-out, Sleep study evaluation) **Modafinil only (off label indications):** • **Cancer-related fatigue:** o For patients age 18 years of age or older after trial and failure of methylphenidate and documentation supports a diagnosis of severe fatigue • **Fatigue due to MS:** o For patient age 16 years of age or older after trial and failure of methylphenidate • **Idiopathic hypersomnia:** o For patients age 16 years of age or older after trial and failure of 2 formulary	**Initial Approval:** • 6 months **Renewal:** • 1 year with clinical notes to support a response to treatment

Medication	Authorization Guidelines/Criteria	Duration of Approval
	stimulants and diagnosis is supported by polysomnography and multiple sleep latency test	
Multaq[xxxiii] Last reviewed: 04/08/15	**For patients who meet the following:** • Diagnosis is atrial fibrillation • Patient has tried and failed amiodarone • Age restriction: must be at least 18 years old.	**Initial Approval:** Indefinite
Multiple Sclerosis Agents[xxxiv] Last reviewed: 09/08/14 Avonex Betaseron Extavia Rebif Copaxone Gilenya Glatopa Mitoxantrone Tecfidera Aubagio	 MS Disease Modifying Agents.doc	
Nasal Steroids[xxxv] Last reviewed: 06/01/15 Flunisolide Fluticasone Nasonex Triamcinolone	Nasacort OTC is the formulary preferred agent. Fluticasone and flunisolide are formulary but require STEP therapy with Nasacort OTC first. **Non-formulary nasal steroids can be approved if the following is met:** • Trial and failure of Nasacort OTC followed by trial and failure of fluticasone & flunisolide; OR • Treatment of nasal polyps (for Nasonex)	**Initial Approval:** Indefinite

Medication	Authorization Guidelines/Criteria	Duration of Approval

Nexavar[xxxvi]
Last reviewed: 10/01/14
	Can be authorized for patients who meet the following:
	• Documented diagnosis of one of the following:
	  ○ Advanced (unresectable or metastatic) renal cell carcinoma
	  ○ Unresectable hepatocellular carcinoma
	  ○ Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment
	• No advanced cardiac conditions
		Initial: 1 year
		Renewal: 3 years if evidence of stable disease (tumor size within 25% of baseline)

Non-Calcium Based Phosphate Binders[xxxvii] Last reviewed: 4/22/15 Fosrenol Velphoro	**For patients that meet all of the following:** • Treatment of hyperphosphatemia due to ESRD • Receiving dialysis • At least 18 years old • Failed Renvela or Renagel (sevelamer) AND failed a calcium-based phosphate binder or has contraindications to both. (Note: Patients with elevated total serum calcium after correcting for albumin should not receive a calcium-based product)	**Initial Approval:** Indefinite
Northera[xxxviii] Last reviewed: 4/22/15	**For patients that meet all of the following:** • At least 18 years old • Patient has a diagnosis of symptomatic neurogenic orthostatic hypotension (NOH) caused by primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, or pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy • Patient has tried and failed or has contraindication/intolerance to fludrocortisone and midodrine	**Initial Approval:** 6 months **Renewal:** Indefinite
Onychomycosis and Tinea[xxxix] Last reviewed: 4/22/15 Luzu Jublia Kerydin	**Luzu can be approved as non-formulary for members who meet the following:** • Topical treatment of tinea pedis, tinea cruris, and tinea corporis. • At least 18 years old • Failure of OR contraindication to terbinafine cream • Failure of at least 1 other formulary topical antifungal agents (ie clotrimazole, ciclopirox, econazole, ketoconazole, miconazole, etc.) OR contraindication to all formulary agents **Jublia or Kerydin can be approved as non-formulary for members who meet the following:** • Treatment of onychomycosis of the toenails with ONE of the following comorbidities:	**Initial (Luzu):** • 30 days **Renewal (Luzu):** • 30 days if responding to therapy **Jublia or Kerydin:** 48 weeks

Medication	Authorization Guidelines/Criteria	Duration of Approval
	○ Diabetes ○ HIV ○ Immunosuppression (i.e. receiving chemotherapy, taking long term oral corticosteroids, taking anti-rejection medications) ○ Peripheral vascular disease ○ Pain caused by the onychomycosis • At least 18 years old • Failure of 2 OR contraindication to all formulary antifungal agents indicated for onychomycosis (ie ciclopirox, griseofulvin, itraconazole and terbinafine tablets)	
Ophthalmic Prostaglandins Last reviewed: 04/08/15 Lumigan Travoprost Travatan Z	**For patients who meet ONE of the following:** • Hypersensitivity to latanoprost, benzalkonium chloride (BAC), or to any other ingredients of the formulation **OR** • The patient has failed latanoprost	**Initial Approval:** Indefinite
Oral Platelet Inhibitors[xl] Last reviewed: 07/1/15 Effient Brilinta Zontivity	**Effient or Brilinta can be approved for patients who meet the following:** • Diagnosis of ACS (unstable angina, STEMI, NSTEMI) • Failure or contraindication/intolerance to clopidogrel, including patients identified as CYP2C19 poor metabolizers • No active pathological bleeding, history of intracranial hemorrhage, or planned CABG • **In addition, for Effient:** 1. Age <75 unless patient is considered high thromboembolic risk 2. Taking concomitant 75-325mg/day aspirin 3. No history of TIA or stroke • **In addition, for Brilinta:** 1. Taking concomitant 75-100mg/day aspirin 2. No severe hepatic impairment 3. No concomitant use with medications known to interact with Brilinta (i.e., potent CYP3A4 inhibitors/inducers and simvastatin or lovastatin in doses >40mg/day) without provider documentation that benefit outweighs the risk	**Initial Approval (Effient and Brilinta):** 12 months Indefinite approval can be given to patients with a history of stent thrombosis/restenosis **Initial Approval (Zontivity):** Indefinite **Renewals (Effient and Brilinta):** 12 months; requires documentation from cardiologist that risk of thrombosis outweighs bleeding risk with long-term use of

Medication	Authorization Guidelines/Criteria	Duration of Approval
	Zontivity can be approved for patients who meet the following: • Prescribed for the secondary prevention of atherothrombosis in patients with PAD or history of MI (drug NOT indicated for ACS) • Must be used with aspirin and/or clopidogrel according to the standard of care for the patient's diagnosis • No evidence of contraindications: history of stroke, transient ischemic attack (TIA), or intracranial hemorrhage (ICH); or active pathological bleeding	antiplatelets
Orencia[xli] Last reviewed: 09/08/14	**For patients who meet all of the following:** • Prescribed by, or in consultation with a rheumatologist • May not be given in combination with TNF-alpha antagonists (e.g. Enbrel, Humira or Remicade) **In addition, for the treatment of Rheumatoid Arthritis for patients 18 years of age and older (IV infusion or SC injection):** • Trial and failure of methotrexate and at least 1 other oral DMARD (sulfasalazine, hydroxychloroquine or leflunomide) as sequential monotherapy for 3 months each or in combination for at least 3 months (or contraindication/intolerance to methotrexate and other DMARDs) AND • Trial and failure of, or contraindication/intolerance to at least 3 months compliant regimen of Enbrel or Humira **In addition, for the treatment of Juvenile Idiopathic Arthritis for patients 6 years of age and older (IV infusion only):** • After trial and failure of a compliant regimen of methotrexate for at least 3 months AND • Trial and failure of, or contraindication/intolerance to at least 3 months of a compliant regimen of Enbrel or Humira	**Initial Approval:** Indefinite
Otezla[xlii] Last reviewed: 4/22/15	**For moderate to severe psoriatic arthritis:** • Age is 18 years or older	**Initial Approval:** 3 months

Medication	Authorization Guidelines/Criteria	Duration of Approval
	• Prescribed by or in consultation with a rheumatologist • Trial and failure of methotrexate for three consecutive months (or documentation showing contraindication) • Trial and failure of Humira or Enbrel for three consecutive months (or documentation showing contraindication, non-responsiveness or diminished response over time) **For moderate to severe plaque psoriasis**: • Age is 18 years or older • Prescribed by or in consultation with a dermatologist • Trial and failure of UVB or PUVA therapy or documentation showing contraindication) • Trial and failure of methotrexate for three consecutive months (or documentation • showing contraindication) • Trial and failure of Humira or Enbrel for three consecutive months (or documentation showing contraindication, non-responsiveness or diminished response over time)	**Renewal:** 12 months Requires: • Patient experiencing positive response to therapy. • Patient is not experiencing depression and/or suicidal thoughts. • Patient has no significant weight loss.
Platelet Inhibitors[xliii] Last reviewed: 02/01/14 Effient Brilinta	**For patients that meet the following:** • Diagnosis of acute coronary syndrome (e.g., unstable angina, STEMI, NSTEMI) • Failure or contraindication/intolerance to clopidogrel • Age restriction: must be at least 18 years old	**Initial Approval:** Indefinite
PAH Agents Last reviewed: 09/08/14 Adcirca Adempas epoprostenol Letairis Opsumit Remodulin Sildenafil 20mg Tracleer Tyvaso Ventavis	**All agents must be prescribed by, or in consultation with a pulmonologist or cardiologist with experience in treating pulmonary hypertension.** • Age restriction (sildenafil 20mg): must be at least 17 years old • Age restriction (Adempas, Opsumit, Veletri): must be at least 18 years old • Diagnosis of pulmonary arterial hypertension (PAH) or chronic thromboembolic pulmonary hypertension (for Adempas only) Additional information may be required on a case-by-case basis to allow for adequate review and to ensure the safety of the patient.	**Initial Approval:** Indefinite

Medication	Authorization Guidelines/Criteria	Duration of Approval
Promacta[xliv] Last reviewed: 4/22/15	**Chronic idiopathic thrombocytopenic purpura (ITP):** • Patient is at least 18 years old • Patient had insufficient response to corticosteroids, immunoglobulins, or splenectomy • Promacta is being used to prevent major bleeding (not in an attempt to achieve platelet counts in the normal range i.e., 150,000-450,000/mm3) **Interferon-induced thrombocytopenia:** • Patient is at least 18 years old • Patient has chronic hepatitis C with severe thrombocytopenia which prevents initiation or ability to maintain interferon-based therapy **Severe aplastic anemia** • Patient is at least 18 years old • Patient has a diagnosis of severe aplastic anemia defined by at least 2 of the following: o Neutrophil count < 0.5 x 10^9/L o Platelet count <20 x 10^9/L o Reticulocyte count < 20 x 10^9/L (value may be given as percent of RBCs) • Trial of or contraindication to first line treatment including allogeneic stem cell transplantation from an appropriate sibling donor or immunosuppressive therapy with a combination of cyclosporine A and antithymocyte globulin (ATG)	**Initial Approval:** 1 month **Renewal:** HCV: up to 1 year total All others: Indefinite *Renewal requirements:* • Platelet count of at least 50,000/mm3 (response rates should be seen at least 1 week after initiation of therapy with a maximum response seen at 2 weeks) Severe aplastic anemia response to treatment would be indicated by hematologic response in at least one lineage – platelets, RBC or WBC.

Medication	Authorization Guidelines/Criteria	Duration of Approval

Proton Pump Inhibitors[xlv]
Last reviewed: 06/15/15
 	
Omeprazole
Omeprazole OTC
 	
Lansoprazole
Prevacid OTC
Prevacid Solutab
 	
Aciphex Sprinkle
Rabeprazole
 	
Pantoprazole
 	
Esomeprazole
Nexium suspension
Nexium OTC
 	
Dexilant
	Omeprazole OTC, Nexium OTC, and Prevacid OTC are the formulary preferred agents.
	
	Non-preferred PPI's can be authorized when the following criteria are met:
	• Trial and failure of at least TWO formulary PPI's
	• Trial and failure of at least ONE formulary PPI at double-daily dose:
	  ○ Omeprazole OTC 40mg
	  ○ Nexium OTC 40mg
	  ○ Prevacid OTC 60mg
	
	High Dose PPI's can be authorized when the following criteria are met:
	• Provider must submit rationale for high dose (e.g., patient has unsatisfactory or partial response to once daily dosing, night-time symptoms, severe erosive esophagitis, stricture, Zollinger-Ellison)
	• Patient must have failed omeprazole OTC 40mg, Nexium OTC 40mg, and Prevacid OTC 60mg
		Initial Approval:
		Once daily NF:
		Indefinite
		
		High dose: 12 months
		
		Renewal:
		High dose: 12 months
		
		Requires:
		Response to therapy and rationale for continuing BID dosing

Ranexa[xlvi]
Last reviewed: 09/08/14
	For patients age 18 years of age or older who meet all of the following:
	• Diagnosis of chronic angina
	• Trial and failure of at least 1 formulary agent from each of 2 different drug classes:
	  ○ **Beta blockers**: acebutolol, atenolol, carvedilol, metoprolol, nadolol, propranolol
	  ○ **Calcium channel blockers**: amlodipine, diltiazem, felodipine, isradipine, nifedipine, nicardipine, verapamil
	  ○ **Long acting nitrates**: Isosorbide dinitrate, isosorbide mononitrate, nitroglycerin patch
	OR
	• Documented contraindication or intolerance to beta blockers, calcium channel
		Initial Approval:
		Indefinite

Medication	Authorization Guidelines/Criteria	Duration of Approval
	blockers, and long-acting nitrates	
Remicade[xlvii] Last reviewed: 09/08/14	**For patients who meet all of the following:** • Prescribed by, or in consultation with a specialist, based on indication (rheumatologist, dermatologist, gastroenterologist) • Not concurrently receiving live vaccines, other TNF-inhibitors or Kineret **In addition, for treatment of ankylosing spondylitis:** • 18 years of age or older • Trial and failure of all of the following: o 2 formulary NSAIDs within the last 60 days (or documented contraindication or intolerance to NSAIDs) o Enbrel or Humira for 3 consecutive months (or documented contraindication or intolerance to Enbrel and Humira) **In addition, for treatment of moderate to severe active Crohn's Disease:** • 6 years of age or older • Trial and failure of all of the following: o Oral corticosteroids (for moderate to severe CD) or intravenous corticosteroids (for severe and fulminant CD) for one month (or documented contraindication or intolerance to PO or IV corticosteroids) o Azathioprine or mercaptopurine for 3 consecutive months (or documented contraindication or intolerance to azathioprine or mercaptopurine) o Trial and failure of parenteral methotrexate (Adults) o Humira for 3 consecutive months (or documented contraindication or intolerance to Humira) **In addition, for treatment of fistulizing Crohn's Disease:** • 18 years of age or older • Diagnosis of fistulizing Crohn's Disease **In addition, for treatment of chronic severe plaque psoriasis:** • 18 years of age or older	**Initial Approval:** • 6 months **Renewal:** • 1 year Requires a response to treatment

Medication	Authorization Guidelines/Criteria	Duration of Approval

	• Trial and failure of all of the following:
	  ○ UVB or PUVA therapy or contraindication to therapy
	  ○ Methotrexate for 3 consecutive months (or contraindication/intolerance to methotrexate)
	  ○ Enbrel or Humira for 3 consecutive months (or contraindication/ intolerance to Enbrel and Humira)
	
	In addition, for treatment of moderate to severe psoriatic arthritis:
	• 18 years of age or older
	• Trial and failure of all of the following:
	  ○ Methotrexate for at least 3 months (or contraindication/intolerance to methotrexate)
	  ○ Enbrel or Humira for 3 months (or contraindication/intolerance to Enbrel and Humira)
	
	In addition, for treatment of moderate to severe RA:
	• 18 years of age or older
	• Will be used with methotrexate
	• Trial and failure of methotrexate and at least 1 other oral DMARD (sulfasalazine, hydroxychloroquine or leflunomide) as sequential monotherapy for 3 months each or in combination for at least 3 months (or contraindication/intolerance to methotrexate and other DMARDs)
	• Trial and failure of Enbrel or Humira for 3 months (or contraindication/intolerance to Enbrel and Humira)
	
	In addition, for treatment of moderate to severe active ulcerative colitis:
	• 6 years of age or older
	• Trial and failure of all of the following:
	  ○ Oral or rectal aminosalicylates (i.e., sulfasalazine or mesalamine) for 2 consecutive months (or contraindication/intolerance to aminosalicylates)
	  ○ Oral or intravenous corticosteroids for one month (or contraindication/intolerance to PO or IV corticosteroids)	

Medication	Authorization Guidelines/Criteria	Duration of Approval
	○ Azathioprine or mercaptopurine for 3 consecutive months (or contraindication/intolerance to azathioprine and mercaptopurine) ○ Humira for at least 2 months (Adults)	
Savella Last reviewed: 12/31/13	Non-formulary use of Savella can be approved when the following are met: • At least 17 years of age • Diagnosis of fibromyalgia (ICD-9 code = 729.10) • Failure of a compliant, 2-month trial of a formulary agent used to treat fibromyalgia (i.e., duloxetine, amitriptyline, gabapentin, cyclobenzaprine, tramadol, tramadol/acetaminophen, or fluoxetine alone or in combination with amitriptyline)	**Initial Approval:** Indefinite
Stelara[xlviii] Last reviewed: 02/01/14	**For the treatment of chronic moderate to severe plaque psoriasis:** • Patient is a candidate for phototherapy or systemic therapy • Patient is 18 years old or older • Failure of or contraindication/intolerance to a 3-month trial of phototherapy (i.e., PUVA, UVB) • Failure of or contraindication to a 3-month trial of Enbrel and Humira **For the treatment of active psoriatic arthritis:** • Failure of or contraindication/intolerance to intolerance to a 3-month trial of Enbrel and Humira • Patient is 18 years old or older	**Initial Approval:** Indefinite
Strattera Last reviewed: 04/01/15	**For patients who meet the following:** • Strattera is being prescribed for the treatment of attention-deficit hyperactivity disorder (ADHD) in a patient 6 years of age or older **AND** • The patient had failure of or intolerance to 2 formulary stimulants [e.g., amphetamine/dextroamphetamine IR/XR (Adderall), dextroamphetamine, dexmethylphenidate IR, methylphenidate/ER/SR tabs/caps (Ritalin, LA/SR), methylphenidate CD (Metadate CD)] **OR** • Patient has a confirmed history of substance abuse	Initial approval: 12 months Renewal: 12 months
Synagis[xlix] Last reviewed: 09/21/2015	**May be authorized for patients in the following groups when the criteria is met:** ○ **Preterm Infants <u>without</u> Chronic Lung Disease (CLD):** ▪ Gestational Age (GA) < 29 weeks, 0 days ▪ 12 months of age or younger at the start of RSV season ○ **Preterm Infants <u>with</u> Chronic Lung Disease (CLD):**	**Initial Approval** 1 dose per month for a maximum of 5 doses per season **Note: infants born during RSV

Medication	Authorization Guidelines/Criteria	Duration of Approval
	▪ Gestational Age (GA) < 32 weeks, 0 days ▪ Patient meets ONE of the following: ○ Is ≤12 months of age at the start of RSV season AND has required >21% oxygen for ≥28 days after birth ○ Is between 12 and 24 months of age at the start of RSV season AND continues to require medical support (e.g., supplemental oxygen, chronic systemic corticosteroid therapy, diuretic therapy, or bronchodilator therapy) within 6 months of the start of RSV season ○ **Infants with Hemodynamically Significant Congenital Heart Disease:** ▪ Patient meets ONE of the following: ○ Is between 12 and 24 months of age at the start of RSV season AND has undergone cardiac transplantation during RSV season ○ Is ≤12 months of age at the start of RSV season AND meets ONE of the following: ○ Has a diagnosis of acyanotic heart disease that will require cardiac surgery AND is currently receiving medication to control heart failure ○ Diagnosis of cyanotic heart disease AND prophylaxis is recommended by a Pediatric Cardiologist ○ Diagnosis of moderate to severe pulmonary hypertension ○ **Children with Anatomic Pulmonary Abnormalities or Neuromuscular Disorder:** ▪ Is 12 months of age or younger at the start of RSV season ▪ Disease or congenital anomaly impairs ability to clear secretions from the upper airway because of ineffective cough ○ **Immunocompromised Children:** ▪ Is 24 months of age or younger at the start of RSV season ▪ Child is profoundly immunocompromised during RSV season ***Note: The following groups are not at increased risk of RSV and should NOT receive Synagis:*** 1. Infants and children with hemodynamically insignificant heart disease (eg, secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)	season may require fewer than 5 doses**

Medication	Authorization Guidelines/Criteria	Duration of Approval
	2. Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure 3. Infants with mild cardiomyopathy who are not receiving medical therapy for the condition Children with cystic fibrosis (unless the child has clinical evidience of CLD and/or nutrional compromise in the first year of life) or Down Syndrome (unless qualifying heart disease or prematuity)	
Tarceva[l] Last reviewed: 10/01/14	**Can be authorized for patients who meet ONE the following:** • Locally advanced, unresectable or metastatic pancreatic cancer when used in combination with gemcitabine (Gemzar) for the first-line treatment • First-line treatment of advanced or metastatic NSCLC with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test (e.g. cobas® EGFR Mutation Test) • Locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen • Maintenance therapy in locally advanced or metastatic NSCLC where disease has not progressed after 4 cycles of platinum-based first-line chemotherapy	**Initial:** 1 year **Renewal**: 3 years if benefit (control of tumor growth with no evidence of increase in tumor size relative to pre-treatment report as shown by radiologic study or direct evaluation, or disease-related symptom improvement, or reduction in paraneoplastic syndromes)
Topical NSAIDs[li] Voltaren gel Pennsaid Flector patch	**Criteria for Approval:** A. Age 18 or older B History of or high risk for adverse GI effects associated with oral NSAID use AND trial and failure of celecoxib; OR C High risk for other adverse effects associated with oral NSAID use (i.e., CHF, renal failure, concomitant use of lithium); OR D. Failure on TWO formulary NSAIDs E. Diagnosis of OA of knee or hand for Voltaren gel F. Diagnosis of OA of knee for Pennsaid Note: Flector patch is only FDA approved for acute pain. Requests for Flector patch for chronic pain should be denied. If patient meets all other criteria above, offer Voltaren Gel or Pennsaid as an alternative.	**Initial Approval:** Flector Patch: 1 month All others: 1 year **Renewal:** Flector Patch: 1 month All others: 1 year

Medication	Authorization Guidelines/Criteria	Duration of Approval
	The risk factors that correlate strongly to adverse GI effects of oral NSAID use are: • History of GERD, GI bleed, or ulcer • Chronic oral steroid use • Current anticoagulant or antiplatelet use • Age 65 or greater	
Tranexamic acid[lii] Last reviewed: 04/01/15	**For patients who meet all of the following:** • Premenopausal female with diagnosis of cyclic heavy menstrual bleeding (menstrual flow >7days) • Trial and failure, intolerance or contraindication to oral NSAIDs • Trial and failure, intolerance or contraindication to oral hormonal cycle control agents or refuses oral hormonal cycle control agents • Age restriction: 12 years of age or order	**Initial Approval:** Indefinite Maximum of 30 tablets per 30 days
Trospium **Tolterodine IR** Last reviewed: 12/21/15	Tolterodine IR, Trospium and Trospium ER require step therapy with oxybutynin/oxybutynin ER for the treatment of overactive bladder. If member has filled oxybutynin/oxybutynin ER twice within the last 90-days, the prescription will automatically process at the pharmacy. Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy. In those cases, tolterodine IR, trospium or trospium ER will be authorized upon receipt of documentation to support failure of, or contraindication to oxybutynin/oxybutynin ER.	
Tysabri[liii] Last reviewed: 09/08/14	**For patients who meet all of the following:** • Must be prescribed by a gastroenterologist, based on indication • Must be prescribed for an FDA approved indication • Must be 18 years of age or older • Not taking antineoplastic, immunosuppressive, or immunomodulating agents (e.g., azathioprine, 6-mercaptopurine cyclosporine, methotrexate, TNF-inhibitors) • Will be used as monotherapy **In addition for Crohn's Disease:** • Trial and failure of a compliant regimen of oral corticosteroids (for moderate to severe CD) or intravenous corticosteroids (for severe and fulminant CD) for one month (or	**Initial Approval:** 3 months **First Renewal:** **For Crohn's Disease:** • 3 months documentation supports therapeutic benefit **Additional Renewals:** **For Crohn's Disease:** • 6 months if patient is responding

Medication	Authorization Guidelines/Criteria	Duration of Approval
	documented contraindication or intolerance to PO or IV corticosteroids); AND • Trial and failure of a compliant regimen of azathioprine or mercaptopurine for three consecutive months (or documented contraindication to azathioprine or mercaptopurine); AND • Trial and failure of a compliant regimen of Humira OR Remicade for at least 3 months (or documented contraindication)	• NOTE: If member is unable to taper off of steroids in the first 6-months, d/c Tysabri
Xeljanz[liv] Last reviewed: 4/22/15	**For patients that meet all of the following:** • Diagnosis is moderate to severely active rheumatoid arthritis • Prescribed by, or in consultation with a rheumatologist • Failure or contraindication/intolerance to methotrexate AND at least 1 other oral DMARD (sulfasalazine, hydroxychloroquine or leflunomide) for at least 3 months (in combination or each as monotherapy) • Failure or contraindication to at least 2 of the following: Enbrel, Humira or Remicade for three consecutive months • Age restriction: must be at least 18 years old	**Initial Approval:** 3 months **Renewal:** Indefinite
Xolair[lv] Last reviewed: 07/01/15	**For the treatment of moderate-severe persistent asthma:** • Prescribed by, or after consultation with a pulmonologist or allergist/immunologist • 12 years of age or older • Baseline IgE levels between 30-700 IU/ml • Weight is less than 150 kg (330 lbs) • Allergic sensitization demonstrated by positive skin testing or in vitro testing for allergen-specific IgE to an allergen that is present year round (a perennial allergen), such as dust mite, animal dander, cockroach, or molds • Evidence of reversible disease (12% or greater improvement in FEV_1 with at least a 200-ml increase or 20% or greater improvement in PEF as a result of a short-acting bronchodilator challenge • Patient should be non-smoking or actively receiving smoking cessation treatment • Patient has tried and failed conventional immunotherapy or immunotherapy is not indicated. (Immunotherapy has demonstrated efficacy against dust mites, animal dander, and pollens but not against molds and cockroach allergies). • Asthma symptoms are not adequately controlled by **high dose** inhaled corticosteroids	**Initial Approval:** **Asthma:** 6 months **Chronic urticaria:** 3 months **Renewal:** **Asthma:** 1 year Requires demonstration of clinical improvement (e.g., ↓ use of rescue medications or systemic corticosteroids, ↑ in FEV_1 from pre-treatment baseline, ↓ in number of ED visits or hospitalizations) and compliance with asthma

Medication	Authorization Guidelines/Criteria	Duration of Approval
	AND a long-acting beta agonist (LABA) for 6 months ○ Inadequate control is defined as: ▪ Requirement for systemic corticosteroids (oral, parenteral) to treat asthma exacerbations OR ▪ Daily use of rescue medications (short-acting inhaled beta-2 agonists) OR ▪ 2 ED visits or 1 hospitalization for asthma in the last 12 months OR ▪ 2-3 unscheduled office visits with documentation of intensive care for acute asthma exacerbation OR ▪ Nighttime symptoms occurring more than once a week **For the treatment of chronic urticaria:** • Symptoms continuously or intermittently present for at least 6 weeks. • Prescribed by an allergist/immunologist or dermatologist • 12 years of age or older • Currently receiving H1 antihistamine therapy • Failure of a 4 week, compliant trial of at least two high dose H1 antihistamines AND • Failure of a 4-week, compliant trial of at least one of the following medications (used in addition to H1 antihistamine therapy): ○ Leukotriene inhibitor (montelukast or zafirlukast) ○ H2 antihistamine (ranitidine or cimetidine) ○ Doxepin AND • Failure of a 4 week, compliant trial of low dose cyclosporine (used in addition to H1 antihistamine therapy) or contraindication to cyclosporine. • NOTE: Anti-inflammatory medications (dapsone, sulfasalazine, or hydroxychloroquine)	controller medications, and non-smoking status. **Chronic urticaria:** 6 months Requires demonstration of adequate symptom control (e.g., ↓ itching)

Medication	Authorization Guidelines/Criteria	Duration of Approval
	may be useful in treating urticaria, however the evidence is limited ***Note: Off-label and not covered for diagnosis of Allergic Rhinitis or food allergy***	
Zafirlukast Last reviewed: 04/01/15	**For members who meet the following:** • Diagnosis of asthma or restrictive airway disease • At least 5 years of age • Previous failure/intolerance to montelukast	**Initial Approval:** • Indefinite

[i] **Acromegaly Agents References**

1. Giustina A, C. P. (2014). Expert consensus document: A consensus on the medical treatment of acromegaly. *Nature Reviews Endocrinology* , Volume:10, Pages:243-248
2. Gold Standard, Inc. (2014, May 1). *Clinical Pharmacology*. Retrieved September 15, 2014, from Clinical Pharmacology: http://www.uptodate.com
3. Katznelson L, A. J. (2011). American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for the Diagnosis and Treatment of Acromegaly – 2011 Update. . *Endocr Pract*, 17 (Suppl 4).
4. Shlomo Melmed, M. (2013, August 27). *Treatment of acromegaly.* Retrieved September 15, 2014, from Uptodate: http://uptodate.com

[ii] **Ampyra References**

1. Drug Facts and Comparisons on-line. (www.drugfacts.com), Wolters Kluwer Health, St. Louis, MO. Updated periodically
2. www.uptodate.com. Accessed on Sept 2, 2014
3. Ampyra prescribing information. Acorda. January 2010
4. National Multiple Sclerosis Society Disease Management Consensus Statement-Recommendations from the MS Information Sourcebook; 2007 Update. National Multiple Sclerosis Society. Available at: http://www.nationalmssociety.org/For-Professionals/Clinical-Care/Managing-MS. Accessed on Sept 2, 2014

[iii] **Injectable Anticoagulants References**

1. Drug Facts and Comparisons on-line. (www.drugfacts.com), Wolters Kluwer Health, St. Louis, MO. Updated periodically
2. Clinical Pharmacology [Internet database]. Gold Standard Inc. Tampa, FL. Updated periodically.
3. PL Detail-Document, Comparison of Injectable Anticoagulants. Pharmacist's Letter/Prescriber's Letter. August 2012,26(9):260902
4. American College of Chest Physicians Evidence-Based Clinical Practice Guidelines: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: February 2012; 141(2_suppl)

[iv] Antidepressant References

1. American Psychiatric Association: Practice guideline for the treatment of patients with major depressive disorder 3rd edition. *Am J Psychiatry.* 2010;167(suppl):1-104.
2. Rush AJ, Trivedi MH, Wisniewski SR, et al. Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: A STAR*D report. *Am J Psychiatry*. 2006;163:1905-1917.

[v] **ARBs References**

1. Gold Standard. (2010, April 9). Benicar. Tampa, Florida. Retrieved November 1, 2014, from http://www.clinicalpharmacology-ip.com/Forms/Monograph/monograph.aspx?cpnum=2750&sec=monindi&t=0

2. Gold Standard. (2012, April 19). Tektuna. Tampa, Florida, USA. Retrieved November 1, 2014, from http://www.clinicalpharmacology-ip.com/Forms/Monograph/monograph.aspx?cpnum=3555&sec=monindi&t=0
3. Gold Standard. (2014, May 29). Valsartan. Tampa, Florida, USA. Retrieved November 1, 2014, from http://www.clinicalpharmacology-ip.com/Forms/Monograph/monograph.aspx?cpnum=2119&sec=monindi&t=
4. James PA, Oparil S, Carter BL, et al. 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults: Report From the Panel Members Appointed to the Eighth Joint National Committee (JNC 8). JAMA. 2014;311(5):507-520. doi:10.1001/jama.2013.284427.

[vi] Long-Acting Injectable Atypical Antipsychotics References:

1. Risperidal Consta [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; Revised 4/2014
2. Invega Sustenna [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; Revised 11/2014
3. Abilify Maintena [package insert]. Tokyo. Japan: Otsuka Pharmaceutical Co., Ltd.:12/2014
4. Zyprexa Relprevv [package insert]. Indianapolis, IN: LillyUSA, LLC: Revised 12/19/2014
5. Kishimoto T, Robenzadeh A, Leucht C, et al. Long-acting injectable vs oral antipsychotics for relapse prevention in schizophrenia: a meta-analysis of randomized trials. Schizophr Bull. 2014; 40 (1):192-213.

[vii] **Botulinum Toxins References**

1. Gold Standard. (2011, July 25). Xeomin. Tampa, Florida, USA. Retrieved September 2, 2014, from http://www.clinicalpharmacology-ip.com/Forms/Monograph/monograph.aspx?cpnum=3701&sec=monindi&t=0

[viii] **Cambia References**

1. Gold Standard. (2014, September 2). Cambia. Tampa, Florida, USA. Retrieved September 2, 2014, from http://www.clinicalpharmacology-ip.com/Forms/Monograph/monograph.aspx?cpnum=183&sec=monindi&t=0
2. Walters Kluwer Health Inc. (2014, March). Cambia. St Louis, Missouri, USA. Retrieved September 2, 2014, from http://online.factsandcomparisons.com/MonoDisp.aspx?monoID=fandc-hcp12749&quick=889109%7c5&search=889109%7c5&isstemmed=True&NDCmapping=-1&fromTop=true#firstMatch

[ix] **Celecoxib References**

1. Standard, G. (2013, May 13). Celebrex. Tampa, Florida, USA. Retrieved September 2, 2014, from http://www.clinicalpharmacology-ip.com/Forms/Monograph/monograph.aspx?cpnum=689&sec=monindi&t=0

[x] **Cimzia References**

1. Cimzia (prescribing information). http://www.cimzia.com/ (accessed March 4, 2014).
2. Farrel, R. "Overview of the medical management of severe or refractory Crohn disease in adults." UpToDate.http://www.uptodate.com (accessed March 4, 2014).
3. Gold Standard, Inc. Cimzia. Clinical Pharmacology [database online]. Available at:http://www.clinicalpharmacology.com (accessed February 26, 2014)
4. Korzenik, Joshua R. "Certolizumab pegol for treatment of Crohn disease in adults." UpToDate. http://www.uptodate.com (accessed March 4, 2014).
5. Lockwood, CJ. "Treatment of rheumatoid arthritis resistant to initial DMARD therapy in adults." UpToDate. http://www.uptodate.com (accessed March 4, 2014).
6. Singh, JA, et al. "2012 Update of the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents for the Treatment of Rheumatoid Arthritis. ." Arthritis Care & Research, May 2012.

[xi] **CSF Agents**

1. Leukine. In:DRUGDEX System (Micromedex 2.0). Greenwood Village, CO: Truven Health Analytics; c1974-2014. http://nv-ezproxy.roseman.edu:3305/micromedex2/librarian/ND_T/evidencexpert/ND_PR/evidencexpert/CS/58BC09/ND_AppProduct/evidencexpert/DUPLICATIONSHIELDSYNC/62165D/ND_PG/evidencexpert/ND_B/evidencexpert/ND_P/evidencexpert/PFActionId/evidencexpert.IntermediateToDocumentLink?docId=1323&contentSetId=31&title=SARGRAMOSTIM&servicesTitle=SARGRAMOSTIM. Accessed April 9, 2015.

2. Larson, RA. Use of granulocyte colony stimulating factors in adult patients with chemotherapy-induced neutropenia and conditions other than acute leukemia, myelodysplastic syndrome, and hematopoietic cell transplantation. In: UpToDate, Drews, RE (Ed), Savarese, DMF (Ed), UpToDate, Waltham, MA. (Accessed on April 25, 2014.)
3. Friel, TJ, Scadden, DT. Hematologic manifestations of HIV infection: Neutropenia. In: UpToDate, Boxer, L (Ed), Tirnauer, JS (Ed), UpToDate, Waltham, MA. (Accessed on April 24, 2014.)
4. Berliner, N; Management of the adult with non-chemotherapy-induced neutropenia. In: UpToDate, Boxer, LA (Ed), Drews, RE (Ed), Tirnauer, JS (Ed), UpToDate, Waltham, MA. (Accessed on April 24, 2014.).
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2014. URL: http://www.clinicalpharmacology.com. Updated December, 2009.
6. Neupogen. In: DRUGDEX System (Micromedex 2.0). Greenwood Village, CO: Truven Health Analytics; c1974-2014. http://nv-ezproxy.roseman.edu:3305/micromedex2/librarian/ND_T/evidencexpert/ND_PR/evidencexpert/CS/0A10B0/ND_AppProduct/evidencexpert/DUPLICATIONSHIELDSYNC/E06E15/ND_PG/evidencexpert/ND_B/evidencexpert/ND_P/evidencexpert/PFActionId/evidencexpert.IntermediateToDocumentLink?docId=1007&contentSetId=31&title=FILGRASTIM&servicesTitle=FILGRASTIM. (Accessed on April 24, 2014)
7. Neulasta. In: DRUGDEX System (Micromedex 2.0). Greenwood Village, CO: Truven Health Analytics; c1974-2014. http://nv-ezproxy.roseman.edu:3305/micromedex2/librarian/ND_T/evidencexpert/ND_PR/evidencexpert/CS/7B6E4F/ND_AppProduct/evidencexpert/DUPLICATIONSHIELDSYNC/3E7447/ND_PG/evidencexpert/ND_B/evidencexpert/ND_P/evidencexpert/PFActionId/evidencexpert.IntermediateToDocumentLink?docId=3316&contentSetId=31&title=PEGFILGRASTIM&servicesTitle=PEGFILGRASTIM.
8. Neumega. . In: DRUGDEX System (Micromedex 2.0). Greenwood Village, CO: Truven Health Analytics; c1974-2014. http://nv-ezproxy.roseman.edu:3305/micromedex2/librarian/ND_T/evidencexpert/ND_PR/evidencexpert/CS/B11C95/ND_AppProduct/evidencexpert/DUPLICATIONSHIELDSYNC/2B8F26/ND_PG/evidencexpert/ND_B/evidencexpert/ND_P/evidencexpert/PFActionId/evidencexpert.IntermediateToDocumentLink?docId=1757&contentSetId=31&title=OPRELVEKIN&servicesTitle=OPRELVEKIN. (Accessed on April 9, 2015).
9. Neulasta (pegfilgrastim) package insert. Thousand Oaks, CA: Amgen Inc. February 2014.
10. National Comprehensive Cancer Network® (NCCN), "Clinical Practice Guidelines in Oncology™: Myeloid Growth Factors," Version 2.2014. Available at http://www.nccn.org/professionals/physician_gls/pdf/myeloid_growth.pdf.

[xii] **Cystic Fibrosis Medications References**

1. Katkin, JP. Cystic fibrosis: Clinical manifestations and diagnosis. In: UpToDate, Mallory, GB (Ed), UpToDate, Waltham, MA. (Accessed on February 24, 2014.).;
2. Simon, RH. Cystic fibrosis: Antibiotic therapy for lung disease. In: UpToDate, Mallory, GB (Ed), UpToDate, Waltham, MA. (Accessed on February 24, 2014.).;
3. Tobi Podhaler [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2013.;
4. Cayston [package insert]. Foster City, CA: Gilead Sciences, Inc; 2012;
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2014. URL: http://www.clinicalpharmacology.com. Updated October, 2010.;
6. Micromedex Healthcare Series. DRUGDEX System. Greenwood Village, CO: Truven Health Analytics, 2014. http://www.thomsonhc.com/. Accessed March 21, 2014.;
7. Fakhoury, K; Kanu, A. Management of bronchiectasis in children without cystic fibrosis. In: UpToDate, Mallory, GB (Ed), UpToDate, Waltham, MA. (Accessed on March 21, 2014.).
8. Amorim , A. (2013). New advances in the therapy of non-cystic fibrosis bronchiectasis. Revista Portuguesa de Pneumologia, 19(6)(266), 266-275. Retrieved from http://www.elsevier.pt/en/revistas/revista-portuguesa-pneumologia-320/artigo/new-advances-in-the-therapy-of-non-cystic-fibrosis-90251782
9. Mogayzel P, Naureckas E, Robinson K, et al. Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. *Am J Respir Crit Care Med*. 2013 Apr 1;187(7):680-9.
10. Pulmozyme [package insert]. San Francisco, CA: Genentech, Inc; 2014;
11. Kalydeco [package insert]. Boston, MA: Vertex Pharmaceuticals Incorporated; 2015;
12. Tobi-tobramycin solution [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2014;
13. Bethkis-tobramycin solution [package insert]. Cary, NC: Chiesi USA, Inc.; 2014;

[xiii] **Daraprim References**

1. Gandhi RT. Toxoplasmosis in HIV-infected patients. Waltham, MA: UptoDate; Last modified September 21, 2015. http://www.uptodate.com/contents/toxoplasmosis-in-hiv-infected-patients?source=search_result&search=daraprim&selectedTitle=6%7E47. Accessed September 25, 2015.
2. Thomas CF, Limper AH. Treatment and prevention of Pneumocystis pneumonia in non-HIV-infected patients. Waltham, MA: UptoDate; Last modified January 6, 2015. http://www.uptodate.com/contents/treatment-and-prevention-of-pneumocystis-pneumonia-in-non-hiv-infected-patients?source=search_result&search=pneumocystis&selectedTitle=4%7E150. Accessed September 25, 2015.
3. Sax PE. Treatment and prevention of Pneumocystis infection in HIV-infected patients. Waltham, MA: UptoDate; Last modified August 27, 2015. http://www.uptodate.com/contents/treatment-and-prevention-of-pneumocystis-infection-in-hiv-infected-patients?source=search_result&search=pneumocystis&selectedTitle=2%7E150#H2384560994. Accessed September 25, 2015.

[xiv] Daliresp References

1. *Global Strategy for the Diagnosis, Management and Prevention of COPD*, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2015. Available from: http://www.goldcopd.org

[xv] Direct Renin Inhibitors References

1. Gold Standard. (2011, January 14). Aliskiren; Amlodipine; Hydrochlorothiazide. Tampa, Florida, USA. Retrieved March 20, 2015, from http://www.clinicalpharmacology-ip.com
2. Gold Standard. (2012, February 1). Aliskiren; Amlodipine. Tampa, Florida, USA. Retrieved March 20, 2015, from http://www.clinicalpharmacology-ip.com
3. Gold Standard. (2010, February 12). Aliskiren; Hydrochlorothiazide. Tampa, Florida, USA. Retrieved March 20, 2015, from http://www.clinicalpharmacology-ip.com
4. Gold Standard. (2013, September 18). Aliskiren. Tampa, Florida, USA. Retrieved March 20, 2015, from http://www.clinicalpharmacology-ip.com
5. James PA, Oparil S, Carter BL, et al. 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults: Report From the Panel Members Appointed to the Eighth Joint National Committee (JNC 8). JAMA. 2014;311(5):507-520. doi:10.1001/jama.2013.284427.

[xvi] **Duavee References**

1. Agency for Healthcare Research and Quality (AHRQ). (2014, Febuary 7). *Management of menopausal symptoms.* Retrieved September 29, 2014, from National Guidleine Clearinghouse: Http://www.guideline.gov/content.aspx?id-47751
2. Duavee ® [package insert] 10/2013. Philadelphia, PA: Wyeth Pharmaceuticals Inc.
3. Gold Standard, Inc. (2014, September 29). Duavee. Clinical Pharmacology [database online]. Retrieved from http://www.clinicalpharmacology.com

[i] **Elidel/tacrolimus References**

1. Gold Standard. (2013, September 26). Elidel. Tampa, Florida, USA. Retrieved August 1, 2015, from http://www.clinicalpharmacology-ip.com/Forms/Monograph/monograph.aspx?cpnum=2670&sec=monindi&t=0
2. Gold Standard. (2013, October 16). Tacrolimus. Tamp, Florida, USA. Retrieved August 1, 2015, from http://www.clinicalpharmacology-ip.com/Forms/Monograph/monograph.aspx?cpnum=587&sec=monindi&t=0

[xvii] **Emend**

1. Basch E, Prestrud AA, Hesketh PJ, et al, "Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update," J Clin Oncol, 2011, 29(31):4189-98. [PubMed21947834]
2. National Comprehensive Cancer Network® (NCCN), "Clinical Practice Guidelines in Oncology™: Antiemesis," Version 1.2013. Available athttp://www.nccn.org/professionals/physician_gls/PDF/antiemesis.pdf
3. Emend capsules (aprepitant) package insert. Whitehouse Station, NJ: Merck & Co., Inc
4. Clinical Pharmacology [Internet database]. Gold Standard Inc. Tampa, FL. Updated periodically. Accessed online 04/07/2015

[xviii] **Enbrel/Humira References**

1. Enbrel [package insert]. Thousand Oaks, CA: Immunex Corporation; November 2013.
2. Humira [package insert]. Abbott Park, IL: AbbVie Inc; May 2014.
3. Gold Standard. (2013, October 29). Enbrel. Tampa, Florida, USA. Retrieved September 2, 2014, from http://www.clinicalpharmacology-ip.com/Forms/Monograph/monograph.aspx?cpnum=2143&sec=monindi&t=0
4. Gold Standard. (2013, October 29). Humira. Tampa, Florida, USA. Retrieved September 2, 2014, from http://www.clinicalpharmacology-ip.com/Forms/Monograph/monograph.aspx?cpnum=2782&sec=monindi&t=0
5. Ringold, S, et al; 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis: Recommendations for the Medical Therapy of Children With Systemic Juvenile Idiopathic Arthritis and Tuberculosis Screening Among Children Receiving Biologic Medications. *Arthritis Rheum*. 2013;65(10):2499-2512.
6. Beukelman, T, et al. American College of Rheumatology 2011 Recommendations for the Treatment of Juvenile Idiopathic Arthritis: Initiation and Safety Monitoring of Therapeutic Agents for the Treatment of Arthritis and Systemic Features. Arthritis Care & Research. 2011: 63(4):465-482.
7. Singh JA, Furst D, Bharat A et al. 2012 Update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care & Research 2012: 64 (5):625-639.
8. Yu, DT, et al, "Assessment and treatment of ankylosing spondylitis in adults" UpToDate. http://www.uptodate.com (accessed September, 2014).
9. Gladman, DD, et al, "Treatment of psoriatic arthritis" UpToDate. http://www.uptodate.com (accessed September, 2014).
10. Schur, PH, et al, "Initial treatment of moderately to severely active rheumatoid arthritis in adults" UpToDate. http://www.uptodate.com (accessed September, 2014).
11. Schur, PH, et al, "Treatment of rheumatoid arthritis resistant to initial DMARD therapy in adults " UpToDate. http://www.uptodate.com (accessed September, 2014).
12. Lehman, TJ, et al, "Systemic onset juvenile idiopathic arthritis: Treatment" UpToDate. http://www.uptodate.com (accessed September, 2014).
13. Feldman, SR , "Treatment of psoriasis" UpToDate. http://www.uptodate.com (accessed September, 2014).
14. Farrell, RJ, et al, "Overview of the medical management of severe or refractory Crohn disease in adults" UpToDate. http://www.uptodate.com (accessed September, 2014).
15. MacDermott, RP, "Immunomodulator therapy in Crohn disease" UpToDate. http://www.uptodate.com (accessed September, 2014).Cohen, RD, et al, "Approach to adults with steroid-refractory and steroid-dependent ulcerative colitis" UpToDate. http://www.uptodate.com (accessed September, 2014).
16. Brooks, M. (2014, September 25). Adalimumab (Humira) Gets FDA Nod for Children With Crohn's. Retrieved September 25, 2014, from medscape: http://www.medscape.com

[xix] **Entyvio References**

1. Cohen RD, S. A. (2014, June 11). Approach to adults with steroid-refractory and steroid-dependent ulcerative colitis. Retrieved September 30, 2014, from Uptodate: http://www.uptodate.com
2. Farrell RJ, P. M. (2014, June 11). Overview of the medical management of severe or refractory Crohn disease in adults. Retrieved September 30, 2014, from UptoDate: http://www.uptodate.com
3. Gold Standard. (2014, May 28). Vedolizumab. Retrieved Septemember 29, 2014, from Clinical Pharmacology: http://www.clinicalpharmacology.com.
4. MacDermott RP. (2014, July 22). Management of mild to moderate ulcerative colitis. Retrieved September 30, 2014, from Uptodate: http://www.uptodate.com
5. Peppercorn MA, F. R. (2014, June 11). Management of severe ulcerative colitis. Retrieved September 30, 2014, from Uptodate: http://www.uptodate.com
6. Takeda. (2014, May). Entyvio prescribing information.
7. Wolters Kluwer. (n.d.). Vedolizumab: Drug Information Lexicomp. Retrieved September 30, 2014, from Uptodate: http://www.uptodate.com

[xx] **ESA Agents References**

1. Gold Standard, Inc. Epogen, Procrit, Aranesp. Clinical Pharmacology [database online]. Available at: http://www.clinicalpharmacology.com. Accessed September 03, 2014.
2. KDOQI Clinical Practice Guideline and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target. Available at http://www.kidney.org/professionals/KDOQI/guidelines_anemiaUP/index.htm. Accessed September 03, 2014

3. Procrit [package insert]. Raritan, NJ: Ortho Biotech Products,.; June 2011, accessed at http://procrit.com/sites/default/files/shared/OBI/PI/ProcritBooklet.pdf#page=1
4. National Comprehensive Cancer Network Practice Guidelines in Oncology v.1.2009 Myelodysplastic Syndromes. Available at: http://www.nccn.org/professionals/physician_gls/PDF/mds.pdf. Accessed September 03, 2014.
5. Clinical Policy Bulletin: Erythropoiesis Stimulating Agents, Available at: http://www.aetna.com/cpb/medical/data/100_199/0195.html Accessed September 03, 2014.
6. National Heart, Lung, and Blood Institute. Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7). Available at: http://www.nhlbi.nih.gov/health-pro/guidelines/current/hypertension-jnc-7/complete-report.htm. Accessed September 03, 2014.
7. Yee HS, Currie SL, Darling JM, et al. Management and treatment of hepatitis C viral infection: Recommendations from the Department of Veterans Affairs Hepatitis C Resource Center Program and the National Hepatitis C Program Office. *Am J Gastroenterol* 2006;101:2360-2378.
8. FDA Drug Safety Communication: Modified dosing recommendations to improve the safe use of Erythropoiesis-Stimulating Agents (ESAs) in chronic kidney disease, 6/24/11, accessed at: http://www.fda.gov/Drugs/DrugSafety/ucm259639.htm on September 03, 2014

[xxi] **Gleevec References**

1. Gleevec [full prescribing information]. East Hanover, NJ: Novartis U.S.; Revised 02/2013
2. NCCN Drugs and Biologics Compendium http://www.nccn.org/professionals/drug_compendium/MatrixGenerator/Matrix.aspx?AID=18 accessed 3/18/2010, 3/24/11, 3/27/12
3. National Comprehensive Cancer Network. Practice Guidelines in Oncology – Chronic Myelogenous Leukemia, Version I.2014 09/09/13.
4. National Comprehensive Cancer Network. Practice Guidelines in Oncology – Acute Lymphoblastic Leukemia, Version I.2013 03/25/13.
5. Alvarado Y, Apostolidou E, Swords R, Giles FJ. Emerging therapeutic options for Philadelphia-positive acute lymphocytic leukemia. *Expert Opin Emerg Drugs*. 2007 Mar;12(1):165-79
6. National Institute for Clinical Excellence (NICE). Imatinib for the treatment of unresectable and/or metastatic gastro-intestinal stromal tumours. London (UK): National Institute for Clinical Excellence (NICE); 2004 Oct. 38 p.
7. Pardanani A, Ketterling RP, Brockman SR, et al: CHIC2 deletion, a surrogate for FIP1L1-PDGFRA fusion, occurs in systemic mastocytosis associated with eosinophilia and predicts response to imatinib mesylate therapy. Blood 2003 Nov 1; 102(9): 3093-6
8. McArthur G. Dermatofibrosarcoma Protuberans: Recent Clinical Progress. Ann Surg Oncol. 2007 Jul 24
9. Fletcher S, Bain B. Diagnosis and treatment of hypereosinophilic syndromes. Curr Opin Hematol. 2007 Jan;14(1):37-42

[xxii] **GnRH Agonists References**

1. American College of Obstetricians and Gynecologists (ACOG). Management of endometriosis. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2010 Jul. (ACOG practice bulletin; no. 1114). Available at : http://www.guideline.gov/content.aspx?id=16327
2. Gold Standard, Inc. Eligard, Lupron, Synarel and Supprelin. Clinical pharmacology [database online] Available at http://www.clinicalpharmacology.com Accessed Jun 2013.
3. Gold Standard, Inc. Trelstar, Zoladex, and Vantas. Clinical pharmacology [database online] Available at http://www.clinicalpharmacology.com Jun 2013.
4. Kaplowitz, MD, PhD, Paul B. Precocious Puberty. emedicine [database online] Available at http://emedicine.medscape.com/article/924002-overview. Accessed April 6, 2010.
5. Lupron Depot [Prescribing Information]: AbbVie Inc, North Chicago , IL; Jan 2013. http://www.rxabbvie.com/pdf/lupron3month11_25mg.pdf. and http://www.rxabbvie.com/pdf/lupron3_75mg.pdf. Accessed Jun 2013
6. Lupron Depot Ped [Prescribing Information]: AbbVie Inc., North Chicago, IL; April 2013. http://www.rxabbvie.com/pdf/lupronpediatric.pdf. Accessed Jun 2013
7. Supprelin LA [Prescribing Information]: Endo Pharmaceuticals Inc., Malvern, PA; April, 2013. http://www.endo.com/File%20Library/Products/Prescribing%20Information/supprelinla.pdf. Accessed Jun 2013;
8. Synarel [Prescribing Information]: Pfizer; New York, NY; Jan 2012. http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/019886s030lbl.pdf. Accessed June 2013
9. Eligard [Prescibing Informationt]: Bridgewater, NJ: Sanofi-Aventis US LLC; Feb 2013. http://products.sanofi.us/eligard/eligard.html. Accessed June 2013

10. Zoladex [Prescribing Information]: AstraZeneca Pharmaceuticals LP, Wilmington DE. 6/2013. http://www1.astrazeneca-us.com/pi/zoladex3_6.pdf. and http://www1.astrazeneca-us.com/pi/zoladex10_8.pdf; Accessed Jun 2013.
11. Vantas [Prescribing Information]: Endo Pharmaceuticals Inc., Malvern, PA; Rev Apr 2013. http://www.endo.com/File%20Library/Products/Prescribing%20Information/vantas.pdf. Accessed Jun 2013
12. Trelstar [Prescribing Information]: Watson Pharma, Inc., Parsippany, NJ: Mar 2013. http://pi.actavis.com/data_stream.asp?product_group=1684&p=pi&language=E. Accessed Jun 2013
13. ACOG Updates Guideline on Diagnosis and Treatment of Endometriosis. http://www.aafp.org/afp/2011/0101/p84.html. accessed 8/23/12
14. National Guideline Clearing House Management of Endometriosis. Available http://guidelines.gov/content.aspx?id=16327; accessed 8/23/12
15. National Guideline Clearing House Alternatives to hysterectomy in the management of leiomyoma. http://guidelines.gov/content.aspx?id=13318; accessed 8/23/12 for fibroids
16. Schenken, RS: Treatment of endometriosis. In UpToDate, Barbieri, RL (Ed), UpToDate, Waltham, MA, Jan 2013.
17. Saenger, P: Treatment of precocious puberty. In UpToDate, Snyder, PJ (Ed), UpToDate, Waltham, MA, April 2013.
18. ESHRE Guideline for the Diagnosis and Treatment of Endometriosis. http://guidelines.endometriosis.org/concise-pain.html; Accessed 8/23/2012
19. Pain Management of Endometrosis. http://www.acog.org/About_ACOG/News_Room/News_Releases/2010/Pain_Management_of_Endometriosis. Accessed 8/23/2012
20. Dysfunctional Uterine Bleeding: http://emedicine.medscape.com/article/257007-medication#8. Accessed 9/7/2012
21. NCCN Prostate Cancer Treatment Guidelines for Patients: http://www.psa-rising.com/download/nccnguidelines.pdf. Accessed 9/7/12

[xxiii] **Growth Hormone References:**

1. A, R. (2014, August). Growth hormone treatment for children born small for gestational age. Retrieved Septement 15, 2014, from Uptodate.
2. Cook DM, Y. K. (2009). American Association of Clinical Endocrinologists. American Association of Clinical Endocrinologists medical guidelines for clinical practice for growth hormone use in growth-hormone-deficient adults and transition Patients – 2009 Update. Endocrine Practice, 15 (Suppl 2):1-27.
3. Gharib H, C. D. (2003). American Association of Clinical Endocrinologists. American Association of Clinical Endocrinologists medical guidelines for clinical practice for growth hormone use in adults and children--2003 update. Endocrine Practice, 9:65-76.
4. Gold Standard, Inc. (2011, July 26). Somatropin, rh-GH . Retrieved September 2014, 2014, from Clinical Pharmacology: www.clinicalpharmacolgy.com
5. KK, H. (2007). Consensus guidelines for the diagnosis and treatment of adults with GH deficiency II: a statement of the GH Research Society in association with the European Society for Pediatric Endocrinology, Lawson Wilkins Society, European Society of Endocrinology, J. European Journal of Endocrinology , 157 695–700.
6. MJ, G. (n.d.). Treatment of Treatment of HIV-associated lipodystrophy. Retrieved September 15 , 2014, from UpToDate: http://www.uptodate.com
7. Molitch ME, C. D. (2011). Endocrine Society. Evaluation and treatment of adult growth hormone deficiency: an Endocrine Society clinical practice guideline. Journal of Clinical Endocrinology and Metabolism, Jun;96(6):1587-609.
8. P, S. (2014, August). Growth hormone deficiency in adults. Retrieved September 15, 2014, from UptoDate: http://www.uptodate.com
9. Serono. (2012, December). Zorbitive Prescribing Information.
10. Serono. (2014, June). Serostim Prescribing Information.
11. TheraTechnologies. (2014, June). Egrifta Prescribing Information.

[xxiv] **Hemophilia Factor References:**

1. Blanchette VS. Prophylaxis in the haemophilia population. *Haemophilia.* 2010;16:181-188.
2. Fischer K, Van der Boom JG, Molho P, Negrier C, Mauser-Bunschoten EP, Roosendaal G, et al. Prophylactic versus on-demand treatment strategies for severe haemophilia: a comparison of costs and long-term outcome. *Haemophilia.* 2002;8:745-752.
3. Hay CRM. Prophylaxis in adults with haemophlia. *Haemophilia*. 2007;13:10-15.
4. Manco-Johnson MJ, Abshire TC, Shapiro AD, Riske B, Hacker MR, Kilcoyne R, et al. Prophylaxis versus episodic treatment to prevent joint disease in boys with severe hemophilia. *N Eng J Med*. 2007;357:535-544.

5. National Hemophilia Foundation Medical and Scientific Advisory Council. MASAC recommendation concerning prophylaxis (regular administration of clotting factor concentrate to prevent bleeding), document #179. November 2007. http://www.hemophilia.org/NHFWeb/Resource/StaticPages/menu0/menu5/menu57/masac179.pdf. Accessed October 24, 2011.
6. Walsh CE, Valentino LA. Factor VIII prophylaxis for adult patients with severe haemophilia A: results of a US survey of attitudes and practices. *Haemophilia.* 2009;15:1014-1021.
7. World Federation of Hemophilia. Guidelines for the management of hemophilia. 2005; 1-56. Available at www.wfh.org. Accessed October 24, 2011.
8. National Hemophilia Foundation. www.hemophilia.org. Accessed March 5, 2012.

[xxv] **Hetlioz References**

1. Clinical Pharmacology [Internet database]. Gold Standard Inc. Tampa, FL. Updated periodically.
2. Hetlioz™ [package insert]. Washington, D.C.: Vanda Pharmaceuticals, Inc.; January 2014
3. Vanda Pharmaceuticals. Efficacy and Safety of Tasimelteon Compared With Placebo in Totally Blind Subjects With Non-24-Hour Sleep-Wake Disorder. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2014 Mar 20]. Available from: http://www.clinicaltrials.gov/ct2/show/NCT01163032 NLM Identifier: NCT01163032.

[ii] **Hyaluronic Acid References:**

1. Synvisc One Prescribing Information, Genzyme. Sept, 2014.
2. Supartz Prescribing information, Smith & Nephew. Sept, 2014.
3. Hyalgan Prescribing information, Sanofi-Synthelabo. Sept, 2014.
4. Orthovisc Prescribing information, Depuy Mitek. Sept, 2014.
5. Euflexxa Prescribing information, Ferring Pharmaceuticals. Sept, 2014
6. American Academy of Orthopedic Surgeons. (Resource of the World Wide Web). http://www.aaos.org/research/guidelines/OAKSummaryofRecommendations.pdf. Accessed on Sept 2, 2014
7. www.uptodate.com. Accessed on Sept 2, 2014.
8. Drug Facts and Comparisons on-line. (www.drugfacts.com), Wolters Kluwer Health, St. Louis, MO. Updated periodically
9. Clinical Pharmacology [Internet database]. Gold Standard Inc. Tampa, FL. Updated periodically.

[xxvi] **Hyperlipidemia Medication References**

1. Berglund L, et al. Evaluation and Treatment of Hypertriglyceridemia: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2012; 97(9): 2969–2989.
2. Cuchel M, et al. Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management. A position paper from the Concensus Panel on Familial Hypercholesterolaemia of the European Atherosclerosis Society. *Eur Heart J*. 2014;
3. Goldberg AC, et al. Familial Hypercholesterolemia: Screening, diagnosis and management of pediatric and adult patients Clinical guidance from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. *J Clin Lipidol.* 2011;(5):S1-S8.
4. Jacobson TA, et al. National lipid association recommendations for patient-centered management of dyslipidemia: Part 1 – executive summary. *J Clin Lipidol*. 2014;8:473-488.
5. Robinson JG. Management of familial hypercholesterolemia: a review of the recommendations from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. *J Manag Care Pharm*. 2013;19(2):139-49.
6. Stone NJ, et al. 2013 ACC/AHA blood cholesterol guideline. *Circulation*. 2013;
7. Watts GF, et al. Integrated guidance on the care of familial hypercholesterolaemia from the International FH Foundation. *Int J Cardiol*. 2014;
8. Crestor® [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; Revised June 2015.
9. Epanova ® [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; Revised September 2014.
10. Juxtapid ® [package insert]. Cambridge, MA: Aegerion Pharmaceuticals, Inc.; Revised April 2015.
11. Kynamro ® [package insert]. Cambridge, MA: Genzyme Corporation; Revised April 2015.

12. Livalo® [package insert]. Indianapolis, IN: Eli Lilly and Company; Revised August 2011.
13. Lovaza ® [package insert]. RTP, NC: GlaxoSmithKline; Revised September 2014.
14. Vascepa ® [package insert]. Bedminster, NJ: Amarin Pharmaceuticals; Revised May 2014.
15. Zetia ® [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; Revised September 2013.

[xxvii] **Idiopathic Pulmonary Fibrosis Agents References**

5. Esbriet [package insert]. Brisbane, CA: InterMune, Inc.; 2014.
6. National Clinical Guideline Centre. Idiopathic pulmonary fibrosis. The diagnosis and management of suspected idiopathic pulmonary fibrosis. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Jun. 32 p. (Clinical guideline; no. 163).
7. National Institute for Health and Care Excellence (NICE). Pirfenidone for treating idiopathic pulmonary fibrosis. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Apr. 66 p.
8. Raghu G, Collard HR, Egan JJ et al. for the ATS/ERS/JRS/ALAT Committee on Idiopathic Pulmonary Fibrosis. An Official ATS/ERS/JRS/ALAT Statement: Idiopathic Pulmonary Fibrosis: Evidence-based Guidelines for Diagnosis and Management. Am J Respir Crit Care Med 2011; 183: 788-824.
9. Ofev [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; Revised October 2014.

[xxviii] **Interferon References:**

1. American Association for the Study of Liver Diseases. (2014, August 11). Recommendations for Testing, Managing, and Treating Hepatitis C. Retrieved September 13, 2014, from American Association for the Study of Liver Diseases and the Infectious Diseases Society of America: http://www.hcvguidelines.org/fullreport
2. Gold Standard, Inc. (2013, October 13). Interferon Gamma-1b. Clinical Pharmacology. Tampa, FL, USA. Retrieved September 13, 2014, from http://www.clinicalpharmacology-ip.com
3. Gold Standard, Inc. (2014, April 22). Interferon Alfa-2b. Clinical Pharmacology. Tampa, FL, USA. Retrieved from http://www.clinicalpharmacology-ip.com
4. Gold Standard, Inc. (2014, April 22). Interferon Alfacon-1. Clinical Pharmacology. Tampa, FL, USA. Retrieved from http://www.clinicalpharmacology-ip.com
5. Gold Standard, Inc. (2014, August 18). Peginterferon Alfa-2b. Clinical Pharmacology. Tampa, FL, USA. Retrieved September 13, 2014, from http://www.clinicalpharmacology-ip.com
6. Lok, A. S., & McMahon, B. J. (2009, September). Chronic Hepatitis B: Update 2009. Retrieved September 14, 2014, from American Association for the Study of Liver Diseases: www.aasld.org
7. National Comprehensive Cancer Network. (2014, April 22). Melanoma. Retrieved September 13, 2014, from NCCN Guidelines: http://www.nccn.org
8. National Comprehensive Cancer Network. (2014, August 22). Non-Hodgkin's Lymphomas. Retrieved September 13, 2014, from NCCN Guidelines : http://www.nccn.org
9. Rosenzweig, S. D., & Holland, S. M. (2014, January 24). Chronic granulomatous disease: Treatment and prognosis. Retrieved September 13, 2014, from Up To Date: http://www.uptodate.com
10. Schering Corporation. (2014, August). Infergen. Whitehouse Station, NJ, USA.
11. Sosman, J. A. (2014, June 10). Adjuvant immunotherapy for melanoma. Retrieved September 13, 2014, from Up To Date: http://www.uptodate.com
12. Tallman, M. S. (2014, February 13). Treatment of hairy cell leukemia. Retrieved September 13, 2014, from Up To Date: http://www.uptodate.com
13. The NIH Osteoporosis and Related Bone Diseases ~ National Resource Center. (2012, December). Osteopetrosis Overview. Retrieved from http://www.niams.nih.gov/health_info/bone/
14. Thomson Micromedex. (2014, August 08). DRUGDEX System. Retrieved September 13, 2014, from Interferon Gamma: http://www.thomsonhc.com

[xxix] **Intravaginal Progesterone Products References**

1. Norwitz, Errol R. Progesterone supplementation to reduce the risk of spontaneous preterm birth. In: UpToDate, Lockwood, Charles J (Ed), Barss, Vanessa A (Ed), UpToDate, Waltham, MA, Apr 8, 2015.
2. Berghella, Vincenzo. Second trimester evaluation of cervical length for prediction of spontaneous preterm birth. In: UpToDate, Lockwood, Charles J (Ed), Levine Deborah (Ed), Barss, Vanessa A (Ed), UpToDate, Waltham, MA, Feb 17, 2015.

3. Tulandi, Togas, Al-Fozan, Haya M. Evaluation of couples with recurrent pregnancy loss. In: UpToDate, Lockwood, Charles J (Ed), Eckler, Kristin (Ed), UpToDate, Waltham, MA Mar 23, 2015.

[xxx] **Lidocaine Patch References**

1. Lidoderm Prescribing Information. Endo Pharmaceuticals Inc., Chadds Ford, PA. March 2010.
2. Bril V, England J, Franklin GM, et al. Evidence-based guideline: Treatment of painful diabetic neuropathy. *Neurology.* 2011;76:1758–1765.

[xxxi] **Lyrica References**

1. Decker, J. E., & Hergenroeder, A. C. (2012, September 21). *Overview of cervical spinal cord and cervical peripheral nerve injuries in the child or adolescent athlete.* Retrieved from Up To Date: http://www.uptodate.com/contents/overview-of-cervical-spinal-cord-and-cervical-peripheral-nerve-injuries-in-the-child-or-adolescent-athlete?source=preview&search=pain+due+to+spinal+cord+injury&selectedTitle=7%7E150&language=en-US&anchor=H2#H13
2. Gold Standard, Inc. (2012, June 21). *Pregabalin*. Retrieved September 13, 2014, from Clinical Pharmacology: http://www.clinicalpharmacology-ip.com
3. Gold Standard, Inc. (2013, May 09). *Gabapentin*. Retrieved September 13, 2014, from http://www.clinicalpharmacology-ip.com
4. Portenoy, R. K., Ahmed, E., & Keilson, Y. Y. (2014, July 30). *Cancer pain management: Adjuvant analgesics (coanalgesics).* Retrieved September 13, 2014, from Up To Date: http://www.uptodate.com/contents/cancer-pain-management-adjuvant-analgesics-coanalgesics?source=machineLearning&search=neuropathic+pain+treatment&selectedTitle=3%7E150&sectionRank=1&anchor=H18#H21
5. Thomson Micromedex. (2014, September 11). Duloxetine. *DRUGDEX System*. Greenwood Village, CO. Retrieved September 13, 2014, from DRUGDEX System: http://www.thomsonhc.com
6. Thomson Micromedex. (2014, September 10). Gabapentin. Greenwood Village, CO. Retrieved September 13, 2014, from http://www.thomsonhc.com
7. Thomson Micromedex. (2014, September 10). Pregabalin. Greenwood Village, CO. Retrieved September 13, 2014, from http://www.thomsonhc.com

[xxxii] **Modafinil/Nuvigil References**

1. Gold Standard, Inc. Clinical Pharmacology [database online]. Available at: http://www.clinicalpharmacology.com. Accessed March 2014.
2. Fosnocht, KM. Approach to the adult patient with fatigue. In: UpToDate, Fletcher, RH (Ed), UpToDate, Waltham, MA. (Accessed on August 15, 2014.)
3. Escalante, CP. Cancer-related fatigue: Treatment. In: UpToDate, Hesketh, PJ (Ed), UpToDate, Waltham, MA. (Accessed on August 15, 2014.)
4. Lavault, S., Dauvilliers, Y., Drouot, X., Leu-Semenescu, S., Golmand, J.-L., Lecendreux, M., et al. (2011). Benefit and risk of modafinil in idiopathic hypersomnia vs. narcolepsy. *Sleep Medicine*, 550-556.
5. Bruera E, Y. S. (2014, May 8). Palliative care: Overview of fatigue, weakness, and asthenia. Retrieved September 15, 2014, from Uptodate: http://www.uptodate.com
6. Chevrin R, C. (2014, April 23). Idiopathic hypersomnia. Retrieved September 15, 2014, from Up To Date: http://www.uptodate.com

[xxxiii] **Multaq References**

1. Clinical Pharmacology [Internet database]. Gold Standard Inc. Tampa, FL. Updated periodically.
2. Drug Facts and Comparisons on-line. (www.drugfacts.com), Wolters Kluwer Health, St. Louis, MO. Updated periodically
3. Fuster V, Ryden LE, Cannom DS, et al. ACC/AHA/ESC guidelines for the management of patients with atrial fibrillation. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines (Writing committee to revise the 2001 guidelines for the management of patients with atrial fibrillation). J Am Coll Cardiol 2006; 48:e14
4. MULTAQ Dronedarone tablets prescribing information products.sanofi.us/Multaq/Multaq.pdf.

[xxxiv] **Multiple Sclerosis Agents References**

1. Multiple Sclerosis Treatment and Management: Available at: http://emedicine.medscape.com/article/1146199-treatment#aw2aab6b6b4; Authors: Christopher Luzzio, MD; Chief Editor: B Mark Keegan, MD. Assessed Sept, 2014
2. National Multiple Sclerosis Society. Clinical Bulletin; Overview of Multiple Sclerosis. Available at: www.nationalmssociety.org. Assessed Sept, 2014
3. Drug Facts and Comparisons on-line. (www.drugfacts.com), Wolters Kluwer Health, St. Louis, MO. Updated periodically. Assessed Sept, 2014
4. Clinical Pharmacology [Internet database]. Gold Standard Inc. Tampa, FL. Updated periodically. Assessed Sept, 2014
5. Novantrone Prescribing information: Rockland, MA: Serono, Inc. Assessed Sept, 2014.

[xxxv] **Nasonex References**

1. Gold Standard. (2014, April 15). *Clinical Pharmacology.* Retrieved from Clinical Pharmacology: http://www.clinicalpharmacology-ip.com/Forms/Monograph/monograph.aspx?cpnum=1457&sec=monindi&t=0
2. Merck & Co., Inc. (2013, March). Nasonex (Mometasone). *package insert*. Whitehouse Station, NJ, USA.

[xxxvi] **Nexavar References**

1. Nexavar prescribing information. Bayer Healthcare Pharmaceuticals Inc;Wayne, NJ: December 2012.
2. Bukowski R, Cella D, Gondek K, et al. Effects of sorafenib on symptoms and quality of life: results from a large randomized placebo-controlled study in renal cancer. Am J Clin Oncol. 2007 Jun;30(3):220-7
3. Sorafenib, NCCN Drugs and Biologics Compendium. [cited 3/25/2010]. Available from: URL: http://www.nccn.org/professionals/drug_compendium/MatrixGenerator/Matrix.aspx?AID=134.
4. NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer. Fort Washington, PA: National Comprehensive Cancer Network, 2013. (Accessed March 4, 2013, at http://www.nccn.org/ professionals/ physician_gls/ PDF/kidney.pdf)
5. NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancer. Fort Washington, PA: National Comprehensive Cancer Network, 2012. (Accessed March 4, 2013, at http://www.nccn.org/professionals/ physician_gls/pdf/hepatobiliary.pdf))

[xxxvii] **Non-Cacium Based Phosphate Binder References**

1. Gold Standard. (2014, April 21). Velphoro. Tampa, Florida, USA. Retrieved 19 December, 2014, from http://www.clinicalpharmacology-ip.com/Forms/Monograph/monograph.aspx?cpnum=2575&sec=monindi&t=0
2. National Kidney Foundation. K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease: Am J Kidney Dis. 2003 Oct;42(4):s1-s201

[xxxviii] **Northera References**

1. Gold Standard. (2014, February 20). Droxidopa. Retrieved October 2, 2014, from Clinical Pharmacology: http://www.clinicalpharmacology.com
2. Gold Standard. (2014, February 25). Midodrine. Retrieved October 2, 2014, from Clinical Pharmacology: http://clinicalpharmacology.com
3. Kaufmann H, K. N. (2014, September 2). Mechanisms, causes, and evaluation of orthostatic hypotension. Retrieved October 02, 2014, from Uptodate: http://www.uptodate.com

[xxxix] **Onychomycosis and Tinea References**

1. El-Gohary M, van Zuuren EJ, Fedorowicz Z, Burgess H, Doney L, Stuart B, Moore M, Little P. Topical antifungal treatments for tinea cruris and tinea corporis. Cochrane Database of Systematic Reviews 2014, Issue 8. Art. No.: CD009992. DOI: 10.1002/14651858.CD009992.pub2.
2. Bell-Syer SEM, Khan SM, Torgerson DJ. Oral treatments for fungal infections of the skin of the foot. Cochrane Database of Systematic Reviews 2012, Issue 10. Art. No.: CD003584. DOI: 10.1002/14651858.CD003584.pub2.
3. Luzu [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; June 2014.
4. Jublia [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; February 2015
5. Rodgers P, Bassler M. Treating onychomycosis. Am Fam Physician. 2001;63:663-672
6. Facts and Comparisons. (2014, September 1). St Lois, Missouri, USA.
7. Gold Standard, Inc. (2013, November 20). Luzu. Retrieved April 08, 2015, from http://www.clinicalpharmacology.com: http://www.clinicalpharmacology.com
8. Gold Standard, Inc. (2015, 01 27). Jublia. Retrieved April 08, 2015, from www.clinicalpharmacology.com: http://www.clinical pharmacology.com

[xl] **Platelet Inhibitors References:**

1. Gordon H. Guyatt, MD, FCCP, Elie A. Akl, MD, PhD, MPH, et al. Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. CHEST Journal February 2012; 141(2_suppl)
2. Simons, Michael. "Antiplatelet agents in acute non-ST elevation acute coronary syndromes." UpToDate.http://www.uptodate.com (accessed March 24, 2014).
3. Cutlip, Donald. “Antithrombotic therapy for percutaneous coronary intervention: General Use.” UpToDate.http://www.uptodate.com (accessed March 24, 2014).
4. Lincolff, Michael A. “Antiplatelet agents in acute ST elevation myocardial infarction.” UpToDate.http://www.uptodate.com (accessed March 24, 2014).

5. Clinical Pharmacology [Internet database]. Gold Standard Inc. Tampa, FL. Updated periodically
6. Effient (prasugrel) package insert. Indianapolis, IN: Eli Lilly and Company
7. Brilinta (ticagrelor) package insert. Wilmington, DE:AstraZeneca LP
8. (O'Gara, Kushner, & Ascheim, 2013)
9. Amsterdam EA, et al. 2014 AHA/ACC Guideline for the Management of Patients With Non–ST-Elevation
10. Acute Coronary Syndromes: Executive Summary. *J Am Coll Cardiol*. 2014;64(24):e139-228.
11. Eikelboom JW, Hirsh J, Spencer FA, Baglin TP, Weitz JI. Antiplatelet drugs: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. CHEST Journal February 2012; 141 (2)(Suppl):e89S–e119S
12. Weitz JI, Eikelboom JW, Samama MM. New Antithrombotic Drugs: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. CHEST Journal February 2012; 141 (2)(Suppl) :e120S–e151S
13. Zontivity (vorapaxar) package insert.

[xli] **Orencia References**

1. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; Revised 12/2013.
2. Gold Standard. (2013, December 24). Orencia. Tampa, Florida, USA. Retrieved September 2, 2014, from http://www.clinicalpharmacology-ip.com/Forms/Monograph/monograph.aspx?cpnum=3446&sec=monindi&t=0
3. Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. Arthritis Care Res (Hoboken) 2013; 65:1551.
4. Beukelman, T, et al. American College of Rheumatology 2011 Recommendations for the Treatment of Juvenile Idiopathic Arthritis: Initiation and Safety Monitoring of Therapeutic Agents for the Treatment of Arthritis and Systemic Features. Arthritis Care & Research. 2011: 63(4):465-482.
5. Singh JA, Furst D, Bharat A et al. 2012 Update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care & Research 2012: 64 (5):625-639.
6. Schur, PH, et al, "Initial treatment of moderately to severely active rheumatoid arthritis in adults" UpToDate. http://www.uptodate.com (accessed September, 2014).
7. Schur, PH, et al, "Treatment of rheumatoid arthritis resistant to initial DMARD therapy in adults " UpToDate. http://www.uptodate.com (accessed September, 2014).

[xlii] **Otezla References**

8. Otezla Prescribing Information, Celgene Corporation, Summit, NJ 07901 9-2014
9. Schafer P. Apremilast mechanism of action and application to psoriasis and psoriatic arthritis. Biochem Pharmacol. 2012;83(12):1583-1590. [PubMed 22257911]
10. National Psoriasis Foundation. Treatment. URL: http://psoriasis.org/treatment. Available from Internet. Accessed 2014 November 5
11. Feldman, S. R. Treatment of psoriasis. In: UpToDate, T. W. Post (Ed.), Waltham, MA, (Accessed on November 5, 2014.)

[xliii] **Platelet Inhibitors References**

14. Gordon H. Guyatt, MD, FCCP, Elie A. Akl, MD, PhD, MPH, et al. Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. CHEST Journal February 2012; 141(2_suppl)
15. Simons, Michael. "Antiplatelet agents in acute non-ST elevation acute coronary syndromes." UpToDate.http://www.uptodate.com (accessed March 24, 2014).
16. Cutlip, Donald. "Antithrombotic therapy for percutaneous coronary intervention: General Use." UpToDate.http://www.uptodate.com (accessed March 24, 2014).
17. Lincolff, Michael A. "Antiplatelet agents in acute ST elevation myocardial infarction." UpToDate.http://www.uptodate.com (accessed March 24, 2014).
18. Clinical Pharmacology [Internet database]. Gold Standard Inc. Tampa, FL. Updated periodically
19. Effient (prasugrel) package insert. Indianapolis, IN: Eli Lilly and Company
20. Brilinta (ticagrelor) package insert. Wilmington, DE:AstraZeneca LP

[xliv] **Promacta References**

1. Promacta [package insert]. Research Triangle Park, NC: GlaxoSmithKline; Revised 12/2011.

2. Gold Standard, Inc. *Clinical Pharmacology* [database online]. Available at: http://www.clinicalpharmacology-ip.com. Accessed September 17, 2012
3. *Facts and Comparisons* [database online]. Available at http://online.factsandcomparisons.com Accessed September 17, 2012
4. Ghany MG, Strader DB, Thomas DL, et al. AASLD practice guidelines: diagnosis, management, and treatment of hepatitis C: an update. Hepatology 2009;49(4):1335-11374. Available at: http://www.aasld.org/practiceguidelines/Documents/Bookmarked%20Practice%20Guidelines/Diagnosis_of_HEP_C_Update.Aug%20_09pdf.pdf
5. Bacon BR, Shiffman ML, Mendes F, et al. Retreating chronic hepatitis C with daily interferon alfacon-1/rivabirin after nonresponse to pegylated interferon/ribavirin: DIRECT results. Hepatology 2009: 49(6): 1838-1846. Available at: http://www3.interscience.wiley.com/cgi-bin/fulltext/121675703/PDFSTART
6. Judith C. W. Marsh, e. a. (2009). Guidelines for the diagnosis and management of aplastic. *British Journal of Hematology*.
7. Marsh, J. R. (2010). Aplastic Anemia: First-line Treatment by Immunosuppression and Sibling Marrow Transplantation. *ASH Education Book*.

[xlv] **Proton Pump Inhibitors References:**

1. Katz P, Gerson L, Vela M. Guidelines for the Diagnosis and Management of Gastroesophageal Reflux Disease. *Am J Gastroenterol* 2013; 108:308-328; doi:10.1038/ajg.2012.444; published online 19 February 2013
2. Fass R, Sontag SJ, Traxler B, Sostek M. Treatment of Patients With Persistent Heartburn Symptoms: A Double-Blind, Randomized Trial. *Clin Gastroenterol Hepatol*; 2006;4:50–56.
3. Fass R, Murthy U, Hayden CW, et al. Omeprazole 40 mg once a day is equally effective as lansoprazole 30 mg twice a day in symptom control of patients with gastro-oesophageal reflux disease (GERD) who are resistant to conventional-dose lansoprazole therapy-a prospective, randomized, multi-centre study. *Aliment Pharmacol Ther.* 2000; 14: 1595-1603.
4. Fass, R. Approach to refractory gastroesophageal reflux disease in adults. In: UpToDate. Talley NJ, ed. *UpToDate*, Waltham, MA: UpToDate; 2015. Available at: http://www.uptodate.com/home. Accessed June 15, 2015.

[xlvi] **Ranexa References**

1. Fihn SD, G. J. (December 2012). 2012 American College of Cardiology Foundation/American Heart Association/American College of Physicians/American Association for Thoracic Surgery/Preventive Cardiovascular Nurses Association/Society for Cardiovascular Angiography and Interventions/Socie. *Journal of the American College of Cardiology*, Volume 60 Issue 24.
2. Gold Standard, Inc. (2013, Decemember 25). *Ranexa*. Retrieved Septemeber 15, 2014, from ClinicalPharmacology: http://www.clinicalpharmacology.com
3. Kannam, J. e. (2014, August 12). *Stable ischemic heart disease: Overview of care* . Retrieved September 15, 2014, from Up to Date: http://www.uptodate.com.

[xlvii] **Remicade References**

1. Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. Arthritis Care Res (Hoboken) 2013; 65:1551.
2. Beukelman, T, et al. American College of Rheumatology 2011 Recommendations for the Treatment of Juvenile Idiopathic Arthritis: Initiation and Safety Monitoring of Therapeutic Agents for the Treatment of Arthritis and Systemic Features. Arthritis Care & Research. 2011: 63(4):465-482.
3. Singh JA, Furst D, Bharat A et al. 2012 Update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care & Research 2012: 64 (5):625-639.
4. Yu, DT, et al, "Assessment and treatment of ankylosing spondylitis in adults" UpToDate. http://www.uptodate.com (accessed September, 2014).
5. Schur, PH, et al, "Initial treatment of moderately to severely active rheumatoid arthritis in adults" UpToDate. http://www.uptodate.com (accessed September, 2014).
6. Schur, PH, et al, "Treatment of rheumatoid arthritis resistant to initial DMARD therapy in adults " UpToDate. http://www.uptodate.com (accessed September, 2014).
7. Gladman, DD, et al, "Treatment of psoriatic arthritis" UpToDate. http://www.uptodate.com (accessed September, 2014).
8. Lehman, TJ, et al, "Systemic onset juvenile idiopathic arthritis: Treatment" UpToDate. http://www.uptodate.com (accessed September, 2014).
9. Steven R Feldman, "Treatment of psoriasis" UpToDate. http://www.uptodate.com (accessed September, 2014).

10. Farrell, RJ, et al, "Overview of the medical management of severe or refractory Crohn disease in adults" UpToDate. http://www.uptodate.com (accessed September, 2014).
11. MacDermott, RP, "Immunomodulator therapy in Crohn disease" UpToDate. http://www.uptodate.com (accessed September, 2014).
12. Bousvaros, A, et al, "Overview of the management of Crohn's disease in children and adolescents" UpToDate. http://www.uptodate.com (accessed September, 2014).
13. Bousvaros, A, et al, "Treatment of ulcerative colitis in children and adolescents" UpToDate. http://www.uptodate.com (accessed September, 2014).
14. Peppercorn, MA, et al, "Management of severe ulcerative colitis" UpToDate. http://www.uptodate.com (accessed September, 2014).
15. Cohen, RD, et al, "Approach to adults with steroid-refractory and steroid-dependent ulcerative colitis" UpToDate. http://www.uptodate.com (accessed September, 2014).
16. Remicade [package insert]. Horsham, PA: Janssen Biotech Inc.; November 2013.
17. Standard, G. (2014, May 16). Remicade. Tampa, Florida, USA. Retrieved September 2, 2014, from http://www.clinicalpharmacology-ip.com/Forms/Monograph/monograph.aspx?cpnum=2284&sec=monindi&t=0
18. Brooks, M. (2014, September 25). Adalimumab (Humira) Gets FDA Nod for Children With Crohn's. Retrieved September 25, 2014, from medscape: http://www.medscape.com

[xlviii] **Stelara References**

1. Ustekinumab. (2014) In Clinical Pharmacology online. Retrieved from http://www.clinicalpharmacology-ip.com/Forms/drugoptions.aspx?cpnum=3586&n=Stelara&t=0.
2. Stelara (ustekinumab) package insert. Horsham, PA: Janssen Biotech, Inc. 2013 May.; 3. Treatment of psoriasis. (2014) UpToDate online. Retrieved from http://www.uptodate.com/contents/treatment-of-psoriasis.

[xlix] **Synagis References**

1. Aetna.com. 2014. *Clinical Policy Bulletin: Synagis (Palivizumab)*. [online] Available at: http://www.aetna.com/cpb/medical/data/300_399/0318.html [Accessed: 28 Jul 2014].
2. Perrin, MD, FAAP, J., Meissner, MD, FAAP, H. and Ralston, MD, FAAP, S. 2014. *Updated AAP Guidance for Palivizumab Prophylaxis For Infants and Young Children at Increased Risk of RSV Hospitalization*. [e-book] pp. 1-23. Available through: American Academy of Pediatrics http://www.aap.org/en-us/my-aap/Pages/rsv.aspx [Accessed: 28 Jul 2014].
3. Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection, COMMITTEE ON INFECTIOUS DISEASES AND BRONCHIOLITIS GUIDELINES COMMITTEE, Pediatrics 2014;134;415; originally published online July 28, 2014; DOI: 10.1542/peds.2014-1665, Accessed online on 8/13/2014 at http://pediatrics.aappublications.org/content/134/2/415.full.html

[l] **Tarceva References**

1. Tarceva® (erlotinib) prescribing information. Genentech, Inc.: South San Francisco, CA. May, 2013..
2. Pfister DG et al. American Society of Clinical Oncology treatment of unresectable non-small-cell lung cancer guideline: update 2003. Journal of Clinical Oncology. 2004 Jan 15;22(2):330-53
3. NCCN Clinical Practice Guidelines: Non-Small Cell Lung Cancer. V.2.2013. Accesssed 08/05/13. Adapted from http://www.nccn.org/professionals/physician_gls/PDF/nscl.pdf
4. NCCN Clinical Practice Guidelines: Pancreatic Adenocarcinoma. V.2.2012. Accessed 03/11/13. Adapted from http://www.nccn.org/professionals/physician_gls/PDF/pancreatic.pdf
5. Moore MJ, et al. Erlotinib plus gemcitabine compared with gemcitabine alone in patients with advanced pancreatic cancer: a phase III trial of the National Cancer Institute of Canada Clinical Trials Group. *J Clin Oncol.* 2007 May 20;25(15):1960-6.
6. Erlotinib hydrochloride NCCN Drugs and Biologics Compendium, NCCN, http://www.nccn.org/professionals/drug_compendium/MatrixGenerator/Matrix.aspx?AID=42 Accessed 03/27/2012, 08/05/2013

[li] **Topical NSAID References**

1. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. 2000 Sep (revised 2012 Apr).
2. American Academy of Orthopaedic Surgeons clinical practice guideline on the treatment of glenohumeral joint osteoarthritis. 2009 Dec 4 (reaffirmed 2014).
3. American Academy of Orthopaedic Surgeons clinical practice guideline on the treatment of osteoarthritis of the knee, 2nd edition. 1996 (revised 2013 May 18).
4. VA/DoD clinical practice guideline for the non-surgical management of hip and knee osteoarthritis. 2014.
5. Voltaren Gel (diclofenac sodium topical gel) package insert. Parsippany, NJ: Novartis Consumer Health; 2007 Oct.
6. Pennsaid (diclofenac sodium) topical solution package insert. Hazelwood, MO: Mallinckrodt Brand Pharmaceuticals, Inc; 2013 Oct.
7. Flector (diclofenac epolamine) [prescribing information]. Bristol, TN: King Pharmaceuticals; August 2011.
8. Beers MH, Ouslander JG, Rollingher I, et al. Explicit criteria for determining inappropriate medication use in nursing home residents. UCLA Division of Geriatric Medicine. *Arch Intern Med* 1991;151:1825-32.
9. The American Geriatrics Society 2012 Beers Criteria Update Expert Panel. American Geriatrics Society updated Beers criteria for potentially inappropriate medication use in older adults. *J Am Geriatr Soc* 2012;60:616-31.
10. Bhatt DL, Scheiman J, Abraham NS, et al. ACCF/ACG/AHA 2008 expert consensus document on reducing the gastrointestinal risks of antiplatelet therapy and NSAID use: a report of the American College of Cardiology Foundation Task Force on Clinical Expert Consensus Documents. *Circulation* 2008;118:1894-909.
11. Masso Gonzalez EL, Patrignani P, Tacconelli S, Garcia Rodriguez LA. Variability among nonsteroidal antiinflammatory drugs in risk of upper gastrointestinal bleeding. *Arthritis Rheum* 2010;62:1592-601.
12. Lanza FL, Chan FK, Quigley EM, Practice Parameters Committee of the American College of Gastroenterology. Guidelines for prevention of NSAID-related ulcer complications. *Am J Gastroenterol* 2009;104:728-38.
13. Hernandez-Diaz S, Rodriguez LA. Incidence of serious upper gastrointestinal bleeding/perforation in the general population: review of epidemiologic studies. *J Clin Epidemiol* 2002;55:157-63.
14. Roth SH, Fuller P. Pooled safety analysis of diclofenac sodium topical solution 1.5% (w/w) in the treatment of osteoarthritis in patients aged 75 years or older. *Clin Interv Aging* 2012;7:127-37.
15. Derry S, Moore RA, Rabbie R. Topical NSAIDs for chronic musculoskeletal pain in adults. *Cochrane Database Syst Rev* 2012;(9):CD007400.
16. Altman RD. Safety advantages of topical versus oral nonsteroidal antiinflammatory drugs. *J Rheumatol* 2011;38:572.
17. Sprix (ketorolac tromethamine) Nasal Spray package insert. Shirley, NY: American Regent, Inc.; 2014 Apr.

[lii] **Tranexamic acid References**

1. Drug Facts and Comparisons on-line. (www.drugfacts.com), Wolters Kluwer Health, St. Louis, MO. Updated periodically
2. Clinical Pharmacology [Internet database]. Gold Standard Inc. Tampa, FL. Updated periodically.Product Information. Lysteda®, tranexamic acid. Ferring Pharmaceuticals, Inc., Bethesda, MD 20814. October, 2013.

[liii] **Tysabri References**

1. Tysabri [package insert]. Cambridge, MA: Biogen Idec Inc; Revised 12/2013
2. Gold Standard. (2014, January 13). Tysabri. Tampa, Florida, USA. Retrieved September 2, 2014, from http://www.clinicalpharmacology-ip.com/Forms/Monograph/monograph.aspx?cpnum=2549&sec=monindi&t=0
3. Walters Kluwer Health Inc. (2014, February 1). Tysabri. St Louis, Missouri, USA. Retrieved September 2, 2014, from http://online.factsandcomparisons.com/MonoDisp.aspx?monoID=fandc-hcp2900&quick=740169%7c5&search=740169%7c5&isstemmed=True&NDCmapping=-1&fromTop=true#firstMatch

[liv] **Xeljanz References:**

1. American College of Rheumatology. (n.d.). *Clinical Practice Guidelines.* Retrieved April 9, 2015, from American College of Rheumatology: https://www.rheumatology.org
2. Gold Standard, Inc. (2012, November 9). *Xeljanz*. Retrieved April 9, 2015, from ClinicalPharmacology: http://www.clinicalpharmacology.com

3. Pfizer Labs. (2014, March). Xeljanz prescribing information.

[lv] **Xolair References**

1. Barnes, P. J. (May 2015). Anti-IgE therapy. UpToDate. (B. S. Bochner, & A. M. Feldweg, Eds.) Waltham, MA. Retrieved June 16, 2015, from http://www.uptodate.com/contents/anti-ige-therapy?source=related_link#H7764932
2. DRUGDEX® Evaluations. (n.d.). Omalizumab. DRUGDEX System. Greenwood Village, CO. Retrieved June 16, 2015, from http://nv-ezproxy.roseman.edu:3305/micromedex2/librarian/ND_T/evidencexpert/ND_PR/evidencexpert/CS/E8C454/ND_AppProduct/evidencexpert/DUPLICATIONSHIELDSYNC/318DA6/ND_PG/evidencexpert/ND_B/evidencexpert/ND_P/evidencexpert/PFActionId/evidencexpert.Intermedi
3. Khan, D. A. (2013, September 19). education, Chronic urticaria: Standard management and patient. UpToDate. (S. Saini, J. Callen, & A. M. Feldweg, Eds.) Waltham, MA. Retrieved from http://www.uptodate.com/contents/chronic-urticaria-standard-management-and-patient-education?source=see_link
4. Khan, D. A. (May 2015). Chronic urticaria: Treatment of refractory symptoms. UpToDate. (S. Saini, J. Callen, & A. M. Feldweg, Eds.) Waltham, MA. Retrieved June 16, 2015, from http://www.uptodate.com/contents/chronic-urticaria-treatment-of-refractory-symptoms?source=see_link#H1
5. National Heart, Blood, and Lung Institute Expert Panel Report 3 (EPR 3): Guidelines for the Diagnosis and Management of Asthma. NIH Publication no. 08-4051, 2007.
6. Gold Standard. (2015) Xolair. Retrieved http://www.clinicalpharmacology-ip.com/Forms/drugoptions.aspx?cpnum=2633&n=Xolair&t=0.
7. Bernstein JA, Lang DM, Khan DA, et al. The diagnosis and management of acute and chronic urticaria: 2014 update. *J Allergy Clin Immunol.* 2014;133:1270-1277.
8. Zuberbier T, Aberer W, Asero R, et al. The EAACI/GA^{2}LEN/EDF/WAO Guideline for the definition, classification, diagnosis, and management of urticaria: the 2013 revision and update. *Allergy.* 2014;69:868–887.