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

PA Guideline	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 2 formulary agents for an adequate duration have not been effective or tolerated **OR** • All other formulary medications are <u>contraindicated</u> 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.	**<u>Initial Approval:</u>** • Minimum of 3 months, depending on the diagnosis, to determine adherence, efficacy and patient safety monitoring **<u>Renewal:</u>** • 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. For a list of agents that have a Step Therapy requirement, go to our health plan website and review the Step Therapy Requirements document at:	**<u>Initial Approval:</u>** Indefinite

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	https://www.aetnabetterhealth.com/illinois/assets/pdf/pharmacy/pa-guidelines/Illinois_Step_Therapy.pdf	
Brand Name Medication Requests	Aetna Medicaid requires use of generic agents that are considered therapeutically equivalent 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/Safety/MedWatch/HowToReport/DownloadForms/UCM082725.pdf	**Initial Approval:** Indefinite
Quantity Level Limits	Prescription requests that exceed established QLLs will require prior authorization. Drugs that are subject to additional utilization management requirements (e.g., non-formulary, clinical prior authorization, step therapy) must meet the clinical criteria and medical necessity for approval in addition to any established QLLs. Approval of QLL exceptions will be considered after the medication specific prior authorization guidelines and medical necessity have been reviewed. **Authorization Criteria For Quantity Limit Exceptions:** • **Quantities that Exceed FDA Maximum Dose:** o Patient has had an inadequate response to the same medication at a lower dosage and the inadequate response is not due to medication non-adherence o Patient is tolerating the medication at a lower dosage o Requested dose is included in drug compendia or evidence-based clinical practice guidelines for the same indication; **OR** o A published, randomized, double blind, controlled trial demonstrating the safety and efficacy of the requested dose for the indication is submitted with the request • **Quantities that do not Exceed FDA Maximum Dose (Dose Optimization):** o Patient had an inadequate response or intolerable side effects to the optimized dose; **OR**	**Initial Approval:** • 1 year **Renewal:** • 3 years

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	○ There is a manufacturer shortage on higher strengths • **Quantities for Medications that do not have Established FDA Maximum Dose:** ○ Patient has had an inadequate response to the same medication at a lower dosage ○ Patient is tolerating the medication at a lower dosage ○ Requested dose is considered medically necessary	
Oncology - Antineoplastic Agents	**Requests for antineoplastic agents will be reviewed based on the following criteria:** • Member is under the care of an Oncologist • Medication is prescribed for an FDA-approved indication OR for a "medically accepted indication" as noted in the following Compendia: ○ NCCN Drugs and Biologic Compendium or NCCN Clinical Practice Guidelines, category 1, 2a, or 2b. ○ Micromedex DrugDex ○ Clinical Pharmacology • The dose prescribed is within the FDA-approved range for the indication and patient specific factors (e.g., age, weight or BSA, renal function, liver function, drug interactions, etc) • Requested medication is formulary preferred. Requests for non-preferred or non-formulary antineoplastics must meet ONE of the following: ○ Trials of formulary preferred agents for an adequate duration were not effective or were poorly tolerated ○ All other formulary preferred alternatives are <u>contraindicated</u> based on the member's other medical conditions or drug interactions ○ There are no formulary preferred medications for the patient's indication ○ Member has a genetic mutation that is resistant to the formulary preferred agents • Medical records, lab results, test results, and clinical markers supporting the diagnosis and treatment are submitted with the request • Member does not have any contraindications to the medication	**<u>Initial Approval:</u>** • 3 months **<u>Renewal:</u>** • 1 year ***Requires:*** • Clinically significant improvement or stabilization of the disease state • Adverse effect monitoring is completed as recommended in the FDA-approved label • Dose is adjusted as needed for adverse effects based on the FDA-approved label

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	• Member is not taking other medications that should be avoided with the requested drug based on the FDA-approved labeling • Request is not for experimental/investigational use or for a clinical trial	

Ampyra[i]	**May be approved when the following criteria are met:**
	• Prescribed by, or in consultation with, a neurologist
	• Patient is 18 years of age or older
	• Diagnosis of multiple sclerosis with one of the following:
	  o Impaired walking ability defined as a baseline 25-ft walking test between 8 and 45 seconds; OR
	  o Expanded Disability Status Scale (EDSS) between 4.5 and 6.5
	• Patient is stabilized on disease modifying therapy for MS (i.e., no recent exacerbations)
	• Patient is NOT wheelchair-bound
	• Patient does not have a history of seizures
	• Patient does not have moderate to severe renal impairment (Crcl < 50 ml/min)
		Initial Approval:
		• 2 months
		
		Renewal:
		• 1 year
		
		Requires:
		At least 20% improvement in timed walking speeds on 25-ft walk within 4 weeks of starting medication
		
		QLL: 2 tablets per day

Anthelmintic[ii] Biltricide Albenza	Biltricide should pay at the point of sale when ONE of the following diagnosis criteria is met without requiring a PA: • ICD-10 codes: B65.** (trematodes, flukes); B66.** (other fluke infections) • ICD-10 codes: B69**, B70**, B71** (tapeworm) Prescriptions that do not pay at the point of sale require prior authorization and may be authorized for members who meet the following criteria: • Member has failed ivermectin, pyrantel, or Albenza **OR**	**Initial Approval:** Roundworm: 21 days All others: 3 days

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	• Member has infection with one of the following:
	  o Flukes
	  o Tapeworms
	
	Albenza should pay at the point of sale when ONE of the following diagnosis criteria is met without requiring a PA:
	
	• ICD-10 code: B77** Ascaris lumbricoides(ascariasis)
	• ICD-10 code: B81.1 Capillaria
	• ICD-10 code: B76** Hookworm
	• ICD-10 code: B79** Whipworm
	• ICD-10 codes: B74.0-74.3 Filiariasis
	• ICD-10 code: B83.1 Gnathostomiasis
	• ICD-10 code: B75** Trichinellosis
	• ICD-10 code: B69** Tapeworm
	
	Prescriptions that do not pay at the point of sale require prior authorization and may be authorized for members who meet the following criteria:
	
	• Member has failed ivermectin OR pyrantel
	OR
	• Member has infection with one of the following:
	  o ICD-10 code: B77** Ascaris lumbricoides(ascariasis)
	  o ICD-10 code: B81.1 Capillaria
	  o ICD-10 code: B76** Hookworm
	  o ICD-10 code: B79** Whipworm
	  o ICD-10 codes: B74.0-74.3 Filiariasis	

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	o ICD-10 code: B83.1 Gnathostomiasis o ICD-10 code: B75** Trichinellosis o ICD-10 code: B69** Tapeworm	
Anticoagulants - Injectable[iii] Enoxaparin Fondaparinux Fragmin Iprivask	**Fragmin, fondaparinux, and enoxaparin should pay at the point of sale for an initial duration of 21 days without a PA.** **For prescriptions of enoxaparin, fondaparinux, and Fragmin that do not pay at the point of sale, prior authorization requests can be authorized for the following indications:** **All 3 agents (enoxaparin, fondaparinux, and Fragmin):** • VTE prophylaxis: o In patients undergoing hip or knee replacement or hip fracture surgery o In patients with restricted mobility during acute illness o Bridge therapy for perioperative warfarin discontinuation o In a high risk pregnancy • VTE treatment: o In patients who are taking warfarin until the INR is in therapeutic range for 2 days o In a high risk pregnancy o For superficial vein thrombosis (SVT) of the lower limb of at least 5 cm in length o For acute upper-extremity DVT (UEDVT) that involves the axillary or more proximal veins o For recurrent VTE that occurred while taking oral anticoagulants **Fragmin and enoxaparin only:** • VTE treatment: o After trial and failure of warfarin AND Eliquis, Pradaxa, or Xarelto • In patients who have cancer VTE prophylaxis: o In cancer patients with solid tumors who are at high risk of thrombosis (i.e., previous	**Initial Approval**: • Prophylaxis (post-ortho surgery) - Up to 35 days • Prophylaxis (non-ortho surgery and major trauma) - Up to 14 days • Prophylaxis (post-surgery with CA)- 4 weeks • VTE treatment, bridge therapy, acute illness - 10 days or as requested • High risk pregnancy - Until 6 weeks after delivery (EDC required for authorization) • Prophylaxis in cancer - 6 months • Upper extremity DVT - 3 months • Lower-limb SVT - 45 days • VTE treatment for warfarin failure or in cancer - 6 months **Renewal:**

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	VTE, immobilization, hormonal therapy, angiogenesis inhibitors, thalidomide, and lenalidomide) o In patients with AFib undergoing cardioversion (up to 3 weeks before and 4 weeks after) o In patients with acute ischemic stroke and restricted mobility o In patients undergoing general and abdominal-pelvic surgery who are at moderate to high risk for VTE o In patients with major trauma **Iprivask may be authorized if all the following criteria are met:** • VTE prophylaxis in patients undergoing hip replacement surgery • Patient had therapeutic failure or intolerance to fondaparinux AND either enoxaparin or Fragmin **OR** • Patient has a contraindication to enoxaparin, fondaparinux, and Fragmin (i.e., allergic to pork, history of heparin induced thrombocytopenia)	Length of renewal authorization based on anticipated length of therapy, indication and/or recent INR if on warfarin
Anticoagulants - Oral Eliquis Pradaxa Xarelto	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. 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)	**Initial Approval:** **Atrial fibrillation** • Indefinite **Tx of VTE (not prophy)** • 6 months **Knee replacement surgery** • Up to 12 days (does not require PA unless >45 days)

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	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.	**Hip replacement surgery** Up to 35 days (does not require PA unless >45 days)
Antidepressants Non-Preferred[iv] **SSRI's:** Trintellix Viibryd Pexeva Fluoxetine weekly Fluoxetine TABLETS Fluvoxamine ER Paroxetine ER Paroxetine mesylate capsule **SNRI's:** Fetzima Venlafaxine SR TABS Pristiq Khedezla desvenlafaxine **Other:** Aplenzin	Members may be approved as continuity of care if the member is currently stable on the requested non-preferred antidepressant. **General Criteria for all new starts:** • Member is 18 years of age or older (except for fluvoxamine and fluoxetine) • Requested agent is FDA-approved for the indication being treated • If there is a formulary preferred agent available in a different formulation of the same ingredient (e.g., Pexeva, Aplenzin, Forfivo XL, fluvoxamine ER, paroxetine mesylate, fluoxetine weekly), the member must have a documented trial and failure of that formulary agent **Additional criteria based on indication:** • **Major Depressive Disorder or Seasonal Affective Disorder:** o Member has had documented failure of, or intolerance to 3formulary agents from at least 2 different classes of antidepressants (SSRI, SNRI, bupropion, or mirtazapine) at an adequate dose and duration (at least 4 weeks); **OR** o Member has had documented failure of, or intolerance to TWO formulary agents AND an acceptable antidepressant augmentation regimen (SSRI or SNRI plus one of the following: bupropion, lithium, atypical antipsychotic, buspirone, or liothyronine) 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) • **Obsessive-Compulsive Disorder:**	**Initial approval:** Indefinite **Quantity Limits:** Pristiq, desvenlafaxine, Trintellix, Viibryd, Fetzima, Aplenzin, Forfivo XL, paroxetine ER: 1 tablet/capsule per day Pexeva: 10mg and 20mg: 1 tablet per day 30mg: 2 tablets per day 40mg: 1.5 tablets per day Fluoxetine Tablets (Sarafem): 1 tablet per day Fluvoxamine ER: 2 tablets per day Fluoxetine weekly:

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Forfivo XL Nefazodone	○ Member has had documented failure of, or intolerance to 3 formulary agents (e.g., SSRI's, clomipramine) at an adequate dose and duration (at least 4 weeks). • **Panic Disorder or Generalized Anxiety Disorder:** ○ Member has had had documented failure of, or intolerance to 3 formulary agents from at least 2 different classes of antidepressants (e.g., SSRI's or SNRI's) at an adequate dose and duration (at least 4 weeks). • **Hot Flashes Associated with Menopause:** ○ Member has had had documented failure of, or intolerance to 3 formulary agents from at least 2 different classes of antidepressants (e.g., SSRI's or SNRI's) at an adequate dose and duration (at least 4 weeks). ○ Trial and failure of, intolerance to, or member preference to avoid hormonal therapy	1 pack per 28 days Paroxetine mesylate capsule: 1 tablet per day Venlafaxine SR Tablets: 37.5mg, 75mg, and 225mg: 1 tablet per day 150mg: 2 tablets per day Nefazodone: 2 tablets/day; up to 600mg max daily dose
ARBs[v] Edarbi Eprosartan Eprosartan/HCTZ Olmesartan Olmesartan/HCTZ Olmesartan/amlodipine Olmesartan/amlodipine/HCTZ Telmisartan/HCTZ Telmistartan/amlodipine	**Non-preferred ARBs** may be approved for members who have meet all of the following: • Diagnosis is for an FDA approved indication • Member had inadequate trial and failure or intolerance to 3 formulary preferred ARBs	**Initial approval:** Indefinite **Quantity limit:** 1 tab per day

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Atypical Antipsychotics less than 8 years old Risperidone Quetiapine Seroquel XR Clozapine Olanzapine Saphris Latuda Fanapt Ziprasidone Invega Aripiprazole	**May be authorized when the following criteria are met:** • Prescribed by a psychiatrist or neurologist or the prescriber must supply proof of a psychiatric consultation • There is documentation of ONE of the following diagnoses: o Organic Psychiatric Conditions o Schizophrenic Disorders o Affective Psychoses (bipolar disorders) o Psychosis o Autism Spectrum Disorders o Tourette's o Reactive Adjustment Disorders • Written, informed consent for the medication must be obtained from the parent or guardian • Non-Formulary atypical antipsychotics also require trial and failure of 2 formulary atypical antipsychotics 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 Risperidone Quetiapine Seroquel XR Clozapine Olanzapine Saphris	**May be authorized when the following criteria are met:** • Prescribed by a psychiatrist or neurologist or the prescriber must supply proof of a psychiatric consultation • There is an appropriate indication/diagnosis for the medication based on FDA approval, nationally established/recognized guidelines, peer-reviewed medical literature or clinical studies • 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	**Initial approval:** 6 months **Renewal:** 1 year

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Latuda Fanapt Ziprasidone Invega Aripiprazole	• Dose is appropriate for age and indication based on FDA approval, nationally established/recognized guidelines, peer-reviewed medical literature or clinical studies • Written, informed consent for the medication must be obtained from the parent or guardian • Non-Formulary atypical antipsychotics also require trial and failure of 2 formulary atypical antipsychotics Risperidone ODT requires ST therapy with risperidone tablets first. Ziprasidone requires ST therapy with both risperidone and quetiapine.	
Atypical Antipsychotics Long-Acting Injectable[vi] Invega Sustenna Invega Trinza Risperdal Consta Abilify Maintena Aristada Zyprexa Relprevv	**Continuity of Care will be allowed for the following conditions:** Members started on an antipsychotic during a recent hospitalization will receive a 90 day approval. Members who are new to the plan and stable on treatment will receive a 6 month approval. Medication must be prescribed for an FDA approved indication and dosing. **May be authorized when all of the following criteria are met:** • Member is 18 years of age or older • Prescribed by, or in consultation with, a psychiatrist • Diagnosis of a FDA approved indication: o Schizophrenia / Schizoaffective Disorder o Bipolar I (Risperdal Consta) • Documentation that member has received the recommended oral dosage (per FDA approved labeling) to confirm tolerability and efficacy • Member had non-adherence to oral antipsychotic medications which places member at risk for poor outcomes • Will not receive concurrent oral antipsychotics after the initial overlap period (per FDA approved labeling)	**<u>Initial Approval:</u>** 1 year **<u>Renewal:</u>** 1 year ***Requires*:** Metabolic screening within the last 60 days **Quantity Limits:** • Invega Sustenna: 1 per 28 days after initial loading doses • Invega Trinza: 1 per 84 days • Risperdal Consta: 2 per 28 days

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	• Provider agrees to support baseline and routine monitoring of all the following: o Weight, body mass index (BMI), or waist circumference o blood pressure o fasting glucose o fasting lipid panel o tardive dyskinesia ▪ using the Abnormal Involuntary Movement Scale (AIMS) OR ▪ Dyskinesia Identification System Condensed User Scale (DISCUS) • For Abilify Maintena and Invega Trinza only: Not taking a CYP3A4 inducer **<u>Additional Drug Specific Criteria</u>** **Invega Trinza**: • Trial of stable dose of Invega Sustenna for 4 months	• Abilify Maintena: 1 per 28 days • Aristada: 1 per 28 days • Aristada 886 mg: 1 per 28 days or 1 per 42 days • Zyprexa Relprevv 210mg and 300mg: 2 per 28 days • Zyprexa Relprevv 405mg: 1 per 28 days
Botulinum Toxins	Botox, Myobloc, Dysport, Xeomin **See Detailed document:** https://www.aetnabetterhealth.com/illinois/assets/pdf/pharmacy/pa-guidelines/medication/botulinum_toxins.pdf	
Cambia[vii]	**May be authorized for patients who meet the following criteria:** • Diagnosis of migraine headaches • 18 years of age or older	**<u>Initial approval:</u>** Indefinite

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	• Tried and failed at least 2 formulary triptans (e.g., sumatriptan, naratriptan) or has a contraindication to triptans • Tried and failed at least 2 formulary NSAIDs (e.g., Ibuprofen, naproxen, diclofenac)	Limit of 9 packets (1 box per month)
Celecoxib[viii]	**Celecoxib should pay at the point of sale when ONE of the following step therapy criteria are met without requiring a PA:** • Patient has filled 3 oral formulary NSAIDs in the previous 180 days • Patient has filled a PPI, H2 receptor antagonist, prednisone, warfarin, Xarelto, Pradaxa, or Eliquis in the previous 90 days **Prescriptions that do not pay at the point of sale require prior authorization and may be authorized for patients who meet the following criteria:** • Not being used within 14 days of CABG • Age ≥2 years old for juvenile rheumatoid arthritis (JRA) OR ≥18 years old for all other indications • Patient meets ONE of the following: o Was unable to achieve clinical benefit with 3 formulary NSAIDs o Has a history of gastritis confirmed by EGD o Is at high-risk for adverse GI events (e.g., ≥65 years of age, concomitant corticosteroid or anticoagulant use, history of GI bleed or PUD) AND currently not taking a daily aspirin	**Initial Approval:** Indefinite Dose limits: • OA: 200 mg/day • All other adult indications: 400 mg/day • JRA: o >25 kg: 100mg BID o 10-25 kg: 50mg BID
Chantix[ix]	**For patients who meet all of the following:** • Is a current smoker who desires to quit • Does NOT have unstable behavioral health symptoms (e.g., active psychosis, suicidal thoughts, active mania) • Had a therapeutic trial and failure of at least one combination smoking cessation regimen (e.g., nicotine patch + gum, nicotine patch + lozenge, or nicotine patch + bupropion); **OR**	**Initial Approval:** 12 weeks **Renewal:** 12 weeks ***Requires:*** Smoking cessation by week 12 of treatment. Total duration is

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	• Had a previous successful quit attempt using Chantix but has now relapsed	limited to 24 weeks per treatment.
Cialis[x]	**For patients who meet all of the following:** • Diagnosis of BPH • Inadequate response, intolerable side effects or contraindication to BOTH of the following: o Two Alpha Blockers (i.e., alfuzosin, tamsulosin, doxazosin, terazosin) o Finasteride for at least 6 months • Member is not using any form of organic nitrate (i.e. nitroglycerin, isosorbide dinitrate, Isosorbide mononitrate or amyl nitrate) or Adempas NOTE: Use of Cialis for treatment of erectile dysfunction including penile rehabilitation is not a covered benefit	**Initial Approval:** 3 months **Renewal:** 12 months ***Requires:*** Demonstration of improvement in symptoms (i.e., International Prostate Symptom Score (I-PSS) or AUA symptom score) **QLL:** 2.5mg or 5mg; #30/30 days
CNS Stimulants[xi] amphetamine/dextroamphetamine dextroamphetamine Evekeo methylphenidate IR, ER, LA, CD/CR Daytrana Aptensio XR Quillivant XR dexmethylphenidate Vyvanse methamphetamine	**Authorization Guidelines for All Agents:** • The prescribed stimulant is a preferred formulary agent OR the patient meets the criteria for a non-preferred stimulant as described below. • Stimulant is prescribed within FDA approved daily dosing guidelines. • The patient is receiving only one stimulant medication, except when using long-acting and short-acting formulations of the same drug. **Additional Guidelines for Adults over 18:** • Patient has a diagnosis of ADHD/ADD, narcolepsy, idiopathic hypersomnia, or fatigue related to cancer or multiple sclerosis • In addition, patients INITIATING stimulants for ADHD/ADD must meet the following: o ADHD/ADD diagnosis is documented in the medical record and is based on a comprehensive evaluation by an appropriate specialist and includes evidence based rating scales such as the Connors or Adult Self-Report Scale-V1.1 (ASRS-V1.1). The	**Initial Approval:** • ADHD <6: 1 year • ADHD 6-18: up to age 21 • ADHD >18: Indefinitely • Narcolepsy: Indefinitely • BED (Vyvanse): 16 weeks **Renewal:** • ADHD <6: 1 year • ADHD 6-18: up to age 21 • ADHD >18: Indefinitely • BED (Vyvanse): 1 year ***Requirements for BED renewal:***

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	symptoms meet the Diagnostic and Statistical Manual of Mental Disorders (DSM5) criteria. o Other conditions (such as depression, anxiety, or substance use) have been ruled out (including a urine drug screen for patients with a history of substance use disorder) OR are being appropriately treated. **Additional Guidelines for Children/Adolescents Age 6-18:** • Patient has a diagnosis of ADHD/ADD or narcolepsy **Additional Guidelines for Children Age 5 and Under:** • The patient continues to have ADHD/ADD symptoms despite evidence-based parent and/or teacher-administered behavior therapy. • Requests for use in children age 5 and under is generally not considered to be medically necessary, since many stimulant medications are not FDA approved for use in this age group. Also, the safety and efficacy in this age group has not been established and is not supported by the currently published peer-reviewed medical literature. Therefore, all requests will be reviewed on a case-by-case basis by the plan Medical Director. **Additional Guidelines (for non-preferred agents):** • Patient meets criteria noted above based on age. • Patient has adverse reaction(s) or contraindication(s) to all preferred agents that does not also exist for the requested non-preferred drug; **OR** • Patient has failed to respond to at least THREE formulary stimulants from both of the stimulant subclasses (e.g., amphetamine/dextroamphetamine AND methylphenidate/dexmethylphenidate). o Requests for a non-preferred, EXTENDED RELEASE product require failure of extended release formulations of the preferred agents.	• Patient continues to receive nutritional OR psychological counseling • Decrease in the number of binge days per week Note: Patients who received authorization for use of a stimulant for ADHD/ADD in childhood/adolescence will require a new PA after age 21 to confirm diagnosis of ADHD using appropriate diagnostic criteria for adults. The PA will also provide evidence that patient requires treatment with stimulants in adulthood.

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	o Requests for a non-preferred, IMMEDIATE RELEASE product require failure of the immediate release formulations of the preferred agents. **Authorization Guidelines for Vyvanse for Binge Eating Disorder (BED):** • Patient is 18 to 55 years of age • Prescribed by, or in consultation with, a psychiatrist • Patient meets DSM-5 criteria for BED diagnosis • Patient has a BMI of >25 kg/m2 • Patient is receiving nutritional counseling OR psychotherapy • Patient had an inadequate response or intolerance to at least TWO formulary medications used for BED such as SSRI's, topiramate, or zonisamide. • Patient has NOT taken monoamine oxidase inhibitors in the past 14 days • There is no recent history of substance abuse • Patient is NOT concurrently taking other stimulants • There is no history of cardiac disease (arrhythmia, cardiac structural abnormalities, CAD)	
Colony-Stimulating Factors (CSF)	Granix, Leukine, Neupogen, Neulasta, Zarxio **See Detailed document:** https://www.aetnabetterhealth.com/illinois/assets/pdf/pharmacy/Colony%20Stimulating%20Factors_508.pdf	
Compounds	**Compounds are not a covered benefit with the following exceptions:** • If each active ingredient is FDA-approved (non-bulk chemicals aka Active Pharmaceutic Ingredient "API") • If each active ingredient is used for an indication that is FDA-approved or compendia supported • The final route of administration of the compound is the same as the FDA-approved or	**Initial Approval:** • For market shortages: 3 months • All others: 1 year **Renewals:**

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	compendia supported route of administration of each active ingredient. (i.e., oral baclofen tablets should not be covered for topical use) • Patient meets ONE of the following: o Has an allergy and requires a medication to be compounded without a certain active ingredient (e.g. dyes, preservatives, fragrances). This situation requires submission of an FDA MedWatch form consistent with DAW1 guidelines. o Cannot consume the medication in any of the available formulations and the medication is medically necessary. o Commercial prescription product is unavailable due to a market shortage (or discontinued) and it is medically necessary. o Request is for 17-alpha hydroxyprogesterone caproate (even if bulk ingredients are used) for the prevention of preterm birth in women who are pregnant with a singleton pregnancy and have history of a prior spontaneous preterm birth. o Request is for a formulary antibiotic or anti-infective for injectable use **NOTE:** All compounds will require authorization and clinical review if total submitted cost exceeds $200. The following compounds are examples of preparations that Aetna considers to be experimental and investigational, because there is inadequate evidence in the peer-reviewed published medical literature of their effectiveness. • Bioidentical hormones and implantable estradiol pellets • Nasal administration of nebulized anti-infectives for treatment of sinusitis • Topical Ketamine, Muscle Relaxants, Antidepressants, NSAIDS, and • Anticonvulsants products typically use for pain • Proprietary bases: PCCA Lipoderm Base, PCCA Custom Lipo-Max Cream, Versabase Cream, Versapro Cream, PCCA Pracasil Plus Base, Spirawash Gel Base, Versabase Gel, Lipopen Ultra	• For market shortages: 3 months • All others: 1 year

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	Cream, Lipo Cream Base, Pentravan Cream/Cream Plus, VersaPro Gel, Versatile Cream Base, PLO Transdermal Cream, Transdermal Pain Base Cream, PCCA Emollient Cream Base, Penderm, Salt Stable LS Advanced Cream, Ultraderm Cream, Base Cream Liposome, Mediderm Cream Base, Salt Stable Cream.	
Corlanor[xii]	**May be authorized for patients at least 18 years old when the following criteria are met:** • Patient has stable chronic heart failure with a left ventricular ejection fraction ≤ 35% • Patient is in sinus rhythm • Resting heart rate ≥ 70 beats per minute (bpm) • Patient will continue therapy with maximally tolerated beta-blocker **OR** Patient has an intolerance or contraindication to beta-blockers • Patient will continue therapy with an ACEI/ARB or Entresto **OR** Patient has an intolerance or contraindication to ACEI/ARB. (Note: Entresto requires PA) • Patient does not have any of the following contraindications to treatment: o Acute decompensated heart failure o Blood pressure < 90/50 mmHg o Pacemaker dependent (i.e. heart rate maintained exclusively by pacemaker) o Sick sinus syndrome, sinoatrial block of third degree AV block (unless a functioning demand pacemaker is present) o Severe hepatic impairment (Child-Pugh class C)	**Initial Approval:** 6 months **Renewals:** Indefinite ***Requires:*** • Patient is responding to treatment • HR ≤ 70 bpm QLL: 2 tablets per day
Cystic Fibrosis (pulmonary) Medications[xiii] Pulmozyme Tobramycin Nebulizer	**Pulmozyme may be authorized when the following are met:** • Patient is at least 5 years old • Patient has a diagnosis of cystic fibrosis **Tobramycin Nebulizer (generic for Tobi) and Kitabis may be authorized when the following are met:** • Patient has a diagnosis of cystic fibrosis	**Initial Approval:** Kalydeco and Orkambi: 3 months All others: Indefinite **Renewal (Kalydeco and**

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Tobi Podhaler Bethkis Kitabis Cayston Kalydeco Orkambi	• Patient is at least 6 years old • FEV_1 is between 25-80% predicted • Sputum cultures are positive for *P.aeruginosa* • Patient is not colonized with *Burkholderia cepacia* **Tobi Podhaler or Bethkis may be authorized when the following are met:** • Patient meets criteria listed above for tobramycin nebulizer solution • Patient has had an inadequate response, or intolerable side effects with tobramycin nebulizer solution (generic) **Cayston may be authorized when the following are met:** • Patient has a diagnosis of cystic fibrosis • Patient is at least 7 years old • FEV_1 is between 25-75% predicted • Sputum cultures are positive for *P.aeruginosa* • Patient is not colonized with *Burkholderia cepacia* • Patient has had an inadequate response, or intolerable side effects with tobramycin nebulizer solution OR sputum cultures show resistance to tobramycin **Kalydeco can be recommended for approval when the following are met:** • Prescribed by, or in consultation with, a pulmonologist • Patient has a diagnosis of cystic fibrosis with one of the following *CFTR* gene mutations: *G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, or R117H* (or other mutations per PI) • Patient is not homozygous for the *F508del* mutation in the *CFTR* gene • Patient is at least 2 years old	**Orkambi):** 6 months ***Requires:*** • Documentation to support response to therapy (symptom improvement and/or stable FEV1) • LFT's: Kalydeco and Orkambi should be temporarily discontinued if AST/ALT are >5x ULN QLL: • Tobramycin: 56 ampules per 56 days (28 days of therapy followed by 28 days off) • Cayston: 84 ampules per 56 days (28 days of therapy followed by 28 days off) • Kalydeco: 56 tablets per 28 days • Orkambi: 112 tablets per 28 days

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Liver function tests have been evaluated and dose has been reduced for patients with moderate to severe hepatic impairment • 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) **Orkambi can be recommended for approval when the following are met:** • Prescribed by, or in consultation with, a pulmonologist • Patient is at least 6 years of age • Patient has a 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 have been evaluated and dose has been reduced for patients with moderate to severe hepatic impairment • 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)	
Cytokines and CAM Antagonists	Actemra, Cimzia, Cosentyx, Enbrel, Entyvio, Humira, Ilaris, Kineret, Orencia, Remicade, Simponi, Stelara, Taltz, Tysabri, Xeljanz **Refer to detailed PA Guideline:** https://www.aetnabetterhealth.com/illinois/assets/pdf/pharmacy/pa-guidelines/Cytokines_CAM_Antagonists.pdf	

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met

Daliresp[xiv]	**May be approved for adults, who meet all of the following:**
	• 18 years of age and older
	• Diagnosis of severe COPD with chronic bronchitis
	• Documented symptomatic exacerbations within the last year
	• Member had an inadequate 3 month trial and failure or contraindication to
	  o long-acting beta-agonist (LABA) + long-acting muscarinic antagonist (LAMA) + inhaled corticosteroid (ICS) or
	  o long-acting beta-agonist (LABA) + inhaled corticosteroid (ICS)
	• Daliresp will be used in conjunction with a LABA+LAMA or LABA +ICS unless contraindicated/intolerant
	• No evidence of moderate to severe liver impairment (Child-Pugh B or C)
		Initial Approval:
		6 months
		
		Renewals:
		Indefinite
		
		Requires:
		improvement in the number of COPD exacerbations
		QLL: 1 tablet per day

Daraprim[xv]	**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:
	  o Patient is asymptomatic
	  o Patient is receiving antiretroviral therapy (ART)
	  o Patient has a suppressed HIV viral load
	  o 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
		Initial Approval:
		• Acute Toxoplasmosis - 6 weeks
		• Acute PCP - 21 days
		• PCP prophylaxis - 3 months
		
		Renewals:
		• Secondary Prophylaxis after Acute Toxoplasmosis treatment - 6 months
		• PCP prophylaxis - 3 month; If CD4 count is <200 or CD4 count % is <14%

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• For PCP prophylaxis in patients with HIV: o Patient has ONE of the following: ▪ CD4 count <200 cells/microL ▪ Oropharyngeal candidiasis ▪ CD4 count percentage <14 percent ▪ CD4 cell count between 200 and 250 cells/microL when frequent monitoring (e.g., every three months) of CD4 cell counts is not possible o Patient has a trial and failure or contraindication to atovaquone **AND** dapsone • For PCP treatment: o Patient is diagnosed PCP infection o 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. o http://www.cdc.gov/malaria/resources/pdf/algorithm.pdf o 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 o http://www.cdc.gov/malaria/travelers/country_table/a.html	
Diabetic Testing Supplies	**Diabetic Test Strip and Glucometer Quantity Limits:** • All diabetic test strips are limited to 150ct/30 days • 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%	**Initial Approval:** 1 year

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	o Accu-Chek Aviva Plus and Nano SmartView are accurate for Hct 10-65% o 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.	
Diclegis[xvi]	**May be authorized when the following criteria are met:** • Member is at least 18 years of age • Diagnosis of nausea and vomiting in pregnancy • Documentation to support member had an inadequate response or intolerable side effects to dietary and lifestyle changes (e.g. avoiding stimuli/triggers, avoiding spicy and fatty foods, eating frequent small meals, an inadequate response to ginger) • Member has had an inadequate response or intolerable side effects to: o A combination of OTC doxylamine and OTC pyridoxine (vitamin B6) **AND** at least 1 of the following:	**Initial Approval:** 3 months **Renewal:** 3 months ***Requires:*** • Member is still pregnant and continues to have nausea and vomiting symptoms QLL: 4 tablets per day

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	o H1 Antihistamines (e.g., diphenhydramine, meclizine, dimenhydrinate) **OR** ondansetron	
Direct Renin Inhibitors[xvii] Tekturna Tekturna HCT Tekamlo	**May be authorized when all of the following criteria are met:** • Member is 18 years of age or older • Diagnosis of Hypertension (HTN) • Documented trial and failure or contraindication to 2 formulary alternatives; an Angiotensin Receptor Blocker (ARB) or an ACE inhibitor • Will not be used in combination with an ACE inhibitor or an ARB	**Initial Approval:** Indefinite QLL: 1 tablet per day
Duavee[xviii]	**Duavee can be approved for adult women under the age of 75 who have an intact uterus and who meet the following criteria based on indication:** • Treatment of vasomotor symptoms associated with menopause (VMS): o 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: o Patient has tried and failed (or has contraindication/intolerance to) raloxifene AND alendronate o Patient has osteopenia (T-score between -1.0 and -2.5) OR is at high risk for OP fracture (as defined by any of the following): ▪ FRAX risk ≥3.0% for hip fracture OR ≥20% for any major OP-related fracture; **OR** ▪ Patient has ≥1 risk factor for fracture: a. low body mass index b. previous fragility fracture c. parental history of hip fracture d. glucocorticoid treatment e. current smoking f. alcohol intake of 3 or more units per day	**Initial Approval:** • 5 years

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	g. rheumatoid arthritis h. secondary causes of osteoporosis	
Dupixent[xix]	**May be authorized when <u>all</u> of the following criteria is met:** • Member is at least 18 years of age • Diagnosis of moderate to severe atopic dermatitis • Prescribed by, or in consultation with, a dermatologist, allergist or immunologist • Member had an inadequate response or intolerable side effects to ALL of the following: o Two preferred (medium to very high potency) topical corticosteroids (e.g. triamcinolone, clobetasol, mometasone, betamethasone, fluocinonide) o One topical calcineurin inhibitors (e.g., tacrolimus)	**<u>Initial Approval:</u>** 4 months **<u>Renewals:</u>** 6 months ***Requires:*** • Compliance and adherence to treatment • At least 20% symptom improvement (e.g., reduction in lesions) or Investor's Static Global Assessment (ISGA) of 0 or 1 'clear' or 'almost clear' **<u>Dosing:</u>** Initial: 600 mg SQ Maintenance: 300 mg SQ every 2 weeks
Egrifta	**May be authorized for treatment of excess abdominal fat in HIV-infected patients with lipodystrophy when the following are met:** • Patient is 18-65 years of age	**<u>Initial Approval:</u>** 1 year

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• No evidence of active neoplastic disease • No evidence of acute critical illness • 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 • Patient is not using Egrifta for weight loss • Patient is at risk for medical complications due to excess abdominal fat • If female, patient is not pregnant and is using a reliable form of birth control (pregnancy category X)	**Renewal:** 3 years with documentation of a clinical response
Eucrisa[xx]	**May be authorized when all of the following criteria is met:** • Member is at least 2 years of age • Diagnosis of mild to moderate atopic dermatitis • Prescribed by, or in consultation with, a dermatologist, allergist or immunologist • Member had an inadequate response or intolerable side effects to ALL of the following: o Two preferred (medium potency) topical corticosteroids (e.g. hydrocortisone, triamcinolone, mometasone, betamethasone, fluticasone) o One topical calcineurin inhibitors (e.g., tacrolimus)	**Initial Approval:** 4 weeks **Renewals:** 3 months ***Requires:*** **Improvement in lesions** • Compliance and adherence to treatment • Investor's Static Global Assessment (ISGA) of 0 or 1 'clear' or 'almost clear' or at least 20% symptom improvement (e.g., reduction in lesions)

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		Quantity Limit: 60 gm tube per month 100 gm tube per month
Entresto[xxi]	**May be authorized for patients who are 18 years of age or older and meet the following criteria:** • Diagnosed with Heart Failure (NYHA Class II-IV) with a reduced ejection fraction (HFrEF)≤ 40% • Patient is tolerating an ACEI or ARB and Entresto will replace the ACEI and/or ARB • Used in conjunction with other heart failure therapies (beta blockers, aldosterone antagonist and combination therapy with hydralazine and isosorbide dinitrate) • Patient is not pregnant • Patient does not have severe hepatic impairment (Child Pugh Class C)	**Initial Approval:** Indefinite QLL: 2 tablets per day
Erythropoiesis Stimulating Agents (ESA's)[xxii] Epogen Procrit Aranesp	**Preferred Product:** Epogen is the preferred ESA. Requests for Procrit require trial and failure of Epogen. Requests for Aranesp require trial and failure of BOTH Epogen and Procrit. **General Authorization Guidelines for All Indications:** • Patient does not have uncontrolled hypertension • Other causes of anemia have been treated (e.g., vitamin deficiency, metabolic or chronic inflammatory conditions, bleeding, etc) • Iron Studies show member has adequate iron stores to support erythropoiesis: o Serum ferritin ≥100 ng/ml and transferrin saturation* (iron saturation) ≥ 20%, or o Normal serum iron, TIBC and serum ferritin, or o Reticulocyte hemoglobin content (CHr) >29 **Additional Criteria Based on Indication:** • **Anemia due to Chronic Kidney Disease (CKD)**	**Initial Approval:** • Perioperative: up to 21 days of therapy per surgery • All other indications: 3 months **Renewals:** • 3 months ***Requires:*** • Follow up iron studies showing member has adequate iron to support erythropoiesis

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	o For initial therapy: Hemoglobin < 10 g/dL within the last 2 weeks o For maintenance therapy: Hemoglobin < 11 g/dL within the last 2 weeks • **Anemia due to Cancer Chemotherapy** o Anemia is due to the effect of concomitant myelosuppresive chemotherapy o Diagnosis of non-myeloid malignancy (e.g., solid tumor) o There is a minimum of two additional months of planned chemotherapy o Provider and patient are enrolled in the ESA APPRISE REMS program o For initial therapy: Hemoglobin < 10 g/dL within the last 2 weeks o For maintenance therapy: Hemoglobin < 11 g/dL within the last 2 weeks • **Anemia in Patients with HIV receiving zidovudine *(Procrit and Epogen only)*** o Zidovudine dose ≤4200 mg/week o Endogenous erythropoietin levels ≤ 500 IU/L o For initial therapy: Hemoglobin <10 g/dL within the last 2 weeks o For maintenance therapy: Hemoglobin <11 g/dL within the last 2 weeks • **Reducing transfusions in patients undergoing elective, noncardiac, nonvascular surgery *(Procrit and Epogen only)*** o Hemoglobin >10 and ≤ 13 g/dL within 30 days prior to planned surgery date o Member is at high risk for perioperative blood loss • **Anemia associated with Myelodysplastic Syndrome (MDS) *(Procrit and Epogen only)*** o Recent endogenous erythropoietin level ≤ 500 IU/L o For initial therapy: Hemoglobin < 10 g/dL within the last 2 weeks o For maintenance therapy: Hemoglobin < 11 g/dL within the last 2 weeks	• Hb < 11 g/dL within the last 2 weeks
Growth Hormone	Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Tev-Tropin, Zorbtive **See Detailed document:**	

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	https://www.aetnabetterhealth.com/illinois/assets/pdf/Growth2.pdf	
Growth Hormone Antagonists Somavert	**See Detailed document:** https://www.aetnabetterhealth.com/illinois/assets/pdf/Growth.pdf	
GnRH Analogs[xxiii] Leuprolide acetate Lupanta Pack Lupron Depot Lupron Depot-PED Eligard Trelstar Vantas Synarel Supprelin LA Zoladex	**For patients who meet the following based on diagnosis:** **Endometriosis** *(Lupron Depot, Lupaneta, Synarel, Zoladex 3.6 mg dose only)* • Prescribed by or in consultation with a gynecologist or obstetrician • Patient is at least 18 years of age • Trial and failure of at least one formulary hormonal cycle control agent (e.g., Portia, Ocella, Previfem), medroxyprogesterone, or Danazol **Uterine Leiomyoma (fibroids)** *(Lupron Depot, Synarel)* • Prescribed by or in consultation with a gynecologist or obstetrician • Patient is at least 18 years of age • Prescribed to improve anemia and/or reduce uterine size for 3-6 months prior to planned surgical intervention **Dysfunctional Uterine Bleeding** *(Zoladex 3.6mg dose only)* • Prescribed by or in consultation with a gynecologist or obstetrician • Patient is at least 18 years of age • Prescribed to thin endometrium prior to planned endometrial ablation or hysterectomy within the next 4-8 weeks	**Initial Approval:** **Endometriosis** • 6 months **Uterine Leiomyoma (fibroids)** • 6 months **Dysfunctional uterine bleeding** • 2 months **Central Precocious Puberty** • Supprelin LA: 12 months • All others: 6 months **Cancer** • 2 years **Renewal:** **Central Precocious Puberty** • 6 months - 1 year (up to age 11 for females and age 12 for males)

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	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, weight, and LH levels **Advanced Prostate Cancer** *(Lupron Depot, Leuprolide acetate solution, Eligard, Zoladex,Vantas Trelstar)* • Prescribed by, or in consultation with an oncologist or urologist • Patient is at least 18 years of age **Advanced Breast Cancer** *(Lupron Depot 3.75 mg, Zoladex 3.6mg dose only)* • Prescribed by, or in consultation with an oncologist • Patient is at least 18 years of age **Advanced Ovarian Cancer** (*Lupron Depot 3.75 and 11.25 mg*) • Prescribed by, or in consultation with an oncologist • Patient cannot tolerate or do not respond to cytotoxic regimens OR the drug is being used for post-operative management	*Requires:* • Clinical response to treatment (i.e., pubertal slowing or decline, height velocity, bone age, LH, or estradiol and testosterone level) **Endometriosis** • Lupron Depot/Lupaneta only: 6 months • Re-treatment is not recommended with Synarel and Zoladex *Requires:* • Bone mineral density within normal limits • Use in combination with norethindrone acetate (excludes Lupaneta) **Uterine Leiomyoma (fibroids) or Dysfunctional Uterine Bleeding** • Long-term use is not recommended • Re-treatment may be

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Patient is at least 18 years of age	considered on a case by case basis
Hemophilia[xxiv] Factor VIIa Factor VIII Factor IX	**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-P, Novoeight • Factor IX: Alphanine SD, Mononine, Bebulin VH, Proplex T, Profilnine SD, Benefix, Rixubis, Alprolix, Ixinity • Anti-Inhibitor Coagulant Complex: FEIBA NF 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) with documented history of two or more episodes of spontaneous bleeding into joints • NOTE: Only Humate-P, Alphanate, and Wilate contain von Willebrand factor in addition to factor VIII and are effective for von Willebrand's disease	**Initial Approval**: 3 months **Renewal:** 1 year Factor VIII and IX should be discontinued upon development of a Factor inhibitor resulting in lack of response to factor VIII or IX

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	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: o Hemophilia A or hemophilia B **with inhibitors** o Congenital factor VII (FVII) deficiency o Glanzmann's thrombasthenia when refractory to platelet transfusions o Acquired hemophilia **FEIBA NF (Anti-Inhibitor Coagulant Complex) is authorized for members who meet the following:** • Treatment of hemorrhagic complications OR prevention of bleeding in surgical or invasive procedures in a patient with hemophilia A or hemophilia B **with inhibitors**	
Hepatitis C	Daklinza, Harvoni, Sovaldi, Zepatier, etc **See Detailed Document:** **https://www.aetnabetterhealth.com/illinois/providers/icp/pharmacy**	
Hetlioz[xxv]	**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
HP Acthar[xxvi]	**HP Acthar may be authorized when the following criteria has been met:**	**Initial Approval:**

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	Infantile Spasm: • Member is 2 years of age and under • Prescribed by or in consultation with a neurologist or epileptologist • Diagnosis of Infantile Spasm (West syndrome) • Confirmation of diagnosis by an electroencephalogram (EEG) **Acute Exacerbation of MS:** • Member meets ONE of the following: o Continues to have functionally disabling symptoms despite a 7 day course of high dose IV corticosteroids (i.e., methylprednisolone 1000mg per day) for the CURRENT exacerbation o Had significant side effects with high dose IV corticosteroids **All other indications have not been supported by clinical trials by the manufacturer and is considered experimental and investigation and hence not medically necessary and will not be covered**	Infantile Spasm -1 month MS - 3 weeks Prolonged use may lead to adrenal insufficiency or recurrent symptoms which make it difficult to stop the treatment, therefore treatment beyond 3 weeks for the same episode is not recommended.
Hyperlipidemia Medications[xxvii] Rosuvastatin Lovaza Vascepa	Rosuvastatin may be approved when the following criteria are met: • Member is at least 7 years old; AND • Member has had a compliant 3 month trial and failure of or intolerance to high intensity atorvastatin (40 mg-80 mg) Lovaza, Vascepa, Epanova, and Omtryg may be approved when the following criteria are met: • Member is at least 18 years old • Drug will be used as an add-on to lifestyle interventions to include diet and exercise	Initial Approval: • 3 months Renewal: • Indefinite *Requires:* • Lipid panel within the past

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Epanova Omtryg	• Treatment of severe hypertriglyceridemia (triglyceride level greater than or equal to 500 mg/dL) • Trial and failure of OTC fish oil and a fibrate such as fenofibrate, fenofibric acid, or gemfibrozil, or contraindication to all formulary agents	90 days showing improvement in fasting lipids • Claims history to support compliance or adherence to adjunctive lipid lowering therapies Quantity Limits: • Rosuvastatin: 1 tablet per day • Lovaza/Vascepa, Epanova, and Omtryg: 4 tablets per day
Idiopathic Pulmonary Fibrosis Agents[xxviii] Esbriet Ofev	**Members may be approved when all of the following are met:** • Member is 18 years of age and older • Prescribed by, or in consultation with, a pulmonologist • Diagnosis idiopathic pulmonary fibrosis (IPF)confirmed by one of the following: o High resolution computed tomography (HRCT) demonstrating usual interstitial pneumonia (UIP) o Surgical lung biopsy with UIP • Forced vital capacity (FVC) ≥ 50 % predicted • Carbon Monoxide Diffusion Capacity (DLco)≥30% • Documentation of baseline liver function tests (LFT's) prior to initiating treatment • Member is not a current smoker	**Initial Approval:** **3 months** **Renewal:** 6 months ***Requires:*** • Documentation of stable FVC (recommended to discontinue if there is a >10% decline in FVC over a 12 month period)

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		• Attestation that LFT's are being monitored • Documentation that the member is not a current smoker • Compliance and adherence to treatment **QLL:** Esbriet: 3 caps/tabs per day Ofev: 2 caps per day
Increlex	**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 diagnosis of Growth hormone (GH) gene deletion and development of neutralizing antibodies to GH **OR** • Documentation supports a diagnosis of Severe, Primary IGF-1 deficiency o Height standard deviation score less than or equal to −3 o Basal IGF-1 standard deviation score less than or equal to −3 o Normal or elevated growth hormone levels o No evidence of secondary forms of IGF-1 deficiency, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of corticosteroids	**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

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Injectable Osteoporosis Agents	Forteo, Prolia, Zoledronic **See Detailed document:** https://www.aetnabetterhealth.com/illinois/assets/pdf/pharmacy/pa-guidelines/Injectable_Osteoporosis_508.pdf	
IL-5 Antagonists[xxix] Nucala Cinqair	**May be authorized for the treatment of severe EOSINOPHILIC asthma when the following are met:** • Member is at least: o 12 years old (Nucala) o 18 years old (Cinqair) • Prescribed by, or after consultation with a pulmonologist or allergist/immunologist • Lab results to support ONE of the following blood eosinophil counts: o ≥ 150 cells/mcl within 6 weeks of dosing or ≥ 300 cells/mcl at any time in the past 12 months (Nucala) **OR** o ≥ 400 cells/mcl at baseline (Cinqair) • Member has been compliant with Medium or High dose inhaled corticosteroids (ICS) + a long-acting beta agonist (LABA) for at least 3 months or other controller medications (e.g., LTRA or theophylline) if intolerant to a LABA • Documentation to support asthma symptoms are poorly controlled as defined by ANY of the following: o At least 2 exacerbations in the last 12 months requiring additional medical treatment (systemic corticosteroids, emergency department visits, or hospitalization) o Daily use of rescue medications (short-acting inhaled beta-2 agonists) o Nighttime symptoms occurring more than once a week • Members with history of exacerbations must have an adequate 2 month compliant trial of	**Initial Approval:** 6 months **Renewal:** 1 year ***Requires:*** Demonstration of clinical improvement (e.g., decreased use of rescue medications or systemic corticosteroids, reduction in number of emergency department visits or hospitalizations) and compliance with asthma controller medications **Dosing:** Nucala: 100mg every 4 weeks Cinqair: 3mg/kg every 4 weeks

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	tiotropium (requires PA) • Member will not receive in combination with Xolair or another IL-5 inhibitor **Note: Not covered for treatment of other eosinophilic conditions or relief of acute bronchospasm or status asthmaticus**	
Insulin Pens[xxx] **Rapid acting:** Apidra Solostar Humalog KwikPen Novolog FlexPen **Short acting:** Humulin R KwikPen **Intermediate acting:** Humulin N KwikPen Humulin 70/30 KwikPen Novolin N Innolet **Basal insulin:** Basaglar KwikPen Lantus Solostar Levemir Flextouch	**For members who meet the following:** • Diagnosis of Type I or Type II Diabetes Mellitus (For plans with age restrictions on formulary pens) • Documentation to support member meets one of the following: 1. A school-aged child requiring multiple daily injections 2. Visual impairment 3. Physical disability or dexterity problems and unable to draw up syringe 4. Environmental factors which prevent use of vial formulation **OR** • Documentation to support an inadequate response, intolerable side effects or contraindication to 2 formulary insulins within the same class (i.e. rapid, regular, or basal) **Toujeo only:** • Documentation to support an inadequate (3 month) response, intolerable side effects or contraindication to formulary basal insulin pens (For hypoglycemia: consistent evidence of hypoglycemia such as a Self-Monitoring Blood Glucose reading must be provided) **OR**	**Initial Approval:** Indefinite

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Toujeo Solostar Tresiba FlexTouch	• Documentation to support required units of basal insulin exceeds 100 units/day	
Interferons[xxxi] ***α-Interferon*** Alferon N Intron A Pegasys Pegintron Sylatron ***β-Interferon*** See Multiple Sclerosis Agents ***γ-Interferon*** Actimmune	**Chronic Hepatitis B (CHB) infection:** *(Intron A, Pegasys)* • Patient is HBsAg positive for more than six months • Prescribed by, or in consultation with, an infectious disease physician, HIV specialist, gastroenterologist, hepatologist, or transplant physician • Patient has compensated liver disease (e.g., bilirubin and albumin WNL, no cytopenias) • There is evidence of viral replication with an HBV DNA level of ≥ 20,000 IU/mL for HBeAg-positive patients or ≥ 2000 IU/mL for HBeAg-negative patients • There is evidence of liver inflammation (e.g., ALT > 2 ULN, 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 **AIDS-related Kaposi's sarcoma:** *(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 • Patient must be at least 18 years old **Hairy-cell Leukemia (HCL):** *(Intron A)* • Prescribed by, or in consultation with, a hematologist/oncologist • Patient has demonstrated less than complete response to cladribine or pentostatin OR has relapsed within 1 year of demonstrating a complete response • Patient has indications for treatment such as:	**Initial Approval:** ***Hepatitis B:*** • Intron A – 16 weeks for adults; 24 weeks for children • Pegasys – 48 weeks ***Osteopetrosis, CGD, HCL, Kaposi's sarcoma:*** • 6 months ***Malignant Melanoma:*** • Intron A: 48 weeks • Sylatron: up to 5 years ***Condylomata acuminate:*** • Intron A: 3 weeks • Alferon N: 8 weeks **Renewal:** ***Hepatitis B:*** • Intron A: additional 16 weeks if still HBeAg-positive

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Systemic symptoms – fatigue, weakness, weight loss, fever, night sweats, recurrent infection ○ Symptomatic splenomegaly or adenopathy ○ Significant cytopenias – hemoglobin < 12 g/dL, platelets < 100,000/mcL, or ANC < 1500/mcL • Patient is at least 18 years of age **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 of age **Chronic Granulomatous Disease (CGD):** *(Actimmune)* • Prescribed by, or in consultation with an immunologist or infectious disease specialist • Patient is also receiving antifungal and antibacterial prophylaxis (e.g., itraconazole and trimethoprim/sulfamethoxazole) • Patient is at least 1 year of age **Malignant Osteopetrosis:** *(Actimmune)* • Prescribed by, or in consultation with a hematologist/oncologist • Prescribed for the treatment of severe, malignant osteopetrosis **Condylomata acuminata (genital or venereal warts):** *(Intron A, Alferon N)* • For intralesional use • Lesions are small and limited in number • Trial and failure of topical treatments or surgical technique (i.e., imiquimod cream, podofilox,	• Intron A: up to 2 years for HBeAg-negative patients ***CGD:*** • 1 year if number and/or severity of infections has decreased ***Osteopetrosis:*** • 1 year if no evidence of disease progression ***Condylomata acuminate:*** • Intron A: 16 weeks • Alferon N: 8 weeks; there must be at least 3 months between treatments unless there are signs of disease progression ***All other indications:*** • 1 year • NOTE: For HCL it is not recommended to continue if disease has progressed

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	cryotherapy, laser surgery, electrodessication, surgical excision) • Patient at least 18 years of age	
Intravaginal Progesterone Products[xxxii] Crinone Endometrin First-progesterone suppositories	**For patients that meet the following:** • Prescribed by, or in consultation with, a provider of obstetrical care • Patient is not on Makena (17-hydroxyprogesterone) • Patient is pregnant with singleton gestation and meets either of the following: o History of spontaneous preterm birth (i.e. delivery of an infant < 37 weeks gestation) o Cervical length < 25 mm before 24 weeks of gestation	**Initial Approval:** Approve as requested until 37 weeks gestation Begin progesterone use no earlier than 16 weeks, 0 days and no later than 23 weeks, 6 days
Jakafi[xxxiii]	**Criteria for the use in myelofibrosis:** • Patient is at least 18 years old • Prescribed by, or in consultation with, a hematologist/oncologist • Diagnosis of primary myelofibrosis, post-polycythemia vera myleofibrosis or post-essential thrombocythemia myelofibrosis • Intermediate or high risk disease defined as having two or more of the following risk factors o Age > 65 years o Constitutional symptoms (weight loss > 10% from baseline and/or unexplained fever or excessive sweats persisting for more than 1 month) o Hemoglobin < 10g/dL o WBC count ≥25 x 10^9/L o Peripheral Blood blasts > 1% o Platelet count <100 X 10^9/L o Red Cell Transfusion o Unfavorable karyotype [i.e., complex karyotype or sole or two abnormalities that	**Initial Approval:** 6 months **Renewal:** 1 year ***Requires:*** For Myelofibrosis: • Spleen size reduction of ≥35%; OR • Symptom improvement (≥50% reduction in total symptom score from baseline); OR • Absence of disease progression For Polycythemia vera • Hematologic improvement

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	include +8, −7/7q-, i(17q), inv(3), −5/5q-, 12p- or 11q23 rearrangement] • No evidence of infection • Baseline platelet count of at least 50 X 10^9/L prior to initiating therapy **Criteria for the use in polycythemia vera:** • Patient is at least 18 years old • Prescribed by, or in consultation with, a hematologist/oncologist • Previous treatment failure with hydroxyurea • Patient has splenomegaly and requires phlebotomy to control symptoms • Baseline Hct of 40-45% • No evidence of infection • Documented baseline platelet count ≥50,000	(decreased hematocrit, platelet count or WBC count); OR • Reduction in palpable spleen length; OR • Improvement in symptoms (e.g., pruritus, night sweats, bone pain) Therapy should be gradually tapered if patient fails to achieve at least 35% decrease from baseline in spleen volume or experiences unacceptable toxicities
Juxtapid/Kynamro [xxxiv]	**May be authorized when ALL of the following criteria are met:** • Member is at least 18 years old • Prescribed by, or in consultation with, a Cardiologist, Endocrinologist, or Lipid Specialist • Diagnosis of homozygous familial hypercholesterolemia (HoFH) as evidenced by: o Genetic confirmation of 2 mutant alleles at LDLR, APO-B100, PCSK9 **OR** o History of untreated LDL greater than 500 mg/dL or treated LDL greater than 300 mg/dL on maximum dosed statin AND evidence of one of the following: ▪ Presence of cutaneous xanthoma before the age of 10 ▪ Evidence of HeFH in both parents (LDL ≥190 mg/dL) • Failed an adequate 90 day trial of 2 high intensity statins* (e.g., atorvastatin ≥ 40 mg and rosuvastatin ≥ 20 mg) at maximum tolerated doses and in	**Initial Approval:** • 3 months **Renewal:** • 6 months ***Requires:*** • Lipid Panel within the past 90 days showing at least a 30% LDL reduction from baseline • Claims history to support

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	combination with other lipid lowering therapies such as ezetimibe or bile acid sequestrants; Intolerance to statin therapy trials requires the following o An intolerance to at least 2 statins (at least one trial being a moderate to high potency statin) for more than 2 weeks with: ▪ Documentation supporting skeletal muscle related symptoms (e.g., myopathy, myositis or abnormal biomarkers) that resolved when statin therapy was discontinued ▪ Documentation the member has been re-challenged with at least 2 different statins at an equivalent or lower dose • Failed a 90 day trial of Repatha (Non Formulary preferred) • Will be used as adjunct to lipid lowering therapies such as statins, ezetimibe, bile acid sequestrants, or LDL apheresis (for Juxtapid only) • Will not be used with a PCSK9 inhibitor **Additional Drug Specific Criteria:** **Juxtapid:** • Member is not pregnant • Will not be used concomitantly with moderate or strong CYP3A4 inhibitors **Kynamro:** • Member will not be receiving adjunctive therapy with LDL apheresis	compliance or adherence to both Juxtapid/Kynamro and adjunctive lipid lowering therapies • ALT and AST are <3x ULN **Quantity Limits:** • Juxtapid: #1 tablet per day • Kynamro: #4 injections per 28 days
Lidocaine Patch[xxxv]	**May be authorized for members who are 17 years of age or older and the following criteria is met:**	**Initial Approval:** 3 months

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Diagnosis of post herpetic neuralgia **OR** • Diagnosis of diabetic peripheral neuropathy AND • Documentation to support trial and failure or intolerance to 2 formulary alternatives (e.g., duloxetine, tricyclic antidepressants, gabapentin)	**Renewals:** Indefinite
Long-Acting Muscarinic Antagonists (LAMA) 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. Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy. **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: o Inhaled corticosteroid o Inhaled corticosteroid with a long-acting beta-2 agonist o Montelukast or zafirlukast NOTE: Spiriva HandiHaler, Tudorza, and Incruse are NOT FDA-approved for asthma	**Initial Approval:** Indefinite
Long Acting Opioids[xxxvi] Oxycontin Butrans Patch	All long-acting opiates require prior authorization. Members with pain due to cancer or sickle cell anemia will be exempt from these requirements for formulary agents. **Criteria for ALL long-acting opioids (formulary and non-formulary):** • Patient is at least 18 years old	**Initial Approval:** 1 year **Renewal:** 1 year

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Exalgo Oxymorphone ER Zohydro ER Xartemis XR Nucynta ER Morphine Sulfate ER Fentanyl Patch Methadone Belbuca Embeda Hysingla Xtampza	• Patient has a treatment plan that includes the diagnosis and goals of therapy • Prescriber has completed an addiction risk assessment • Prescriber has recently reviewed the state Prescription Monitoring Program (PMP) database • Patient has a pain management agreement that addresses the following: o Consequences of lost medication or taking more than prescribed o Consequences of obtaining controlled substances from other prescribers o Member agreement to only use one pharmacy **In addition, criteria for Oxymorphone ER:** • Treatment of chronic pain • Patient had inadequate response or intolerance to at least TWO formulary long-acting opioids (i.e., fentanyl patch, morphine sulfate ER, methadone) • Trials of formulary agents were for at least 2 weeks and at maximum tolerated doses **In addition, criteria for all other Non-Preferred Long-Acting Opioids:** • For treatment of chronic pain o Patient had inadequate response or intolerance to oxymorphone ER AND at least TWO other formulary long-acting opioids o Trials of formulary agents were for at least 2 weeks and at maximum tolerated doses • For treatment of diabetic peripheral neuropathy (Nucynta ER): o Patient had inadequate response or intolerance to duloxetine AND tramadol AND at least ONE additional formulary medication (e.g., gabapentin, amitriptyline, nortriptyline, or topical capsaicin) indicated for neuropathy o Trials of formulary agents were for at least 4 weeks and at maximum tolerated doses Note: Oxycontin may be authorized for the treatment of pain due to cancer or sickle cell anemia and is not subject to the criteria.	**Quantity limits:** Oxycontin: 3 tablets/day Oxymorphone ER: 2 tablets/day Butrans patch: #4/28 days Hysingla: 1 tablet/day Nucynta ER: 2 tablets/day Xartemis: 12 tablets/day Belbuca: 2 tablets/day Embeda: 2 tablets/day Zohydro: 2 tablets/day Xtampza: BID dosing Maximum 288mg/day

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	Note: Women of reproductive age should be counseled about opioid use during pregnancy and neonatal abstinence syndrome (NAS)	
Lyrica[xxxvii]	**Lyrica is authorized for members who are 18 years of age or older with a diagnosis of partial onset seizures and spinal cord injury.** **Authorization Criteria for Post-Herpetic Neuralgia:** • Patient is 18 years of age or older • Patient had inadequate efficacy or intolerable side effects with a compliant 3-month trial of gabapentin at maximum tolerated doses **Authorization Criteria for Fibromyalgia:** • Patient is 18 years of age or older • Patient had inadequate efficacy or intolerable side effects with a compliant 3-month trial of BOTH of the following: o Duloxetine at maximum tolerated doses o Gabapentin OR a tricyclic antidepressant at maximum tolerated doses **Authorization Criteria for Diabetic Peripheral Neuropathy or Cancer-Related Neuropathic Pain:** • Patient is 18 years of age or older • Patient had inadequate efficacy or intolerable side effects with a compliant 3-month trial of duloxetine AND at least 1 other formulary agent used for neuropathy such as topical capsaicin, tricyclic antidepressants, tramadol, venlafaxine, or gabapentin at maximum tolerated doses	**Initial Approval:** Indefinite
Makena[xxxviii]	**For members who meet the following criteria:** • Prescribed by, or in consultation with, a provider of obstetrical care	**Initial Approval:** Until 37 weeks gestation

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Patient is currently pregnant with singleton gestation • Patient has a history of a spontaneous preterm singleton delivery (i.e. delivery of an infant < 37 weeks gestation)	Injections begin no earlier than 16 weeks, 0 days and no later than 23 weeks, 6 days
Modafinil/Armodafinil[xxxix]	Modafanil is the preferred formulary agent, however still requires PA. Armodafinil is non-formulary and may be authorized if the patient meets criteria and also has a documented trial and failure of modafinil. **May be authorized for patients at least 17 years old for excessive daytime sleepiness associated with narcolepsy when the following is met:** • Diagnostic testing, such as multiple sleep latency test (MSLT) or polysomnography, supports diagnosis of narcolepsy **May be authorized for patients at least 17 years old for excessive daytime sleepiness associated with Obstructive Sleep Apnea (OSA) when the following is met:** • Prescribed by, or in consultation with, a sleep specialist • Polysomnography has confirmed the diagnosis of OSA • Patient remains symptomatic despite optimization of CPAP or BIPAP therapy and compliance for at least 1 month • CPAP or BIPAP will be continued after modafinil or armodafinil is started • The daytime fatigue is significantly impacting, impairing, or compromising the patient's ability to function normally **May be authorized for patients at least 17 years old for excessive daytime sleepiness associated with Shift-Work Disorder (SWD) when the following is met:** • Prescribed by, or in consultation with, a sleep specialist	**Initial Approval:** 6 months **Renewal:** OSA and SWD: 1 year All others: Indefinite ***Requires:*** • Response to treatment • For OSA: patient must be compliant with CPAP or BIPAP • For SWD: patient must still be a shift-worker

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Polysomnography has ruled out other types of sleep disorders • Symptoms have been present for ≥3 months • The sleepiness is significantly impacting, impairing, or compromising the patient's ability to function normally **May be authorized for patients at least 17 years old for the treatment of excessive sleepiness associated with idiopathic hypersomnia when the following criteria is met:** • Prescribed by, or in consultation with, a sleep specialist • Trial and failure of 2 stimulants (e.g., amphetamine, dextroamphetamine, methylphenidate) • Diagnosis is supported by polysomnography, MSLT, and clinical evaluation including the following: o Daily periods of irrepressible need to sleep or daytime lapses into sleep for ≥3 months o MSLT documents no more than one sleep-onset rapid eye movement period (SOREMP), OR no SOREMPs if the REM sleep latency on the preceding polysomnogram was ≤15 minutes o The presence of at least one of the following: ▪ MSLT shows a mean sleep latency of ≤8 minutes ▪ Total 24-hour sleep time is ≥660 minutes (typically 12 to 14 hours) on 24-hour polysomnography or by wrist actigraphy in association with a sleep log o Other causes of sleep disorder have been ruled out • The sleepiness is significantly impacting, impairing, or compromising the patient's ability to function normally	
Movantik[xl]	**May be authorized for when the following are met:** • Members is 18 years of age or older • Diagnosis of Opioid-Induced Constipation (OIC) due to chronic non-cancer pain • Member has been taking opioids for at least 4 weeks	**Initial Approval:** 3 months **Renewals:**

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Trial and failure of 3 formulary laxatives (e.g., lactulose, polyethylene glycol 3350, senna, bisacodyl, docusate sodium, magnesium hydroxide, and magnesium citrate)	1 year ***Requires:*** Continuation on opioid therapy **QLL:** 30 tablets for 30 days
Multaq[xli]	**May be authorized for adult patients, 18 years of age and older, who meet the following criteria:** • Must be prescribed by, or in consultation with a cardiologist • Patient does not have any contraindications to Multaq • Diagnosis of paroxysmal or persistent atrial fibrillation currently in normal sinus rhythm OR with intent of cardioversion to normal sinus rhythm • Inadequate response, or intolerable side effects to, amiodarone, propafenone, flecainide, or sotalol, or contraindications to all • Patient is not currently using the following medications: o Statin > 10mg, sirolimus, tacrolimus, o Class I antiarrhythmics: quinidine, procainamide, disopyramide, lidocaine, mexiletine, flecainide, propafenone o Class III antiarhythmics: dofetilide, sotalol, ibutilide	**Initial Approval:** Indefinite
Multiple Sclerosis Agents	Aubagio, Avonex, Betaseron, Copaxone, Extavia, Gilenya, Lemtrada, Mitoxantrone, Plegridy, Rebif, Tecfidera, Tysabri, Zinbryta **See Detailed document:** https://www.aetnabetterhealth.com/illinois/assets/pdf/pharmacy/pa-guidelines/medication/ms-disease-modifying-agents.pdf	
Non-Stimulant	**Criteria for all agents for use in patients age 6 through 17 with a diagnosis of ADHD/ADD:**	**Initial Approval:**

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
ADHD Medications[xlii] Guanfacine ER Clonidine ER 0.1mg Kapvay 0.2mg Strattera	• Prescribed within FDA approved daily dosing guidelines either as monotherapy or as augmentation to stimulants in the treatment of ADHD. • The diagnosis of ADHD/ADD is documented in the medical record and is based on a comprehensive evaluation by an appropriate specialist or primary care provider. The evaluation must include use of an evidence based rating scale such as the Connors, Behavior Assessment System for Children (BASC), or the Child Behavior Checklist/Teacher Report Form. • There is documentation that other conditions (such as depression, anxiety, conduct disorders, or substance use) have been ruled out. • There is documentation confirming that the member is actively participating in an evidence-based behavioral therapy (child, teacher, and/or caregiver). • There is a lack of satisfactory improvement in core symptoms of ADHD on the maximum dose of at least 2 formulary stimulants OR known history of intolerable adverse effects from stimulants OR patient is a poor candidate for stimulants (i.e., tic disorder, substance use disorder, MI, hypertension, hyperthyroidism). o NOTE: 80% of school-aged children respond to a stimulant and 50% who do not respond to the initial stimulant will respond to a different stimulant. • Patient is not currently taking mirtazapine (for guanfacine ER and clonidine ER only) • Patient is not currently taking a CNS stimulant (for Strattera only) **Criteria for Strattera for use in patients age 18 and older with a diagnosis of ADHD/ADD:** • Strattera is prescribed within FDA approved daily dosing guidelines • The diagnosis of ADHD/ADD is documented in the medical record and is based on a comprehensive evaluation by an appropriate specialist and includes evidence based rating scales such as the Connors or Adult Self-Report Scale-V1.1 (ASRS-V1.1). The symptoms meet the most current Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria. • There is documentation that other conditions (such as depression, anxiety, or substance use) have been ruled out.	Indefinite

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• There is a lack of satisfactory improvement in core symptoms of ADHD on the maximum dose of at least 2 formulary stimulants OR a known history of intolerable adverse effects OR patient is a poor candidate for stimulants (i.e., tic disorder, substance use disorder, MI, hypertension, hyperthyroidism). • Patient is not currently taking a CNS stimulant • NOTE: Guanfacine ER and clonidine ER have not been studied in adults and are not approved for treatment of adult ADHD. Guanfacine IR and clonidine IR are available without PA. **Children age 5 and under:** Guanfacine ER, clonidine ER, and Strattera are not FDA approved for use in children ages 5 and under. The safety and efficacy in this age group has not been established and is not supported by the currently published peer-reviewed medical literature. For preschool-aged children (4–5 years of age), the American Academy of Pediatrics recommends that the primary care or treating clinician prescribe evidence-based parent and/or teacher-administered behavior therapy as the first line treatment.	

Nuedexta[xliii]	**May be authorized when all of the following criteria are met:**
	
	• Member is 18 years of age or older
	• Diagnosis of pseudobulbar affect (PBA)
	• Documentation that member has at least ONE underlying neurologic conditions associated with PBA
	  o Amyotrophic lateral sclerosis (ALS)
	  o Multiple Sclerosis (MS)
	
	• Cognitive assessment to evaluate for the presence of PBA
	  o Center for Neurologic Study-Lability Scale (CNS-LS) ≥ 13
		Initial Approval:
		3 months
		
		Renewal:
		1 year
		
		Requires:
		documentation to support of ONE of the following:
		• CNS-LS score improvement
		Decreased PBA episodes

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Member does not have any contraindication to therapy (e.g., QT prolongation, Atrioventricular (AV) block or currently on MAOI therapy)	
Onychomycosis Jublia Kerydin	**Medication may be approved for members who meet All of the following:** • Member is at least 18 years old • Medical records confirming diagnosis of onychomycosis of the toenail due to one of the following: o KOH preparation test o Fungal culture o Nail biopsy • Failure of or contraindication to two formulary antifungal agents (i.e. itraconazole, oral terbinafine, or ciclopirox) • Treatment of onychomycosis of the toenails is for one of the following medical condition: (e.g., Diabetes, HIV, Immunosuppressed patients, Peripheral vascular disease or pain caused by the onychomycosis)	**Initial Approval:** • 48 weeks **QLL** Jublia: 8ml/month Kerydin: 10ml/month
Otezla[xliv]	**Criteria for Psoriatic Arthritis (PsA):** • Patient is at least 18 years old • Prescribed by or in consultation with a rheumatologist • Patient is currently on an NSAID and will be continued when Otezla is initiated OR has a contraindication to NSAID use • Patient has active PsA (≥3 swollen/tender joints) despite a 3-month trial of adequate dose MTX (or leflunomide or sulfasalazine if MTX is contraindicated) or an anti-TNF (NOTE: anti-TNF's require PA) **Criteria for Plaque Psoriasis:** • Patient is at least 18 years old	**Initial Approval:** 4 months **Renewal:** 12 months ***Requires:*** • At least 20% symptom improvement • Patient is not experiencing depression and/or suicidal

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Prescribed by or in consultation with a dermatologist • Symptoms are not controlled with topical therapy • Disease has a significant impact on physical, psychological or social wellbeing • Patient has failed a 3-month compliant trial with MTX or cyclosporine or has a true contraindication to both • Psoriasis is severe and extensive (for example, more than 10% of body surface area affected or a PASI score of more than 10) • Phototherapy has been ineffective, cannot be used or has resulted in rapid relapse (rapid relapse is defined as greater than 50% of baseline disease severity within 3 months)	thoughts. • Patient's BMI is ≥18.5 **QLL (after initial 5 day titration):** 60 tablets per 30 days
PCSK9's[xiv] Repatha Praluent	**Criteria for all patients and indications:** • Current lipid panel results within the past 90 days • Failed an adequate 90 day trial of 2 high intensity statins (e.g., atorvastatin ≥ 40 mg and rosuvastatin ≥ 20 mg) at maximum tolerated doses and in combination with other lipid lowering therapies such as ezetimibe or bile acid sequestrants ; intolerance to statin therapy trials requires the following: o An intolerance to at least 2 statins (at least one trial being a moderate to high potency statin) for more than 2 weeks. ▪ Documentation supporting skeletal muscle related symptoms (e.g., myopathy, myositis or abnormal biomarkers) that resolved when statin therapy was discontinued ▪ Documentation the member has been re-challenged at a lower dose with a different statin. • Will be used in combination with maximum tolerated dosed statin and other lipid lowering therapies such as (ezetimibe) or bile acid sequestrants **Additional Criteria based on Indication:**	**Initial Approval**: 3 months **Renewal:** 6 months ***Requires:*** • Current Lipid Panel within the past 3 months • Claims history to support compliance or adherence • LDL reduction from baseline **QLL:** • Praluent: 2 syringes per 28 days • Repatha (for ASCVD or HeFH): 2 syringes per 28 days. May be increased to 3

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	Repatha or Praluent • Atherosclerotic Cardiovascular Disease (ASCVD)): o There is supporting evidence of high CVD risk (i.e., history of acute coronary syndrome, history of MI, stable or unstable angina, coronary or other revascularization (PCI/CABG), stroke, TIA, Peripheral Arterial Disease (PAD) presumed to be of atherosclerotic origin) o Lab results to support an LDL ≥ 70 mg/dL (treated) • Heterozygous Familial Hypercholesterolemia (HeFH) o There is evidence of ONE of the following: ▪ LDL-C > 190 mg/dL (age ≥ 18 years) either pretreatment or highest on treatment and physical evidence of tendon xanthomas or evidence of these signs in a 1st or 2nd degree relative ▪ DNA based evidence of an LDL receptor (LDLR) mutation, APO-B100, or PCSK9 mutation or ▪ Who/Dutch Lipid Network Criteria result with a score of > 8 points o Lab results to support a current LDL ≥ 70 mg/dL on treatment o Member is at least 18 years of age **Repatha** • Homozygous Familial Hypercholesterolemia (HoFH): o Genetic confirmation of 2 mutant alleles at LDLR, APO-B100, or PCSK9 **OR** o History of untreated LDL over 500mg/dL or treated LDL over 300mg/dL on maximum dosed statin AND evidence of ONE of the following: ▪ Presence of cutaneous xanthoma before the age of 10 ▪ Evidence of HeFH in both parents o LDL reduction was <50% on current lipid lowering therapy (high intensity statin +	(140mg) syringes OR 1 (420mg) syringe per 28 days if LDL is >70 after initial trial • Repatha (for HoFH): 3 (140mg) syringes OR 1 (420mg) syringe per 28 days

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	another treatment) o Member age is at least 13 years of age	
Platelet Inhibitors[xlvi] Prasugrel Brilinta Zontivity	**May be approved for members who meet the following:** **Brilinta:** • Diagnosis of ACS (e.g., unstable angina, STEMI, NSTEMI) • Failure or contraindication/intolerance to clopidogrel • Aspirin dose does not exceed 100 mg/day • No active pathological bleeding, history of intracranial hemorrhage, or planned CABG **Prasugrel:** • Diagnosis of ACS (e.g., unstable angina, STEMI, NSTEMI) • Failure or contraindication/intolerance to clopidogrel • Aspirin dose does not exceed 100 mg/day • No history of TIA or stroke **Zontivity:** • Member has a history of MI or PAD • Will be used with aspirin and/or clopidogrel • No history of stroke (TIA), or intracranial hemorrhage (ICH) or active pathological bleeding (e.g., peptic ulcer)	**Recommend approval for members stabilized in the hospital** **<u>Initial Approval:</u>** Prasugrel and Brilinta: • 12 months • Indefinite approval is allowed for members with a history of stent thrombosis or restenosis ***Zontivity:*** • Indefinite **<u>Renewals:</u>** Prasugrel and Brilinta: • 12 months May be renewed if member has no high risk of bleeding or no significant overt bleeding

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		QLL: Prasugrel: 1 tablet per day Brilinta: 2 tablets per day Zontivity: 1 tablet per day
Pulmonary Arterial Hypertension[xlvii] Adcirca Revatio Adempas epoprostenol Letairis Opsumit Tracleer Remodulin Tyvaso Orenitram Uptravi Veletri Ventavis	**Preferred Agents:** sildenafil, Adcirca**,** Tracleer, Letairis, and epoprostenol **Authorization Guideline for All Agents:** • Prescribed by (or in consultation with) a pulmonologist or cardiologist • Evidence of right heart catheterization (RHC) with a mean PAP ≥ 25 mm Hg • Medical records supporting diagnosis of Pulmonary Arterial Hypertension (PAH) WHO Group I with NYHA Functional Class II to IV symptoms. • Inadequate response, or intolerance to, a calcium channel blocker (CCB) Note: Adempas may include WHO Group IV and does not require a trial of CCB **Additional Drug Specific Criteria:** **Brand Revatio** (sildenafil) oral suspension • Documentation to support the inability to swallow and the necessity of the brand suspension formulation. **Adcirca** (tadalafil) • Documentation to support trial and failure of or intolerance to sildenafil **Opsumit** (macitentan) • Member has tried and failed 2 preferred oral agents o One PDE-5 inhibitor (e.g., sildenafil or Adcirca)	Initial Approval: • 6 months Renewal: • 1 year Medical records and lab results to support response to therapy; to maintain or achieve a low risk profile (e.g., improvement in 6 min walk distance, functional class, or reducing time to clinical worsening) **Quantity Limit:** Adcirca: 60 tabs per 30 days Adempas: 90 tabs per 30 days Opsumit: 30 tabs per 30 days Orenitram: Determine by tolerability Sildenafil tabs: 90 tabs per 30 days

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	o One Endothelin Receptor Antagonist (e.g., Tracleer or Letairis) **Adempas** (riociguat) • Diagnosis of WHO (PAH) Group I (as described above) and member has tried and failed 2 preferred oral agents o One PDE-5 inhibitor (e.g., sildenafil or Adcirca) o One Endothelin Receptor Antagonist (e.g., Tracleer or Letairis) **OR** • Diagnosis of CTEPH, WHO Group IV and one of the following: o Recurrent or persistent CTEPH, after surgical treatment o Inoperable CTEPH **Uptravi** (selexipag), **Orenitram** (treprostinil) • Member has tried and failed 2 preferred oral agents o One PDE-5 Inhibitor (e.g., sildenafil or Adcirca) o One Endothelin Receptor Antagonist (e.g., Tracleer or Letairis) **Tyvaso** (trepostinil), **Ventavis** (Iloprost), **Remodulin** (trepostinil) • Member must have NYHA Functional Class III-IV (i.e.,Tyvaso and Ventavis) or NYHA Functional Class (II-IV) (i.e.,Remodulin) • Member has tried and failed 2 preferred oral agents o One PDE-5 inhibitor (e.g., sildenafil or Adcirca) o One Endothelin Receptor Antagonist (e.g., Tracleer or Letairis) **<u>Coverage Limitation:</u>** Any contraindications to treatment including but not limited to the following: • Pregnancy: Endothelin Receptor Antagonist (ERA's) and Adempas	Tracleer: 60 tabs per 30 days Letairis: 30 tabs per 30 days Uptravi: 60 tabs per 30 days (may be higher during titration phase) Tyvaso: 54 mcg (9 breaths) per treatment session, 4 times daily

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Concurrent use of organic nitrates (i.e., isosorbide mononitrate, isosorbide dinitrate, nitroglycerin): PDE-5 inhibitors including Adempas • Child Pugh class C hepatic impairment: Orenitram • HF with severe left ventricular dysfunction: Veletri/epoprostenol • Pulmonary veno-occlusive disease (PVOD): Adcirca, sildenafil, Letairis, Opsumit, epoprostenol, and Tracleer **Additional Information:** PAH is a rare and complex disease with the risk of high morbidity and mortality. Diagnosis of PAH is primarily based on RHC with mean PAP ≥ 25 mmHg, PAWP ≤ 15mmHg and PVR> 3 wood units. Additional treatment options have recently increased within this disease and consists of 3 key drug classes which includes the PDE-5 inhibitors (e.g., sildenafil or tadalafil), ERA's (e.g., Tracleer, Letairis, and Opsumit), and Prostacyclin analogues (e.g., treprostonil, epoprostonol, and iloprost). Treatment is considered in a stepwise approach often beginning with monotherapy followed by combination treatment such as with an ERA and PDE5 Inhibitor. However, severity of treatment such as rapid disease progression or worsening clinical prognosis may require initiation of treatment with a prostanoid before a PDE-5 or ERA. Current national guidelines recommend prior to initiation of treatment patients should be referred to Expert Treatment Centers for PAH.	
Promacta[xlviii]	Chronic idiopathic thrombocytopenic purpura (ITP): • Patient is at least 1 year old • Patient had insufficient response to corticosteroids, immunoglobulins, or splenectomy • Promacta is being used to prevent major bleeding in a patient with a platelet count of <30,000/mm3 and NOT in an attempt to achieve platelet counts in the normal range i.e., 150,000-450,000/mm3	**Initial Approval:** 4 weeks **Renewal:** • ITP (with PLT increase to ≥50,000): Indefinite at current dose.

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	Hepatitis C with thrombocytopenia: • Patient is at least 18 years old • Patient has chronic hepatitis C with baseline thrombocytopenia (platelet count < 90,000/mm3) which prevents initiation of interferon-based therapy when interferon is required Severe aplastic anemia: • Patient is at least 18 years old • Diagnosis of severe aplastic anemia is confirmed by ONE of the following: o Bone marrow biopsy showing <25% of normal cellularity; OR o Bone marrow biopsy showing <50% of normal cellularity AND at least TWO of the following: ▪ Absolute neutrophil count <500/mm3 ▪ Platelet count <20,000/mm3 ▪ Absolute reticulocyte count <40,000/mm3 (value may be given as percent of RBCs) • Anemia is refractory to a previous first line treatment including hematopoietic cell transplantation or immunosuppressive therapy with a combination of cyclosporine A and antithymocyte globulin (ATG) When to Discontinue Promacta: • Decrease dose if PLT >200,000 and stop if >400,000. • ITP: If PLT is NOT ≥50,000 after 4 weeks of 75mg dose, discontinue treatment. • HCV: If PLT is NOT ≥90,000 after 8 weeks or on max dose of 100mg, discontinue treatment. • Aplastic Anemia: Discontinue if NONE of the following occur after 16 weeks; 1) platelet increase by 20,000 above baseline; 2) Stable platelet counts with transfusion independence for ≥8 weeks; 3) hemoglobin increase by >1.5 g/dL; 4) Decrease of ≥4 units of RBC transfusions for	• ITP (without PLT increase to ≥50,000): 4 additional weeks with dose increase to 75mg. • HCV (with PLT increase to ≥90,000): Duration of Peg-INF treatment • HCV (without PLT increase to ≥90,000): 4 additional weeks with a dose increase of 25mg every 2 weeks until platelets are ≥90,000 or to a maximum of 100mg. • Aplastic anemia (with PLT increase to ≥50,000): Indefinite at current dose. • Aplastic Anemia (without PLT increase to ≥50,000): Every 4 weeks with a dose increase of 50mg every 2 weeks until PLT ≥50,000 or to a maximum of 150mg.

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	8 consecutive weeks; 5) Doubling of baseline ANC or an increase >500.	

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Proton Pump Inhibitors[xlix] Formulary: Nexium OTC Omeprazole Prilosec OTC Pantoprazole Rabeprazole Lansoprazole Prevacid OTC First-lansoprazole First-omeprazole Formulary with PA: Prevacid Solutab Non-Formulary: Dexilant Esomeprazole Nexium granules/susp Prilosec granules Aciphex Sprinkle Protonix Granules Omeprazole-sodium	**Dexilant, esomeprazole Rx, and Omeprazole/Sodium-Bicarbonate may be authorized when the following criteria are met:** • Trial and failure of at least THREE formulary PPI's • One of the trials must be with a formulary PPI at double the usual starting dose: o Omeprazole 40mg o Nexium OTC 40mg o Lansoprazole 30mg o Pantoprazole 40mg o Rabeprazole 40mg **Prevacid Solutab, Prilosec granules, Aciphex Sprinkle, Protonix granules, and Nexium granules (suspension) may be authorized when the following criteria are met:** • Patient is unable to swallow capsules/tablets or is using feeding tube for medications. • Trial and failure of BOTH First-omeprazole and First-lansoprazole **High Dose PPI's may be authorized if the following criteria are met:** • Provider submits 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) • Requests for high dose non-formulary PPI's require use of a formulary PPI at high dose	**Initial Approval:** • Once daily NF: Indefinite • Severe erosive esophagitis, stricture, Zollinger-Ellison: indefinite • All Others: 12 months **Renewal:** • Once daily NF: Indefinite • Severe erosive esophagitis, stricture, Zollinger-Ellison: indefinite • All Others: 12 months ***Requires:*** • Response to therapy and rationale for continuing high dose • Failure to once daily dosing after completion of high dose course.

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
bicarbonate		
Ranexa[I]	**For patients age 18 years of age or older who meet all of the following:** • Diagnosis of chronic angina • Patient meets ONE of the following: o Ranexa is prescribed as ADD-on therapy after failure to achieve therapeutic benefit on at least 1 formulary agent from EACH of the following 3 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 o Has a documented contraindication or intolerance to beta blockers, calcium channel blockers, **AND** long-acting nitrates	**Initial Approval:** Indefinite
Rectiv	**Rectiv may be authorized when the following criteria are met:** • Patient has a diagnosis of pain associated with anal fissures.	**Initial Approval:** 6 months **Renewal:** 1 year
Restasis and Xiidra[Ii]	**May be approved when all of the following criteria are met:** • Member is 16 years age and older (Restasis); 17 years of age and older (Xiidra) • Prescribed by, or in consultation with, an ophthalmologist or optometrist • Diagnosis of Keratoconjunctivitis Sicca (KCS – dry eyes) Dry Eye Disease, or Dry Eyes due to Sjogren's Syndrome • Trial and failure or intolerance of at least 2 different forms (i.e., gels, ointments, or liquids) of formulary artificial tears used at least 4 times per day	**Initial Approval:** • **6 months** **Renewal:** • **Indefinite** **QLL:**

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		60 per 30 days
Sensipar[lii]	**Criteria for secondary hyperparathyroidism due to chronic kidney disease:** • Patient is at least 18 years of age • Serum calcium ≥ 8.4mg/dL prior to initiation of therapy • Intact parathyroid hormone (iPTH) ≥ 70pg/mL prior to initiation of therapy • Patient had inadequate response or intolerable side effects to at least one type of Vitamin D analog AND at least one type of phosphate binder **Criteria for parathyroid cancer:** • Patient is at least 18 years of age • Serum calcium ≥ 12.5mg/dL prior to initiation of therapy **Criteria for primary hyperparathyroidism:** • Patient is at least 18 years of age • Patient is not a candidate for parathyroidectomy • Serum calcium ≥ 12.5mg/dL prior to initiation of therapy	**Initial Approval:** 12 months **Renewal:** Indefinite ***Requires:*** • Serum Ca 8.4-12.5mg/dL **Dose limits:** 180mg/day
Somatostatin Analogs[liii] Octreotide Sandostatin LAR Signifor Signifor LAR Somatuline Depot	**Preferred Products:** Octreotide and Sandostatin LAR are the preferred products. In addition to the clinical criteria, Sandostatin LAR requires the use of octreotide immediate release injection for at least 2 weeks to show benefit and tolerability. In addition to the clinical criteria, non-preferred agents require trial and failure of Sandostatin LAR. **General Authorization Criteria for ALL Indications:** • Patient is 18 year of age or older (unless prescribed for pediatric chemotherapy-induced diarrhea) • Sandostatin LAR: Baseline A1c or fasting glucose, TSH, and EKG • Somatuline Depot: Baseline A1c or fasting glucose	**Initial Approval:** 6 months **Renewal:** • Acromegaly, Cushing's, Carcinoid and VIPomas: Indefinite • All other indications: 6 months

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Signifor and Signifor LAR: Baseline A1c, fasting plasma glucose, EKG, potassium, magnesium, TSH, and LFT's **Additional Criteria Based on Indication:** • **Acromegaly (octreotide, Sandostatin LAR, Somatuline Depot, Signifor LAR):** o Prescribed by, or in consultation with, an endocrinologist o Patient has persistent disease following pituitary surgery, or surgical resection is not an option as evidenced by one of the following: ▪ Majority of tumor cannot be resected ▪ Patient is a poor surgical candidate based on comorbidities ▪ Patient prefers medical treatment over surgery, or refuses surgery o Baseline IGF-1 is ≥2x ULN for age OR IGF-1 remains elevated despite a 6 month trial of maximally tolerated dose of cabergoline (unless patient cannot tolerate cabergoline or has a contraindication) • **Carcinoid Tumor or VIPomas (octreotide, Sandostatin LAR, Somatuline Depot):** o Prescribed by, or in consultation with, an oncologist or endocrinologist • **Cushing's Syndrome (Signifor):** o Patient has persistent disease after pituitary surgery, or surgery is not an option o Patient had an inadequate response, intolerable side effects, or contraindication to cabergoline o Baseline A1c, fasting plasma glucose, EKG, potassium, magnesium, TSH and LFT's o NOTE: Patient does not need a trial of octreotide or Sandostatin LAR for approval • **Hepatorenal syndrome (octreotide):** o Prescribed by hepatologist or nephrologist o Must be used in combination with midodrine and albumin • **Gastroenteropancreatic neuroendocrine tumor (GEP-NET) (octreotide, Sandostatin LAR, Somatuline Depot):**	***Requires:*** • A1c or fasting glucose • Response to therapy • For Acromegaly: Decreased or normalized IGF-1 levels • For Carcinoid and VIPomas: Symptom improvement • For Cushing's: Decreased or normalized cortisol levels • For Signifor: LFT's **Quantity Limits:** • Octreotide: Maximum dose is 1500mcg/day • Sandostatin LAR: Maximum dose is 40mg every 4 weeks o 10mg and 30mg vials: 1 vial per 28 days o 20mg vials: 2 vials per 28 days • Signifor: 2 vials per day • Signifor LAR: 1 vial per 28 days • Somatuline Depot: 1 syringe per 28 days

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	o Prescribed by, or in consultation with, an oncologist or endocrinologist o Patient has persistent disease after surgical resection, or is not a candidate for surgery **Octreotide may be reviewed for medical necessity and may be approved for treatment of the following:** • Chemotherapy induced diarrhea in pediatrics, when prescribed by, or in consultation with, an oncologist • Dumping Syndrome in adults ≥18 years of age • Enterocutaneous fistula in adults ≥18 years of age • Hyperthyroidism due to thyrotropinoma in adults ≥18 years of age • Short bowel syndrome (associated diarrhea) in adults ≥18 years of age • Portal hypertension and/or upper GI bleed related to variceal bleeding in patients with esophageal varices in adults ≥18 years of age	
Synagis[liv]	**May be authorized for patients in the following groups when the criteria is met:** • **Preterm Infants without Chronic Lung Disease (CLD):** o Gestational Age (GA) < 29 weeks, 0 days o 12 months of age or younger at the start of RSV season • **Preterm Infants with Chronic Lung Disease (CLD):** o Gestational Age (GA) < 32 weeks, 0 days o 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	**Initial Approval:** 1 dose per month for a maximum of 5 doses per season ****Note:** infants born during RSV season may require fewer than 5 doses** ***Requires:*** Current weight to confirm correct vial size at 15mg/kg dose

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• **Infants with Hemodynamically Significant Congenital Heart Disease:** o 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:** o Is 12 months of age or younger at the start of RSV season o Disease or congenital anomaly impairs ability to clear secretions from the upper airway because of ineffective cough • **Immunocompromised Children:** o Is 24 months of age or younger at the start of RSV season o Child is profoundly immunocompromised during RSV season **The following groups are not at increased risk of RSV and should NOT receive Synagis:** • 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) • Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure • Infants with mild cardiomyopathy who are not receiving medical therapy for the condition • Children with cystic fibrosis (unless the child has clinical evidence of CLD and/or nutritional	

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	compromise in the first year of life) or Down Syndrome (unless qualifying heart disease or prematurity)	
Testosterone agents[lv] **Preferred:** Testosterone enanthate Testosterone cypionate Testosterone gel Testosterone packets **Branded Products Non-Preferred** Androderm Androgel Aveed Axiron Delatestryl Depo-Testosterone Fortesta Natesto Striant Testim Testopel	**Non-Preferred products required trial and failure of formulary agents in addition to meeting the clinical criteria** **Testosterone Replacement Therapy:** • Documentation and lab results provided to support all of the following including evidence of signs and symptoms to support hypogonadism: • Diagnosis of Hypogonadism in males with consistent symptoms supported by one of the following: o Two pretreatment serum total testosterone levels confirmed on two separate mornings with results below normal range(<280 ng/dL) or less than the reference range for the lab) o One pretreatment free or bioavailable testosterone level (<5 ng/dL or less than the reference range for the lab) o Diagnosis of one of the following: ▪ Bilateral Orchiectomy ▪ Genetic disorder due to hypogonadism (e.g., Klinefelter's syndrome) ▪ Panhypopituitarism • Member does not have the following : • Prostate cancer • Male breast cancer **Female to Male Transsexualism:** **Member must meet all of the following:** • 18 years of age or older • Diagnosed with gender dysphoria as defined by the current version of Diagnostic and Statistical	**Initial Approval:** • Transsexualism- 6 months • Delayed puberty- 6 months • Indefinite for all others **Renewal:** • Transsexualism- 12 months • Delayed puberty-12 months ***Requires:*** Documentation to support response to treatment

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Vogelxo	Manual of Mental Disorders (DSM V) • If significant medical or mental health concerns are present , they must be reasonably well controlled • Had a period of psychotherapy of a duration specified by a mental health professional after initial evaluation (at least 6 months) **Delayed Puberty:** • Member is at least 14 years of age • Prescriber is a pediatric endocrinologist or urologist • Prescriber has evaluated member and indicates that there are significant psychological reasons for use **Palliative treatment of inoperable breast cancer in women :** • Prescribed by oncologist	
Transmucosal Immediate Release Fentanyl (TIRF) Agents[lvi] Abstral (fentanyl) sublingual tablets fentanyl citrate lozenge	TIRF agents are opioid analgesics that are approved for the management of breakthrough cancer pain in members who are receiving and are tolerant to opioid therapy for underlying persistent cancer pain. TIRF agents are available only through a restricted TIRF REMS Access program. The preferred formulary product is the generic fentanyl citrate with PA. **May be authorized for members when all of the following criteria are met:** • Member is at least 16 years old (for Actiq or generic fentanyl citrate lozenge) and at least 18 years old (for Abstral, Fentora, Lazanda, and Subsys) • Prescribed by, or in consultation with, an oncologist or pain specialist • Documentation to support diagnosis of cancer and that treatment will be used for breakthrough cancer pain	**Initial Approval:** 6 months **Renewals:** 1 year Requires: • Documented improvement in breakthrough cancer pain • Continued use of a long-acting opioid around-the-clock while on treatment

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Fentora (fentanyl) buccal tablets Lazanda (fentanyl citrate) nasal spray Subsys (fentanyl) sublingual spray	• Member is on a long-acting opioid around-the-clock for treatment of cancer pain • Members must be considered opioid-tolerant and are considered opioid-tolerant if they have received at least one week of treatment on one of the following medications: o Morphine sulfate at doses of at least 60 mg/day o Fentanyl transdermal patch at doses of at least 25 mcg/hour o Oxycodone at doses of at least 30 mg/day o Oral hydromorphone at doses of at least 8 mg/day o An alternative opioid at an equianalgesic dose for at least a week (e.g., oral methadone at doses of at least 20 mg/day) AND • For all other non-formulary agents, member had inadequate response or intolerable side effects with generic fentanyl citrate lozenge. **NOTE: TIRFs are not covered for the management of acute or postoperative pain including migraine headaches or for members who are not tolerant to opioids and who are not currently on opioid therapy.	**QLL**: Abstral: 4 tablets/day Actiq: 4 lozenges/day Fentora: 4 tablets/day Lazanda: 1 bottle/day Subsys: 4 sprays/day
Topical Hyaluronic Acid Agents[lvii] 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	**Initial Approval:** Burns or dermatitis: • 3 fills of generic agent Xerosis: • Up to 1,000 grams of equivalent generic agent per 30 days for three months

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		Renewal: 3 months
Topical NSAIDs for Arthritis and Pain[lviii] Diclofenac 1% gel Pennsaid Flector patch	**General Criteria for All Agents:** • Age 18 or older • Patient is at high-risk for adverse GI events (e.g., ≥65 years of age, concomitant corticosteroid or anticoagulant use, or history of GI bleed, PUD, GERD, or gastritis); **OR** • Patient is at high-risk for other adverse effects associated with oral NSAID use (e.g., CHF, renal failure, concomitant use of lithium); **OR** • Patient has had a trial and failure of THREE formulary NSAIDs **Additional Criteria for Specific Agents:** • Pennsaid o Prescribed for OA of knee o Patient has had a trial and failure of diclofenac 1% gel • Flector patch o Prescribed for acute pain from minor strains, sprains, or contusions o Patient has had a trial and failure of diclofenac 1% gel	**Initial Approval:** Flector Patch: 1 month All others: 1 year **Renewal:** Flector Patch: 1 month All others: indefinite **QLL's:** Flector: 60 patches per 30 days Pennsaid: 450ml (3 bottles) per 30 days
Tranexamic acid tablets[lix]	**Criteria for the treatment of cyclic heavy menstrual bleeding:** • Patient had an inadequate response, intolerable side effects, or contraindication to oral NSAIDs • Patient had an inadequate response, intolerable side effects, or contraindication to ANY of the following: oral hormonal cycle control combinations, oral progesterone, progesterone-containing IUD, or medroxyprogesterone depot • Patient is at least 12 years old • Patient does not have any of the following:	**Initial Approval:** • 90 days for menstrual bleeding • Indefinite for hemophilia **Renewal:** • Indefinite **QLL:**

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• history of thrombosis or thromboembolism • concurrent use of combination hormonal contraception Tranexamic acid may also be authorized for the treatment and prevention of acute bleeding episodes in patients with hemophilia.	• 30 tablets per 30 days for menstrual bleeding • 84 tablets per 30 days for hemophilia

Viscosupplements[lx]
 	
Gel-One
Hyalgan
 	
Euflexxa
Supartz
Supartz FX
Synvisc
Synvisc-One
Monovisc
Orthovisc
Gel-Syn
GenVisc 850
Hymovis
	Preferred Product: Hyalgan and Gel-one are the preferred viscosupplements for OA. **Non-preferred products will not be covered.**
	
	Authorization Criteria:
	• Patient is 22 years of age or older for Monovisc and Genvisc
	• Patient is 18 years of age or older for all other products
	• Treatment knee(s) is noted in request (right, left, or bilateral)
	• Patient had inadequate response, intolerable side effects, or contraindications to all of the following:
	  o Conservative non-pharmacologic therapy (i.e., physical therapy, land based or aquatic based exercise, resistance training, or weight loss)
	  o Adequate trial of pharmacologic therapy such as acetaminophen, NSAID's, capsaicin, or tramadol
	  o Steroid injections
	• The member reports pain which interferes with functional activities (e.g., ambulation, prolonged standing)
	• The pain is not attributed to other forms of joint disease
	• Patient has not had surgery on the same knee in the past 6 months
	• Treatment is not requested for the following indications:
	  o Temporomandibular joint disorders
	  o Chondromalacia of patella (chondromalacia patellae),
		Initial Approval:
		• 1 series
		
		Renewal:
		• 1 series
		• No more than 2 series of injections allowed per lifetime
		
		Requires:
		• 6 months has elapsed since previous treatment
		• Documentation to support improved response to previous series such as a dose reduction with NSAIDs or other analgesics

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Pain in joint, lower leg (patellofemoral syndrome), ○ Osteoarthrosis and allied disorders (joints other than knee) ○ Diagnosis of Osteoarthritis of the hip, hand, shoulder, etc • Radiographic evidence of mild to moderate osteoarthritis of the knee (e.g., severe joint space narrowing, subchondral sclerosis, osteophytes); OR IF UNAVAILABLE • Documented symptomatic osteoarthritis of the knee according to American College of Rheumatology (ACR) clinical and laboratory criteria, which requires knee pain and at least **5** of the following: ○ Bony enlargement ○ Bony tenderness ○ Crepitus (noisy, grating sound) on active motion ○ Erythrocyte sedimentation rate (ESR) less than 40 mm/hr ○ Less than 30 minutes of morning stiffness ○ No palpable warmth of synovium ○ Over 50 years of age ○ Rheumatoid factor less than 1:40 titer (agglutination method) ○ Synovial fluid signs (clear fluid of normal viscosity and WBC less than 2000/mm3)	
Xifaxan[lxi]	**Xifaxan 200mg may be authorized when the following are met:** • Patient is at least 12 years old • Patient has had an inadequate response, intolerable side effects, or a contraindication to a fluoroquinolone for the treatment of traveler's diarrhea **Xifaxan 550mg may be authorized for patients 18 years of age or older when ONE of the following are met:** • Patient had an inadequate response or intolerable side effects to 2 of the following agents: Loperamide, bile acid sequestrants, antispasmodics, or tricyclic antidepressants for the	**Initial Approval:** • Traveler's Diarrhea: 3 days • HE: 12 months • IBS-D: 1 time only authorization of 14 days **Renewal:** • HE: Indefinite ○ Requires decreased

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	treatment of irritable bowel syndrome with diarrhea (IBS-D); **OR** • Patient had an inadequate response or intolerable side effects to lactulose for the treatment of hepatic encephalopathy (HE) o Patients who tolerate lactulose should continue use when Xifaxan is started instead of switching to Xifaxan monotherapy	HE symptoms OR ammonium levels • IBS-D: 14 days; Maximum of 3 treatment courses per year o Requires symptom resolution during previous treatment course **QLL:** • IBS-D: 3 tablets per day • Traveler's Diarrhea: 3 tablets per day • HE: 2 tablets per day
Xolair[lxii]	**May be authorized when all of the following are met:** • Member 6 years of age and older • Diagnosis of severe persistent asthma • Prescribed by, or after consultation with a pulmonologist or allergist/immunologist • Positive skin test or in vitro reactivity to a perennial allergen (e.g. dust mite, animal dander, cockroach, etc.) • Documentation to support IgE is between 30 and 1500 IU/mL • Member has been compliant with medium to high dose inhaled corticosteroids (ICS) + a long-acting beta agonist (LABA) for at least 3 months or other controller medications (e.g., LTRA or theophylline) if intolerant to a LABA • Asthma symptoms are poorly controlled on one of the above regimens as defined by ANY of the following:	**Initial Approval:** **Asthma:** • 6 months **Chronic urticaria:** • 3 months **Renewal:** **Asthma:** • 1 year Requires demonstration of

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	o Daily use of rescue medications (short-acting inhaled beta-2 agonists) o Nighttime symptoms occurring more than once a week o At least 2 exacerbations in the last 12 months requiring additional medical treatment (systemic corticosteroids, emergency department visits, or hospitalization) • Member will not receive in combination with IL-5 antagonists (Nucala or Cinqair) May be authorized when all of the following criteria are met: • Member is 12 years of age and older • Diagnosis of chronic urticaria • Prescribed by an allergist/immunologist or dermatologist • Currently receiving H1 antihistamine therapy • Failure of a 4 week, compliant trial of a high dose, second generation antihistamine (cetirizine, loratadine, fexofenadine) AND • Failure of a 4-week, compliant trial of at least THREE of the following combinations: o H1 antihistamine + Leukotriene inhibitor (montelukast or zafirlukast) o H1 antihistamine + H2 antihistamine (ranitidine or cimetidine) o H1 antihistamine + Doxepin o First generation + second generation antihistamine ***Note: Off-label use for Allergic Rhinitis or food allergy is not covered***	clinical improvement (e.g., decreased use of rescue medications or systemic corticosteroids, reduction in number of emergency department visits or hospitalizations) and compliance with asthma controller medications **Chronic urticaria:** • 6 months Requires demonstration of adequate symptom control (e.g., decreased itching) **Dosing Restriction:** **Asthma:** Per manufacturer. Do not exceed 375mg every 2 weeks **Urticaria:** Initial dose of 150mg per 4 weeks. Dose may be increased to 300mg per 4 weeks if necessary.

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