Aetna Better Health® of California

Pharmacy Prior Authorization
Non-Formulary and Prior Authorization Guidelines

Scroll down to see PA Criteria by drug class, or Ctrl+F to each 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:** • Appropriate diagnosis/indication for requested medication • Appropriate dose of medication based on age and indication • Member meets one of the following: ○ Documented trial of three formulary agents for adequate duration has not been effective or tolerated ○ All other formulary medications are contraindicated based on member diagnosis, other medical conditions or other medication therapy ○ There are no other medications available on the formulary to treat member condition • For combination drug product requests: ○ Documented reasoning that combination product is clinically necessary and not just for convenience Note: Patient medication trials and adherence are determined by review of pharmacy claims data over preceding twelve months. Additional information may be requested on a case-by-case basis to allow for proper review. **Off-Label and Orphan Drugs can be approved when the following criteria is met:** • Prescribed by physician treating a chronic, disabling, or life-threatening disease • The drug has been approved by the Food and Drug Administration (FDA) • Documentation of trial and failure, intolerance or contraindication to Food and Drug Administration (FDA) approved medications (formulary and non-formulary) for same indication, if available	**Initial Approval:** Six months or lesser of requested duration based on course of therapy **Renewal Approval:** One year or lesser of requested duration based on course of therapy ***Requires:*** ○ Documentation of positive response to therapy

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	• The drug is listed in any of the following standard drug reference compendium as accepted for off-label use ○ The United States Pharmacopoeia Drug Information ○ National Comprehensive Cancer Network ○ American Hospital Formulary Service Drug Information ○ Thomson Micromedex DrugDex ○ Clinical Pharmacology	
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.	**Initial and Renewal Approval**: One year ***Requires***: Member response to treatment
Brand Name Medication	**Aetna Medicaid requires use of generic agents that are considered therapeutically equivalent by the Food and Drug Administration (FDA)**	**Approval:** One year

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Requests (i)	**For authorization of Brand Name Medication, submit the following:** • A hard copy or confirmation of electronic submittal of the Food and Drug Administration (FDA) MedWatch form detailing trial and failure, or intolerance/adverse effect to generic formulation, made by two different manufacturers The completed hard copy form also requires to be submitted to the Food and Drug Administration (FDA) and is available at: FDA MedWatch Form • Online reporting of the Food and Drug Administration (FDA) MedWatch form can be accessed at: https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=professional.reporting1	
Quantity Level Limits	Requests that exceed established Quantity Level Limits will require prior authorization Drugs subject to additional utilization management requirements (for example, non-formulary, clinical prior authorization, and step therapy) must meet clinical criteria and medical necessity for approval, in addition to any established Quantity Level Limit Approval of Quantity Level Limit exceptions are considered after medication specific prior authorization guideline and medical necessity review **Authorization Criteria for Quantity Limit Exceptions:** • **Quantities that Exceed Food and Drug Administration (FDA) Maximum Dose:** ○ Member is tolerating medication with no side effect, but had inadequate response at lower dose, and the inadequate response is not due to medication non-adherence	**Initial Approval:** One year **Renewal Approval:** One year

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	○ Request meets one of the following: ▪ Dose is included in drug compendia or evidence-based clinical practice guidelines for same indication ▪ Published randomized, double blind, controlled trial, demonstrating safety and efficacy of requested dose is submitted with request • **Quantities that <u>do not</u> Exceed Food and Drug Administration (FDA) Maximum Dose (Dose Optimization):** ○ Request meets one of the following: ▪ There was inadequate response or intolerable side effect to optimized dose ▪ There is a manufacturer shortage on higher strengths ▪ Member is unable to swallow tablet/capsule due to size, and cannot be crushed ▪ Effect of medication is wearing off between doses ▪ Member cannot tolerate entire dose in one administration • **Quantities for Medications that <u>do not</u> have Established Food and Drug Administration (FDA) Maximum Dose:** ○ Member is tolerating medication with no side effects, but had inadequate response at lower dose, and the inadequate response is not due to medication non-adherence ○ 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 or Hematologist • Medication is prescribed for an Food and Drug Administration (FDA)-approved indication OR for a "medically accepted indication" as noted in the following Compendia: ○ National Comprehensive Cancer Network (NCCN) Drugs and Biologic Compendium or	**<u>Initial Approval:</u>** 3 months **<u>Renewal Approval:</u>** 1 year

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	National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines, category 1, 2a, or 2b. ○ Micromedex DrugDex ○ Clinical Pharmacology • The dose prescribed is within the Food and Drug Administration (FDA)-approved range for the indication and patient specific factors (for example., age, weight or Body Surface Area (BSA), renal function, liver function, drug interactions, etc) • Requests for non-preferred or non-formulary antineoplastics must meet one of the following: ○ Trials of formulary preferred agents (when available based on Food and Drug Administration (FDA) indication and National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines) for an adequate duration were not effective or were poorly tolerated ○ All other formulary preferred alternatives (when available based on Food and Drug Administration (FDA) indication and National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines) are contraindicated 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 ○ All other formulary preferred agents are not alternatives supported by National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines for the indication • Medical records, lab results, test results, and clinical markers supporting the diagnosis and	***Requires:*** • Attestation of clinically significant improvement or stabilization of disease state

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	treatment are submitted with the request ○ If a test with adequate ability to confirm a disease mutation exists, documentation that the test was performed to confirm the mutation ○ Documentation has been provided of the results of required genetic testing where required per the drug package insert) • Member does not have any contraindications to the medication • Member is not taking other medications that should be avoided with the requested drug based on the Food and Drug Administration (FDA)-approved labeling • Request is not for experimental / investigational use or for a clinical trial	
Dalfampridine (Ampyra)[i]	**May be approved when documentation of the following criteria is presented:** • Prescribed by, or in consultation with, a neurologist • Member is 18 years of age or older • Diagnosis of multiple sclerosis with one of the following: ○ Impaired walking ability defined as a baseline 25-foot walking test between 8 and 45 seconds ○ Expanded Disability Status Scale between 4.5 and 6.5 • Member is not wheelchair-bound • Does not have a history of seizures • Member has not had disease exacerbation in the previous 60 days • Does not have moderate to severe renal impairment (Creatinine Clearance less than 50	**Initial Approval:** 3 months **Renewal:** 1 year *Requires:* • Member meets one of the following criteria: ○ There is improvement in timed walking speed on 25-foot

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	mL/min)	walk ○ There is stability or improvement in Expanded Disability Status Scale score • Member does not have moderate to severe renal impairment (creatinine clearance less than 50 mL/min) • Annual Electroencephalography (EEG) testing is completed **<u>Quantity Level Limit</u>:** 2 tablets per day
Anthelmintic[ii] Praziquantel	**<u>Praziquantel</u> pays at Point of Sale when one of the following infections is present:** • Flukes ▪ Clonorchiasis	**<u>Initial Approval:</u>** Roundworm: 21 days All others: 3 days

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(Biltricide) Albendazole (Albenza)	▪ Opisthorchiasis ▪ Paragonimiasis ▪ Fasciolopsis • Tapeworms ▪ Schistosomiasis ▪ Taeniasis ▪ Cysticercosis/Neurocysticercosis **Prescriptions for praziquantel that do not pay at Point of Sale may be approved for members who meet one of the following:** • Trial and failure with ivermectin or pyrantel • Infection falls either under Fluke or Tapeworm: ○ Flukes ▪ Clonorchiasis ▪ Opisthorchiasis ▪ Paragonimiasis ▪ Fasciolopsis ○ Tapeworms ▪ Schistosomiasis ▪ Taeniasis ▪ Cysticercosis/Neurocysticercosis **<u>Albendazole</u> pays at Point of Sale when one of the following infections is present:** ○ Tapeworm ▪ Taeniasis	**<u>Exceptions to Initial Approval</u>:** <u>*Praziquantel*</u>: • Cysticercosis/Neurocysticercosis: Up to 15 days <u>*Albendazole*</u>: • Cysticercosis/Neurocysticercosis: 120 tablets per month • Clonorchiasis and Opisthorchiasis: Up to 7 days • Hydatid Disease: Up to 112 tablets every 42 days for 4 months (112 tablets every 28 days with a 14-day drug-free period. Repeat up to 2 more cycles)

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	▪ Cystericerosis/Neurocystercosis ▪ Hydatid disease/Echinococcosis ○ Roundworm ▪ Capillariasis ▪ Trichinellosis/Trichinosis ▪ Ascariasis ▪ Toxocariasis ▪ Baylisascariasis ○ Flukes ▪ Clonorchiasias ▪ Opisthorchis **Prescriptions for albendazole that do not pay at Point of Sale may be approved for members who meet one of the following:** • Trial and failure with ivermectin or pyrantel • Infection is with one of the following: ○ Tapeworm ▪ Taeniasis ▪ Cystericerosis/Neurocystercosis ▪ Hydatid disease/Echinococcosis ○ Roundworm ▪ Capillariasis ▪ Trichinellosis/Trichinosis ▪ Ascariasis	• Toxocariasis: 400 mg by mouth twice a day for five days

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	▪ Toxocariasis ▪ Baylisascariasis o Flukes ▪ Clonorchiasas ▪ Opisthorchis	
Anticoagulant - Injectable[iii] **Low Molecular Weight Heparins:** Enoxaparin Fondaparinux Fragmin	**Enoxaparin is the preferred medication AND will require prior authorization after exceeding recommended limit of 21 days' supply** • **May be authorized for the following indications:** Venous thromboembolism (VTE) prophylaxis (prevention of deep vein thrombosis (DVT) or pulmonary embolism (PE)): o In members undergoing hip or knee replacement or hip fracture surgery o In members with restricted mobility during acute illness o Bridge therapy for perioperative warfarin discontinuation o In high risk pregnancy (for example: homozygous for factor V Leiden deficiency, Prothrombin Mutation 20210 or family history of venous thromboembolism (VTE)) o In cancer members with solid tumors who are at high risk of thrombosis (for example: previous venous thromboembolism (VTE), immobilization, hormonal therapy, angiogenesis inhibitors, thalidomide, and lenalidomide) o In members undergoing general and abdominal-pelvic surgery who are at moderate to high risk for venous thromboembolism (VTE) o In members with major trauma (for example traumatic brain injury (TBI) or Spinal Cord Injury) o In members with atrial fibrillation undergoing cardioversion (up to 3 weeks before and 4	**Initial Approval**: **Low Molecular Weight Heparins:** • Prophylaxis (post-ortho surgery) – Up to 35 days • Prophylaxis (non-ortho surgery and major trauma) – Up to 14 days • Prophylaxis (post-surgery with cancer) – 4 weeks • Venous thromboembolism (VTE) treatment, bridge therapy with warfarin – 10 days or

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	weeks after) • Venous thromboembolism (VTE) treatment (treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE)): ○ After trial and failure of Eliquis or Xarelto and warfarin (in non-cancer patients for long-term treatment) ○ In members who are taking warfarin until the international normalized ratio (INR) is in therapeutic range for 5 days ○ In a high risk pregnancy ○ For recurrent venous thromboembolism (VTE) that occurred while taking oral anticoagulants ○ For superficial vein thrombosis (SVT) of the lower limb ○ For acute upper-extremity deep vein thrombosis (UEDVT) that involves the axillary or more proximal veins **In addition, for all non-formulary agents**: • Documentation to support trial and failure, intolerance, or contraindication to enoxaparin	as requested • Cardioversion with warfarin – up to 7 weeks • High risk pregnancy – Until 6 weeks after delivery (estimated date of confinement required for authorization) • Prophylaxis in cancer – 6 months • Lower-limb Superficial Vein Thrombosis (SVT) – 45 days • Venous thromboembolism (VTE) and cancer Low to moderate bleeding risk – indefinite; High bleeding risk – 3

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		months • Provoked venous thromboembolism (VTE) –3 months • Unprovoked venous thromboembolism (VTE) Low to moderate bleeding risk – indefinite; High bleeding risk – 3 months **Renewal:** • Length of renewal authorization based on anticipated length of therapy, indication and/or recent international normalized ratio (INR) if on warfarin

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Anticoagulants - Oral[iv] Eliquis Pradaxa Xarelto Savaysa	**Xarelto and Eliquis are the formulary preferred agents** **May be authorized for members who meet all of the following:** • Member is age 18 years and older • Diagnosis of one of the following: ○ Prophylaxis of Deep Vein Thrombosis (DVT) after hip or knee replacement surgery ○ Non-valvular atrial fibrillation ○ Member does not have moderate-to-severe mitral stenosis or a mechanical heart valve ○ Member has a CHA_2DS_2-VASc score of 1 or more ○ Treatment of Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE) ○ Member received 5 – 10 days of initial therapy with a parenteral anticoagulant (For Pradaxa and Savaysa only) ○ Risk reduction of recurrent Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE) (Savaysa not indicated) ○ Member has received at least 6 months of standard anticoagulation treatment (3 months for Pradaxa) ○ Risk reduction of cardiovascular (CV) events in chronic coronary artery disease (CAD) or peripheral artery disease (PAD) when used in combination with aspirin (Xarelto only) **In addition, for all non-formulary agents**: • Documentation to support trial and failure, intolerance, or contraindication to Xarelto or Eliquis	**Initial Approval:** • Atrial fibrillation: 1 year • Knee replacement: Up to 12 days from day of surgery • Hip replacement: Up to 35 days from day of surgery • Treatment of Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE): 3 months • Risk reduction of recurrent Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE): 6 months • Xarelto for Coronary Artery Disease (CAD) or Peripheral Artery Disease (PAD): 3

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		months **Renewals:** • Atrial fibrillation: 1 year • Treatment of Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE): 3 months • Risk reduction of recurrent Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE): 6 months • The American College of Chest Physicians (CHEST) recommends 3 month duration for most acute Venous Thromboembolism (VTE) treatment • Xarelto for Coronary

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		Artery Disease (CAD) or Peripheral Artery Disease (PAD): 6 months **Quantity Level Limit:** • Pradaxa: 2 caps per day • Savaysa: 1 tablet per day • Eliquis: 2 tablets per day • Xarelto: 1 tablet per day • Xarelto for Coronary Artery Disease (CAD) or Peripheral Artery Disease (PAD): 2 tablets per day
Antidepressants Non-Preferred[v] **Selective**	• Members who are stable (new to plan and/or using samples) that are on non-preferred antidepressant will receive 3-month approval as continuity of care, in order to transition to preferred antidepressant • Members who have started non-preferred antidepressant during recent hospitalization will	**Initial Approval:** 1 year **Renewal Approval:** 1 year

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Serotonin Reuptake Inhibitors (SSRI): Trintellix Viibryd Pexeva Fluoxetine weekly Fluoxetine tablets Fluvoxamine ER Paroxetine ER Paroxetine mesylate capsule **Serotonin and Norepinephrine Reuptake Inhibitors (SNRI):** Fetzima	receive 1-year initial approval **General Criteria for All New Starts** • Member is 18 years of age or older (except for fluvoxamine and fluoxetine) • Requested agent is Food and Drug Administration (FDA) approved for the indication being treated • If formulary preferred agent is available in different formulation with same ingredient (for example, Pexeva, Aplenzin, Forfivo XL, fluvoxamine ER, paroxetine mesylate, fluoxetine weekly), member must have documented trial and failure of that formulary agent **Additional Criteria Based on Indication** **Major Depressive Disorder or Seasonal Affective Disorder (One of the Following)** • Documented failure, or intolerance to 3 formulary agents from at least 2 different classes of antidepressants ○ Selective Serotonin Reuptake Inhibitor, Serotonin Norepinephrine Reuptake Inhibitor, bupropion, or mirtazapine at adequate dose and duration (at least 4 weeks) ▪ One of these trials must be with preferred formulary agent from same class (Selective Serotonin Reuptake Inhibitor, or Serotonin Norepinephrine Reuptake Inhibitor) • Documented failure, or intolerance to 2 formulary agents and acceptable antidepressant augmentation regimen ○ Selective Serotonin Reuptake Inhibitor , or Serotonin Norepinephrine Reuptake Inhibitor, plus bupropion, lithium, atypical antipsychotic, buspirone, or liothyronine, at adequate dose and duration (at least 4 weeks)	***Requires*:** Response to therapy **Quantity Level 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

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Venlafaxine SR tabs Pristiq Khedezla desvenlafaxine **Other:** Aplenzin Forfivo XL Nefazodone	▪ One of these trials must be with preferred formulary agent from same class (Selective Serotonin Reuptake Inhibitor, or Serotonin Norepinephrine Reuptake Inhibitor) **Obsessive-Compulsive Disorder** • Documented failure, or intolerance to 3 formulary agents ○ Selective Serotonin Reuptake Inhibitors, clomipramine, at adequate dose and duration (at least 4 weeks) **Panic Disorder or Generalized Anxiety Disorder** • Documented failure, or intolerance to 3 formulary agents from at least 2 different classes of antidepressants ○ Selective Serotonin Reuptake Inhibitors, or Serotonin Norepinephrine Reuptake Inhibitors, at adequate dose and duration (at least 4 weeks) **Hot Flashes Associated with Menopause** • Documented failure, or intolerance to 3 formulary agents from at least 2 different classes of antidepressants ○ Selective Serotonin Reuptake Inhibitors, or Serotonin Norepinephrine Reuptake Inhibitors, at adequate dose and duration (at least 4 weeks) ▪ Trial and failure, intolerance, or contraindication, or member preference to avoid hormonal therapy **Premenstrual Dysphoric Disorder** • Documented failure, or intolerance to 3 formulary Selective Serotonin Reuptake Inhibitors, at adequate dose and duration (at least 4 weeks)	Fluoxetine weekly: 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

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Atypical Antipsychotics [vi] **Formulary:** Aripiprazole tablets quetiapine risperidone olanzapine ziprasidone clozapine **Non-Formulary:** paliperidone ER quetiapine ER Saphris	**Members under 18 years of age:** Prior authorization is required for all agents. **Members 18 years of age and older:** Prior authorization is required for non-preferred agents. **Continuity of Care:** Members who are stable (new to the plan and/or using samples) on non-preferred antipsychotic therapy will receive a 6-month approval in order to transition to a preferred antipsychotic therapy. Members who started a non-preferred antipsychotic therapy during a recent hospitalization will receive a 6-month initial approval. **Non-Coverage:** • Use of more than one antipsychotic, unless cross titration is needed for up to 60 days • Use for indications that are not included in this guideline **All Agents - Children Ages 6-17:** **Criteria for ALL indications:** • Antipsychotic is prescribed within Food and Drug Administration (FDA) approved daily	**Initial Approval:** 6 months **Renewal:** One year ***Requires*:** Documentation of following: ○ Improvement in target symptoms ○ Treatment plan containing rationale for continued use or plan for discontinuation ○ Member weight ○ Screen for movement disorders ○ Metabolic screen

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Latuda Fanapt Rexulti Vraylar Secuado	dosing guidelines, treatment guidelines or recognized compendia • Baseline and yearly blood glucose using a test for hemoglobin A1c (HBA1c) or blood glucose • Baseline and yearly cholesterol using a test of low-density lipoprotein-cholesterol (LDL-C) or cholesterol • Weight at baseline and yearly • Screen for movement disorders associated with antipsychotic therapy • Diagnosis was based on a comprehensive evaluation by a psychiatrist, psychologist, neuropsychologist, neurologist or developmental pediatrician, and the member's symptoms meet the Diagnostic and Statistical Manual of Mental Disorders (DSM5) criteria for that diagnosis • New starts of antipsychotic therapy only: ▪ Member continues to have residual symptoms despite use of evidence-based non-pharmacologic therapies such as behavioral, cognitive, and family based therapies **Additional Criteria for Bipolar Disorder, Schizophrenia, Psychomotor Agitation Associated with Autism Spectrum Disorder OR Chronic Tic Disorder (including Tourette's Syndrome) requires one of the following:** • Requested antipsychotic is preferred formulary agent • Member had inadequate response, or intolerable side effect to two preferred formulary atypical antipsychotics. **Additional Criteria for Major Depressive Disorder requires all the following**:	**Quetiapine** QLL 90/30 25mg, 50mg, 200mg, 300mg QLL 60/30 400mg **Quetiapine ER** QLL 60/30 50mg, 300mg, 400mg QLL 30/30 150mg, 200mg **Risperidone** QLL 60/30 0.25mg, 0.5mg, 1mg, 2mg QLL 90/30 3mg

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Member had inadequate response, or intolerable side effect to three different medication regimens for depression at an adequate dose and duration (at least 4 weeks): ▪ Antidepressant monotherapy ▪ Antidepressant augmentation (Selective Serotonin Reuptake Inhibitor (SSRI) or Serotonin- Norepinephrine Reuptake Inhibitor (SNRI) plus bupropion, Lithium, buspirone, or liothyronine), and • Member meets one of the following: ▪ Requested antipsychotic is preferred formulary agent, or ▪ Member had inadequate response, or intolerable side effect to two preferred formulary atypical antipsychotics **<u>Non-Preferred Agents - Adults Age 18 and Older:</u>** **Criteria for ALL indications:** • Antipsychotic is prescribed within Food and Drug Administration (FDA) approved daily dosing guidelines, treatment guidelines or recognized compendia • Baseline and yearly blood glucose using a test for hemoglobin A1c (HBA1c) or blood glucose • Baseline and yearly cholesterol using a test of low-density lipoprotein-cholesterol (LDL-C) or cholesterol • Weight at baseline and yearly • Screen for movement disorders associated with antipsychotic therapy **Additional Criteria for Bipolar Disorder or Schizophrenia:** • Member had inadequate response, or intolerable side effect to two preferred formulary atypical antipsychotics.	QLL 120/30 4mg QLL 480mL/30 1mg/mL **<u>Olanzapine</u>** QLL 30/30 2.5mg, 5mg, 7.5mg, 10mg, 15mg 20mg **<u>Ziprasidone</u>** QLL 60/30 20mg, 40mg, 60mg, 80mg **<u>Aripiprazole</u>** QLL 30/30 **<u>Paliperidone ER</u>** QLL 30/30

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	Additional Criteria for Major Depressive Disorder requires all the following: • Member had inadequate response, or intolerable side effect to three different medication regimens for depression at an adequate dose and duration (at least 4 weeks): ○ Antidepressant monotherapy ○ Antidepressant augmentation (Selective Serotonin Reuptake Inhibitor (SSRI) or Serotonin- Norepinephrine Reuptake Inhibitor (SNRI) plus bupropion, Lithium, buspirone, or liothyronine) • Member had inadequate response, or intolerable side effect to two preferred formulary atypical antipsychotics **Children Age 5 and Under:** • Most antipsychotics are not Food and Drug Administration (FDA) approved for use in children ages 5 and under. Safety and efficacy in this age group has not been established and is not supported by the currently published peer-reviewed medical literature including the American Academy of Child and Adolescent Psychiatry (AACAP) Practice Parameter for the Use of Antipsychotics in Children & Adolescents. • Request for coverage of antipsychotics in children age 5 and under is generally not considered to be medically necessary and should be reserved for use when member continues to have residual symptoms despite use of evidence-based non-pharmacologic therapies such as behavioral, cognitive, and family based therapies. • Requests will be reviewed on a case-by-case basis by the Plan Medical Director. • Baseline and routine monitoring of weight, body mass index (BMI) or waist circumference,	1.5mg, 3mg, 9mg QLL 60/30 6mg **Latuda** QLL 30/30 **Fanapt** QLL 60/30 **Rexulti** QLL 30/30 **Saphris** QLL 60/30 **Vraylar** QLL 30/30 **Secuado** **QLL 30/30**

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	blood pressure (BP), fasting glucose, fasting lipid panel, and tardive dyskinesia using the Abnormal Involuntary Movement Scale (AIMS) or Dyskinesia Identification System (DISCUS) should be completed.	
Atypical Antipsychotics Long-Acting Injectable[vii] **Formulary** Abilify Maintena Aristada Invega Sustenna Invega Trinza Risperdal Consta **Non-formulary** Aristada Initio Perseris Zyprexa Relprevv	**Continuity of Care:** Members who are stable (new to the plan and/or using samples) on non-preferred antipsychotic therapy will receive a 6-month approval in order to transition to a preferred antipsychotic therapy. Members who started a non-preferred antipsychotic therapy during a recent hospitalization will receive a 1-year initial approval. **May be authorized when all the following criteria are met:** • Member is 18 years of age or older • Prescribed by, or in consultation with a psychiatrist • Diagnosis of a Food and Drug Administration (FDA) approved indication: ○ Schizophrenia / Schizoaffective Disorder ○ Bipolar I (Risperdal Consta, Abilify Maintena) • Documentation that member has received the recommended oral dosage (per FDA approved labeling) to confirm tolerability and efficacy • Member has had or is at high risk for non-adherence to oral antipsychotic medications which places member at risk for poor outcomes (Clinical Justification Required) • Will not receive concurrent oral antipsychotics after the initial overlap period (per Food and Drug Administration (FDA) approved labeling) • Provider agrees to support baseline and routine monitoring of all the following:	**Initial Approval:** 1 year **Renewal:** 1 year ***Requires*:** • Improvement in target symptoms • Metabolic screening within the last 60 days • Screen for tardive dyskinesia **Quantity Limits:** • Invega Sustenna: 1 per 28 days after initial loading doses • Invega Trinza: 1 per

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Weight, body mass index (BMI), or waist circumference ○ blood pressure ○ fasting glucose ○ fasting lipid panel ○ tardive dyskinesia ▪ using the Abnormal Involuntary Movement Scale (AIMS) OR ▪ Dyskinesia Identification System Condensed User Scale (DISCUS) • For Abilify Maintena and Invega Trinza/Sustenna only: Not taking a CYP3A4 inducer **<u>Additional Drug Specific Criteria:</u>** **Invega Trinza**: • Trial of stable dose of Invega Sustenna for 4 months **Aristada Initio:** • Use with one 30 mg dose of oral aripiprazole in conjunction with the first Aristada injection	84 days • Risperdal Consta: 2 per 28 days • Perseris: 1 per 28 days • Abilify Maintena: 1 per 28 days • Aristada 441 or 662mg: 1 per 28 days • Aristada 882mg: 1 per 28 days or 1 per 42 days • Aristada 1,064mg: 1 every 2 months • Aristada Initio 675mg: 1 single dose ○ Only to be used as a single dose and not repeated dosing, but may also be approved to allow member to re-initiate

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		Aristada following a missed dose of Aristada • Zyprexa Relprevv 210mg: 2 per 28 days • Zyprexa Relprevv 300mg: 2 per 28 days or 1 per 28 days • Zyprexa Relprevv 405mg: 1 per 28 days
Bonjesta **Doxylamine Succinate and Pyridoxine Hydrochloride** (Diclegis)[viii]	**May be authorized when the following criteria are met:** • Member is at least 18 years of age • Diagnosis of nausea and vomiting in pregnancy • Inadequate response or intolerable side effects to dietary and lifestyle changes ○ For example, avoiding stimuli/triggers, avoiding spicy or fatty foods, eating frequent small meals, or inadequate response to ginger • Use of individual products (over-the-counter doxylamine and pyridoxine) as separate dosage forms has not achieved adequate treatment response ○ Pyridoxine is available as a single agent and recommended dose 10-25mg orally every six to eight hours. ○ Doxylamine is available as over-the-counter and as prescription products, with recommended dose as one-half 25mg over-the-counter tablet, or two chewable 5mg	**Initial Approval:** 3 months **Renewal:** 3 months ***Requires:*** • Documentation member is still pregnant and continues to have nausea and vomiting symptoms

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	prescription tablets • For Bonjesta: Use of generic prescription doxylamine succinate and pyridoxine hydrochloride has not achieved adequate treatment response	**Quantity Level Limit**: Diclegis or generic Doxylamine Succinate and Pyridoxine Hydrochloride: 4 tablets per day Bonjesta: 2 tablets per day
Botulinum Toxins	Botox, Myobloc, Dysport, Xeomin https://www.aetnabetterhealth.com/california/providers/pharmacy/prior-auth	
Cablivi[ix]	**Member meets all the following criteria:** • Age is 18 years or older • Medication is prescribed by, or in consultation with a hematologist • Diagnosis is for acquired thrombotic thrombocytopenic purpura (aTTP) • Diagnosis is confirmed by one of the following: ○ Member has severe thrombocytopenia with microangiopathic hemolytic anemia (MAHA), confirmed by red blood cell fragmentation on peripheral blood smear ▪ For example, schistocytes ○ Testing shows ADAMTS13 activity levels of less than 10% • Medication will be given in combination with plasma exchange and immunosuppressive	**Initial Approval:** 30 days **Renewal Approval:** 28 days ***Requires:*** Additional therapy up to a maximum of 28 additional days will be considered when

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	therapy ○ For example, systemic glucocorticoids, rituximab • Cablivi will be discontinued if member experiences more than 2 recurrences of aTTP while on treatment with Cablivi	provider submits the following: • Documentation of remaining signs of persistent underlying disease ○ For example, suppressed ADAMTS13 activity levels • Documentation date of prior episode and date of new episode • Medication will be given in combination with plasma exchange and immunosuppressive therapy ○ For example, systemic glucocorticoids, rituximab

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		• Member has not experienced more than 2 recurrences while on Cablivi **Quantity Level Limit:** Total treatment duration per episode is limited to 58 days beyond last therapeutic plasma exchange
Calcipotriene[x]	**Calcipotriene will pay at the point of sale (without requiring a prior authorization) for 2 months when the following criteria is met:** • Diagnosis of psoriasis (ICD-10 L40.0 through L40.9*) **Prescriptions that do not pay at the point of sale require prior authorization and may be authorized for members who meet the following criteria:** • Diagnosis of psoriasis	**Initial Approval:** • 2 months **Renewal:** • 2 months ***Requires*:** Improvement in symptoms **Quantity Level Limit (QLL)**: Ointment, cream:

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		120gm/30 days Solution: 60ml/30 days
Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists[xi] Aimovig Ajovy Emgality Nurtec ODT Ubrelvy Vyepti	**May be authorized when member meets the following criteria:** • Prescribed by, or in consultation with neurologist for preventative treatment of migraines, treatment of acute migraines, or treatment of cluster headaches • Age is 18 years or older • **Chronic Migraine** (Aimovig, Emgality, Ajovy, Vyepti): ○ Headache occurring on 15 or more days per month with at least 8 migraine days per month for more than 3 months • **Episodic Migraine** (Aimovig, Emgality, Ajovy, Vyepti): ○ Headache occurring less than 15 days per month with 4 to 14 migraine days per month • For Chronic and Episodic migraines, there is documented inadequate response, or intolerable side effects, to at least three medications for migraine prophylaxis from two different classes, for at least 3 months: ○ Beta-Blockers: Propranolol, metoprolol, atenolol ○ Anticonvulsants: Valproic acid, or divalproex, topiramate ○ Antidepressants: Amitriptyline, venlafaxine ○ Angiotensin-Converting Enzyme Inhibitors (ACE-Is)/Angiotensin II Receptor Blockers (ARBs): Lisinopril, candesartan, losartan, valsartan ○ Calcium Channel Blockers: Diltiazem, nifedipine, nimodipine, verapamil • **Acute Migraine** (Ubrelvy, Nurtec ODT): ○ Medication is for moderate or severe pain intensity ○ Documented inadequate response, or intolerable side effect, with at least two triptans,	**Initial Approval**: 3 months **Renewal:** 6 months ***Requires:*** • Documentation of clinical response to treatment by reduction in migraine or headache days • Aimovig 140mg monthly injection requires trial and failure with the 70mg injection • Vyepti 300mg 90-day intravenous infusion requires trial and failure with the

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	or member has a contraindication to triptan use ○ Ubrelvy: ▪ Member does not have End Stage Renal Disease (CrCl less than 15 mL/min) ▪ Member does not experience more than 8 migraine days per month ○ Nurtec ODT: ▪ Member does not experience more than 15 migraine days per month ▪ Member does not have End Stage Renal Disease (CrCl less than 15 mL/min or is on hemodialysis ▪ Member does not have severe hepatic impairment (Child-Pugh class C) • **Episodic Cluster Headaches:** (Emgality) ○ Headaches occurring at maximum 8 attacks per day, or minimum one attack every other day ○ Trial and failure with verapamil for preventive treatment or sumatriptan (nasal or subcutaneous) for acute treatment • Aimovig 140mg monthly injection, requires trial and failure with the 70mg injection • Vyepti 300mg 90-day intravenous infusion requires trial and failure with the 100mg intravenous infusion Medication will not be used in combination with another Calcitonin Gene-Related Peptide Receptor (CGRP) antagonist, or with Botulinum toxin (Botox)	100mg infusion • Medication will not be used in combination with another Calcitonin Gene-Related Peptide Receptor (CGRP) antagonist, or with Botulinum toxin (Botox) **<u>Quantity Level Limits:</u>** **Aimovig**: • 1mL per 30 days **Ajovy:** • 1.5mL per 30 days or 4.5mL per 90 days **Emgality for Cluster Headaches:** • 3mL for 1st 30 days then 1mL per 30 days

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		Emgality for Migraine Headaches: • 2mL for 1st 30 days then 1mL per 30 days **Nurtec ODT:** • 15 tablets per 30 days **Ubrelvy:** • 16 tablets per 30 days **Vyepti:** **3mL per 90 days**
Capecitabine (Xeloda)[xii]	**General Criteria:** ○ Prescribed by or in consultation with an oncologist ○ Member is 18 years of age or older **In addition, capecitabine may be authorized when one of the following criteria is met:** • Locally unresectable or metastatic colorectal cancer • Triple negative breast cancer (estrogen receptor, progesterone receptor, and HER2-negative) when there is residual disease after preoperative therapy with a taxane, an alkylator, and an anthracycline • Recurrent or metastatic breast cancer with one of the following: ○ Human epidermal growth factor receptor 2 (HER2) negative alone or in combination with docetaxel	**Initial Approval:** **1 year** **Renewal Approval:** **3 years** ***Requires:*** Clinically significant improvement or stabilization of disease state

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	○ Human epidermal growth factor receptor 2 (HER2) positive recurrent or metastatic breast cancer in combination with trastuzumab (Herceptin), lapatinib (Tykerb), or neratinib (Nerlynx) • Rectal cancer • Metastatic renal cell carcinoma (RCC) in combination with gemcitabine • Pancreatic adenocarcinoma and pancreatic neuroendocrine tumors (PNET) (Islet tumors) • Esophageal, esophagogastric junction or gastric cancers • Recurrent, unresectable, or metastatic head and neck cancer • Hepatobiliary cancers (extra/intra – hepatic cholangiocarcinoma and gallbladder cancer) • Neuroendocrine tumors of lung and thymus • Poorly differentiated neuroendocrine carcinoma (PDNEC) • Occult primary tumors • Ovarian cancer • Penile cancer	
Celecoxib[xiii]	**Celecoxib pays at Point of Sale when one of the following Step Therapy criteria are met:** • Member has filled 3 oral formulary Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) in the previous 180 days • Member has filled one of the following in the previous 90 days: ○ Proton Pump Inhibitor ○ Histamine H2 Receptor Antagonist ○ Prednisone ○ Warfarin ○ Xarelto ○ Pradaxa	**Initial and Renewal Approval:** One Year **Quantity Level Limit:** 50mg, 100mg, 200mg: 60 capsules per 30 days 400mg:

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Eliquis **Prescriptions that do not pay at Point of Sale require prior authorization (PA) and Celecoxib may be authorized when one of the following criteria are met:** • Member had previous history of Gastro-Intestinal bleed, or Peptic Ulcer Disease • Trial and failure of 3 formulary oral Non-Steroidal Anti-inflammatory Drugs (NSAIDs) • Member had a trial with one of the following: ○ Proton Pump Inhibitor ○ Histamine H2 Receptor Antagonist ○ Prednisone ○ Warfarin ○ Xarelto ○ Pradaxa ○ Eliquis	30 capsules per 30 days
Cinacalcet[xiv] (Sensipar)	**Criteria for Secondary Hyperparathyroidism due to Chronic Kidney Disease on Dialysis:** • Member is at least 18 years of age • Serum calcium greater than or equal to 8.4mg/dL, prior to initiation of therapy • Intact parathyroid hormone (iPTH) greater than or equal to 300pg/mL, prior to initiation of therapy • Inadequate response or intolerable side effect to at least one type of phosphate binder • Member meets one of the following criteria: ○ Inadequate response or intolerable side effect to calcitriol or paricalcitol ○ Serum phosphate greater than or equal to 5.5mg/dL, or serum calcium greater than or	**Initial Approval:** 6 months **Renewal Approval:** 1 year ***Requires:*** Serum Calcium 8.4-12.5mg/dL

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	equal to 9.5mg/dL, and there is persistently elevated parathyroid hormone (PTH), despite maximum therapies to decrease phosphate **Criteria for Parathyroid Cancer:** • Member is at least 18 years of age • Serum calcium is greater than or equal to 12.5mg/dL, prior to initiation of therapy **Criteria for Primary Hyperparathyroidism:** • Member is at least 18 years of age • Member is not a candidate for parathyroidectomy • Serum calcium greater than or equal to 12.5mg/dL, prior to initiation of therapy	**Dosing information:** 1) Dialysis member with secondary hyperparathyroidism: Up to 300 mg/day 2) Hypercalcemia associated with parathyroid carcinoma or primary hyperparathyroidism: Up to 360 mg/day
Colony Stimulating Factors	https://www.aetnabetterhealth.com/california/providers/pharmacy/prior-auth Zarxio, Nivestym, Granix, Neupogen, Neulasta, Neulasta Onpro, Fulphila, Leukine, Udenyca, Ziextenzo	
Constipation Agents[xv]	**Irritable Bowel Syndrome with Constipation (IBS-C) or Chronic Idiopathic Constipation (CIC)** **Amitiza may be authorized when the following are met:**	**Initial Approval:** • Linzess: 6 months • Amitiza, Movantik,

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Amitiza Movantik Symproic Linzess (Nonpreferred/ Nonformulary)	• Member is 18 years of age or older • Diagnosis of Irritable Bowel Syndrome with Constipation (IBS-C) or Chronic Idiopathic Constipation (CIC) • Member had a treatment failure on at least **TWO** of the following classes, **ONE** of which is an osmotic laxative: ○ Osmotic Laxatives (for example, lactulose, polyethylene glycol, sorbitol); ○ Bulk Forming Laxatives (for example, psyllium, fiber); ○ Stimulant Laxatives (for example, bisacodyl, senna) **Linzess may be authorized when the following are met:** • Member is 18 years of age or older • Diagnosis of Irritable Bowel Syndrome with Constipation (IBS-C) or Chronic Idiopathic Constipation (CIC) • Member had a treatment failure on Amitiza **AND** at least **TWO** of the following laxative classes, **ONE** of which is an osmotic laxative ○ Osmotic Laxatives (for example, lactulose, polyethylene glycol, sorbitol); ○ Bulk Forming Laxatives (for example, psyllium, fiber); ○ Stimulant Laxatives (for example, bisacodyl, senna) **<u>Opioid-Induced Constipation (OIC)</u>** **Amitiza/Movantik/Symproic may be authorized when the following are met:** • Member is 18 years of age or older • Diagnosis of Opioid-Induced Constipation (OIC)	and Symproic: Indefinite (*Amitiza/Movantik/ Symproic for Opioid-Induced Constipation requires at least 30 days of opioids in the prior four weeks*) **<u>Renewal Approval</u>**: • Linzess: 6 months • Amitiza, Movantik, and Symproic: Indefinite (*Amitiza/Movantik/ Symproic for Opioid-Induced Constipation requires at least 30 days of opioids in the prior four weeks*) **<u>Quantity Level Limit (QLL):</u>**

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	• Member has at least 30 days of opioids in the prior four weeks • Member had a treatment failure of at least one medication from **TWO** of the following classes: ○ Osmotic Laxatives (for example, polyethylene glycol (PEG) 3350, lactulose, magnesium citrate/hydroxide) ○ Stimulant Laxatives (for example, bisacodyl, sodium picosulfate, senna)	Linzess: 30 tablets for 30 days
Corlanor[xvi]	**May be authorized for members 18 years of age or older when the following criteria are met:** • Diagnosis of stable symptomatic chronic heart failure (New York Heart Association (NYHA) Class II-III) • Left ventricular ejection fraction (LVEF) is less than or equal to 35% • Member is in sinus rhythm with a resting heart rate greater than or equal to 70 beats per minute • Continuation of therapy with maximally tolerated beta-blocker, or there is intolerance or contraindication to beta-blockers • Continuation of therapy with angiotensin-converting-enzyme inhibitor (ACEI)/Angiotensin Receptor Blockers (ARB), or Entresto, or there is intolerance, or contraindication to angiotensin-converting-enzyme inhibitor (ACEI)/Angiotensin Receptor Blockers (ARB), or Entresto ○ Note: Entresto requires Prior Authorization • Provider attestation that no contraindications to treatment exist: ○ Acute decompensated heart failure ○ Blood pressure less than 90/50 mmHg	**Initial Approval:** 6 months **Renewals:** 1 year ***Requires:*** • Member is responding to treatment • Heart rate is within recommended range for continuation of maintenance dose • For example, 50-60 beats per minute, or dose

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Pacemaker dependent (for example: heart rate maintained exclusively by pacemaker) ○ Sick sinus syndrome, sinoatrial block of third-degree AV block (unless functioning demand pacemaker is present) ○ Severe hepatic impairment (Child-Pugh class C) **May be authorized for pediatric members 6 months of age or older when the following criteria are met:** • Diagnosis of heart failure due to dilated cardiomyopathy • Member is in sinus rhythm with a resting heart rate of greater than or equal to 70 beats per minute • Provider attestation that no contraindications to treatment exist: ○ Acute decompensated heart failure ○ Blood pressure less than 90/50 mmHg ○ Pacemaker dependent (for example, heart rate maintained exclusively by pacemaker) ○ Sick sinus syndrome, sinoatrial block of third-degree AV block (unless functioning demand pacemaker is present) ○ Severe hepatic impairment (Child-Pugh class C)	adjusted accordingly to achieve goal **Quantity Level Limit**: Adults and Pediatrics: 60 tablets per 30 days Oral solution for pediatrics: 120 ampules per 30 days
Compounds[xvii]	**Compounds are not a covered benefit with the following exceptions:** • If each active ingredient is Food and Drug Administration (FDA)-approved (non-bulk chemicals also known as Active Pharmaceutical Ingredient (API)) • If each active ingredient is used for an indication that is Food and Drug Administration (FDA)-approved or compendia supported	**Initial Approval:** For market shortages: 3 months All others: 6 months

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	• The final route of administration of the compound is the same as the Food and Drug Administration (FDA)-approved or compendia supported route of administration of each active ingredient. (for example, oral baclofen tablets should not be covered for topical use) • Member meets one of the following: ○ Has an allergy and requires a medication to be compounded without a certain active ingredient (for example dyes, preservatives, fragrances) ▪ This situation requires submission of a Food and Drug Administration (FDA) MedWatch form consistent with Dispense as Written (DAW) 1 guidelines ○ Cannot consume the medication in any of the available formulations and the medication is medically necessary ○ Commercial prescription product is unavailable due to a market shortage (or discontinued) and is medically necessary ○ 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 prior spontaneous preterm birth ○ Request is for formulary antibiotic or anti-infective for injectable use (For example, formulary injection needing to be mixed with sodium chloride to create an IV compound) **NOTE:** All compounds will require authorization and clinical review if total submitted cost	**Renewals:** For market shortages: 3 months All others: 1 year

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	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: o Bioidentical hormones and implantable estradiol pellets o Nasal administration of nebulized anti-infectives for treatment of sinusitis o Topical Ketamine, Muscle Relaxants, Antidepressants, Non-Steroidal Anti-Inflammatory Drugs (NSAIDS) o Anticonvulsants products typically used for pain o 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 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	
Central Nervous System (CNS) Stimulants[xviii] **Formulary**	**Authorization Guidelines for All Agents:** • The prescribed stimulant is a preferred formulary agent, or the member meets the criteria for a non-preferred stimulant as described below • Stimulant is prescribed within Food and Drug Administration (FDA) approved daily dosing guidelines • Member will be taking only one type of stimulant medication as therapy (methylphenidate	**Initial Approval:** • Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) less

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
amphetamine/ dextroamphet-amine dexmethyl-phenidate dextroamphet-amine methylphenidat e IR, ER, LA, CD/CR **Non-Formulary** Vyvanse Evekeo Aptensio XR Daytrana Quillivant XR Methamphet-amine Dyanavel XR Mydayis Adhansia XR Jornay PM	or amphetamine-based drug) ○ A short-acting stimulant medication to be combined with a long-acting stimulant medication of the same drug type may be approved when there is documentation of the long-acting version not lasting for sufficient daily duration **Additional Guidelines for Adults over 18:** • Member has a diagnosis of Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD), narcolepsy, idiopathic hypersomnia, or fatigue related to cancer or multiple sclerosis • In addition, members initiating stimulant for Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) must meet the following: ○ Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) diagnosis is documented in medical record and is based on comprehensive evaluation by appropriate specialist, and includes evidence-based rating scale ▪ For example, but not limited to Adult Self Report Scale V1.1 (ASRS V1.1). ▪ The symptoms must also meet Diagnostic and Statistical Manual of Mental Disorders (DSM5) criteria ○ Other conditions (such as depression, anxiety, conduct disorder or tics) have been ruled out or are being appropriately treated ○ For members with history of substance abuse disorder, a urine drug screen is included in the treatment plan (does not require submission of results) **Additional Guidelines for Children Ages 6-18:** • Member has a diagnosis of Attention Deficit Hyperactivity Disorder/Attention Deficit	than 6 years: 1 year • Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) 6-18 years: Up to age 21 • Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) greater than 18 years: 1 year • Narcolepsy, idiopathic hypersomnia, or fatigue related to cancer or multiple sclerosis: 1 year • Binge Eating Disorder (Vyvanse): 12 weeks ***Renewal Approval:***

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Aptensio XR Contempla XR-ODT	Disorder (ADHD/ADD), or narcolepsy • In addition, members initiating stimulant for of Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) must meet the following: ○ Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) diagnosis is documented in medical record and is based on comprehensive evaluation by appropriate specialist or primary care provider. ○ The evaluation must include an evidence-based rating scale ▪ For example, but not limited to Swanson, Nolan, Pelham-IV Questionnaire (SNAP-IV)). ▪ The symptoms must also meet Diagnostic and Statistical Manual of Mental Disorders (DSM5) criteria ○ Other conditions (such as depression, anxiety, conduct disorder or tics) have been ruled out or are being appropriately treated ○ For members with history of substance abuse disorder, a urine drug screen is included in the treatment plan (does not require submission of results) ○ Evidence-based behavioral therapy (child, teacher, and/or caregiver) has been considered as part of the treatment plan. The therapy can be ongoing, previously completed or noted as not appropriate or necessary in this case **<u>Additional Guidelines for Children Age 5 and Under:</u>** • Member continues to have Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) symptoms despite evidence-based parent and/or teacher-administered behavior therapy • Requests for use in children age 5 and under are generally not considered to be medically	• Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) less than 6 years: 1 year • Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) 6-18 years: up to age 21 • Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) greater than 18 years: 1 year • Narcolepsy, idiopathic hypersomnia, or fatigue related to cancer or multiple

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	necessary, since many stimulant medications are not Food and Drug Administration (FDA) approved for use in this age group • Safety and efficacy in this age group has not been established and is not supported by the currently published peer-reviewed medical literature • All requests will be reviewed on a case-by-case basis by the plan Medical Director **<u>Additional Guidelines for Non-Preferred Agents:</u>** • Member meets criteria noted above based on age • Member has adverse reaction or contraindication to all preferred agents that does not also exist for the requested non-preferred drug, **or** • Member has failed to respond to at least two formulary stimulants (one formulary stimulant from each of the stimulant subclasses) (for example, amphetamine/dextroamphetamine and methylphenidate/ dexmethylphenidate). ○ Requests for a non-preferred, extended release product, require failure of extended release formulation of the preferred agents ○ Requests for a non-preferred, immediate release product, require failure of the immediate release formulation of the preferred agents **<u>Authorization Guidelines for Vyvanse for Binge Eating Disorder:</u>** • Member is 18 years of age or older • Prescribed by, or in consultation with, a psychiatrist • Member meets Diagnostic and Statistical Manual of Mental Disorders (DSM5) criteria for Binge Eating Disorder (BED) diagnosis • Member has a Body Mass Index (BMI) of greater than 25 kg/m^2	sclerosis: 1 year • Binge Eating Disorder (Vyvanse): 12 weeks ***Renewal Requirements for Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) and Narcolepsy:*** • Attestation of response to therapy • Attestation of member adherence to therapy ***Renewal Requirements for Binge Eating Disorder:*** • Member continues to receive evidence based behavioral therapy

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	• Attestation and/or claims history review of the following: ○ Member is receiving nutritional counseling or psychotherapy ○ Member had inadequate response or intolerance to at least two formulary medications used for Binge Eating Disorder (BED) (for example, Selective Serotonin Reuptake Inhibitors (SSRIs), topiramate, or zonisamide) ○ Member has not taken monoamine oxidase inhibitors in the past 14 days ○ There is no recent history of substance abuse ○ Member is not concurrently taking other stimulants ○ There is no history of cardiac disease (arrhythmia, cardiac structural abnormalities, coronary artery disease)	• Decrease in the number of binge days per week
Cystic Fibrosis (pulmonary) Medications[xix] Pulmozyme Tobramycin Nebulizer Tobi Podhaler Bethkis Kitabis Cayston Kalydeco	**Medical Records required for all Cystic Fibrosis Medications** **Pulmozyme may be authorized when the following are met:** • Member has a diagnosis of Cystic Fibrosis • Member is at least 5 years of age **Tobramycin Nebulizer Solution (generic for Tobi) may be authorized when the following are met:** • Member has a diagnosis of Cystic Fibrosis • Member is at least 6 years of age • Forced Expiratory Volume in one second (FEV_1) is between 25-80% predicted • Sputum cultures are positive for *P.aeruginosa.*	**Initial Approval:** Kalydeco, Symdeko and Orkambi, Trikafta: 3 months Non-cystic fibrosis bronchiectasis Tobramycin nebulizer solution, Kitabis, Tobi Podhaler, Bethkis: 12 months

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Orkambi Symdeko Trikafta	• Member is not colonized with *Burkholderia cepacia* **Tobi Podhaler, Bethkis or Kitabis may be authorized when the following are met:** • Member meets above criteria for tobramycin nebulizer solution • Member had an inadequate response, or intolerable side effect(s) with tobramycin nebulizer solution (generic). **Tobramycin Nebulizer Solution (generic for Tobi), Kitabis, Tobi Podhaler or Bethkis may be authorized for non-cystic fibrosis bronchiectasis when the following are met** • Sputum cultures or chart notes document the presence of pseudomonas aeruginosa • Member has tried formulary alternatives (for example, ciprofloxacin, sulfamethoxazole/trimethoprim) or formulary alternatives are contraindicated for non-cystic fibrosis bronchiectasis • In addition, for Tobi Podhaler, Bethkis and Kitabis member had an inadequate response, or intolerable side effect(s) with tobramycin nebulizer solution (generic) **Cayston may be authorized when the following are met:** • Member has a diagnosis of Cystic Fibrosis • Member is at least 7 years of age • Forced expiratory volume in one second (FEV_1) is between 25-75% predicted • Sputum cultures are positive for *P.aeruginosa*. • Member is not colonized with *Burkholderia cepacia* • Member had an inadequate response, or intolerable side effect(s) with 2 different formulary	All others: Indefinite **Renewal:** Kalydeco, Symdeko, Orkambi, Trikafta: 12 months ***Requires:*** • Documentation to support response to therapy (symptom improvement and/or stable Forced Expiratory Volume in one second (FEV_1)). • Pediatric members: Eye exam due to the possible development of cataracts. • Transaminase (Aminotransferase (ALT), Aspartate

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	tobramycin nebulizer solution products 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 • Member has a diagnosis of Cystic Fibrosis • Member is at least 1 year of age • Lab results to support member has one gating mutation OR one residual function mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene that is responsive to Kalydeco (ivacaftor). • Member is not homozygous for the Phe*508del* mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene. • For pediatric members, an eye examination is required at baseline and periodically throughout therapy. • Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring and liver function tests have been evaluated and dose has been reduced for members with moderate to severe hepatic impairment • For members taking a moderate or strong CYP3A inhibitor (for example, fluconazole, erythromycin, ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, and clarithromycin), reduce Kalydeco dose **Orkambi can be recommended for approval when the following are met:** • Prescribed by, or in consultation with pulmonologist • Member has a diagnosis of Cystic Fibrosis	Aminotransferase (AST)) monitoring • Liver Function Tests: Kalydeco, Symdeko, Orkambi and Trikafta should be temporarily discontinued if Alanine Aminotransferase (ALT)/Aspartate Aminotransferase (AST) are greater than 5 times the upper limit of normal (ULN) or Alanine Aminotransferase (ALT) or Aspartate Aminotransferase (AST)) is greater than3 times the upper limit of normal (ULN) with bilirubin greater than 2 times

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	• Member is at least 2 years of age • Lab results to support member is homozygous for the F508del mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene • For pediatric members, an eye examination is required at baseline and periodically throughout therapy. • Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring at baseline and liver function tests have been evaluated and dose reduced for members with moderate to severe hepatic impairment • For members initiating Orkambi and are currently taking a strong Cytochrome P450, family 3, subfamily A (CYP3A) inhibitor (for example, ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, and clarithromycin), reduce Orkambi dose **Symdeko can be recommended for approval when the following are met:** • Prescribed by, or in consultation with pulmonologist • Member has a diagnosis of Cystic Fibrosis • Member is at least 12 years of age • Lab results to support ONE of the following: ○ Member is homozygous for the F508del mutation in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene ○ Member has at least one mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene that is responsive to Symdeko(tezacaftor-ivacaftor) • For members who are homozygous for the F508del mutation in the Cystic Fibrosis	the upper limit of normal (ULN) Non-cystic fibrosis bronchiectasis Tobramycin nebulizer solution, Kitabis, Tobi Podhaler, Bethkis: 12 months *Requires*: Documentation to support response to therapy QLL: • Tobramycin: 56 ampules per 56 days (28 days of therapy followed by 28 days off)

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	Transmembrane Conductance Regulator (CFTR) gene, the member had an inadequate response, or intolerable side effect(s) with Orkambi • Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring at baseline, and liver function tests have been evaluated and dose reduced for members with moderate to severe hepatic impairment • For members taking a moderate to strong Cytochrome P450, family 3, subfamily A (CYP3A) inhibitor (for example, fluconazole, erythromycin, ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, and clarithromycin), reduce Symdeko dose. **Trikafta can be recommended for approval when the following are met:** • Prescribed by, or in consultation with pulmonologist • Member has a diagnosis of Cystic Fibrosis • Pretreatment forced expiratory volume (FEV_1) • Member is at least 12 years of age • Lab results to support the following: • Member has at least one F508del mutation in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene • For members who are homozygous for the F508del mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene, the member had an inadequate response, or intolerable side effect(s) with Orkambi • Transaminase (Aminotransferase (ALT), Aspartate Aminotransferase (AST)) monitoring at baseline, and liver function tests have been evaluated and dose reduced for members with moderate to severe hepatic impairment	• 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 • Symdeko: 56 tablets per 28 days • Trikafta: 84 tablets per 28 days

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	• For members taking a moderate to strong Cytochrome P450, family 3, subfamily A (CYP3A) inhibitor (for example, fluconazole, erythromycin, ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, and clarithromycin), reduce Trikafta dose	
Cytokines and Cell Adhesion Molecule (CAM) Antagonists	https://www.aetnabetterhealth.com/california/providers/pharmacy/prior-auth Actemra, Arcalyst, Cimzia, Cosentyx, Enbrel, Entyvio, Humira, Ilaris, Ilumya, Inflectra, Kevzara, Kineret, Olumiant, Orencia, Remicade, Renflexis, Siliq, Simponi, Simponi Aria, Skyrizi, Stelara, Taltz, Tremfya, Tysabri, Xeljanz, Xeljanz XR	
Daliresp[xx]	**May be approved for adults who meet all of the following:** • Member is 18 years of age or older • Diagnosis of severe Chronic Obstructive Pulmonary Disease (COPD), (for example FEV_1 less than or equal to 50% of predicted) with chronic bronchitis • Member had symptomatic exacerbations within the last year • Member had inadequate response to a three-month trial and failure, or contraindication to one of the following: ○ long-acting beta-agonist (LABA) + long-acting muscarinic antagonist (LAMA) + inhaled corticosteroid (ICS) ○ long-acting beta-agonist (LABA) + inhaled corticosteroid (ICS) ○ long-acting beta-agonist (LABA) + long-acting muscarinic antagonist (LAMA) • Daliresp will be used in conjunction with one of the following unless contraindicated or intolerant: ○ long-acting beta-agonist (LABA) ○ long-acting muscarinic antagonist (LAMA)	**Initial Approval:** 6 months **Renewals:** 12 months ***Requires:*** Improvement in the number of Chronic Obstructive Pulmonary Disease (COPD) exacerbations **Quantity Level Limit**: 1 tablet per day

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ long-acting beta-agonist (LABA) + long-acting muscarinic antagonist (LAMA) ○ long-acting beta-agonist (LABA) + inhaled corticosteroid (ICS) • No evidence of moderate to severe liver impairment (Child-Pugh B or C)	
Diabetic Testing Supplies[xxi]	**Diabetic Test Strip and Glucometer Quantity Limits:** • All diabetic test strips are limited to 150 count per 30 days • Glucometers are limited to 1 glucometer per 12 months **Criteria to Receive Non-Formulary Diabetic Supplies (Member meets one of the following):** • Physical limitation (manual dexterity or visual impairment) that limits utilization of formulary product • Insulin pump requiring a specific test strip • Hematocrit levels chronically less than 35% or greater than 45% ○ Accuchek Aviva, Accuchek Nano, Accuchek Performa, and Freestyle Freedom Lite are accurate for hematocrit 10-65% **Criteria to Receive Greater Than 150 Test Strips Per Month (Member meets one of the following):** • Newly diagnosed diabetes or gestational diabetes • Children with diabetes that are less than 18 years of age	**Initial and Renewal Approvals:** 1 year **Initial Approval for Continuous Glucose Monitoring**: 6 months • One Monitor/Reader/ Display Device • Sensors/Transmitters allotted for 6 months (or approximately up to 6 months): ○ Freestyle Libre 10 day: 18

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Member is on insulin pump • Member is on high intensity insulin therapy, and needs to routinely test more than 4-5 times daily **Criteria to Receive Greater Than One Glucometer Per Year (Member meets one of the following):** • Current glucometer is unsafe, inaccurate, or no longer appropriate based on medical condition • Current glucometer no longer functions properly, has been damaged, or was lost or stolen **Criteria to receive a Continuous Glucose Monitoring (for example, FreeStyle Libre, Dexcom G5, Dexcom G6) system requires all of the following:** • Prescribed by, or in consultation with an endocrinologist • Diagnosis of Type 1 or Type 2 Diabetes • Member age is appropriate for prescribed Continuous Glucose Monitor • Member is using an insulin pump or on multiple daily insulin injections (3 or more daily injections) • Member is compliant with self-monitoring and requires one of the following: ○ Monitoring blood glucose 4 or more times per day with frequent self-adjustments of insulin dosage OR	sensors per 180 days ○ Freestyle Libre 14 day: 12 sensors per 168 days ○ Dexcom G5: 24 sensors per 168 days ○ Dexcom G6: 18 sensors per 180 days • Transmitters: ○ Dexcom G5, G6: 2 transmitter

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ History of hypoglycemic unawareness • Attestation the member has completed a comprehensive diabetes education program **Criteria to receive another Continuous Glucose Monitoring system requires all of the following**: • Current monitor not functionally operating • Current monitor is out of warranty	s per 180 days **Renewal Approval for Continuous Glucose Monitoring**: *Requires documentation of continued medical necessity* 6 months • Sensors/Transmitters allotted for 6 months (or approximately up to 6 months): ○ Freestyle Libre 10 day: 18 sensors per 180 days ○ Freestyle

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		Libre 14 day: 12 sensors per 168 days ○ Dexcom G5: 24 sensors per 168 days ○ Dexcom G6: 18 sensors per 180 days • Transmitters: ○ Dexcom G5, G6: 2 transmitters per 180 days
Direct Renin Inhibitors[xxii]	• Member is 6 years of age or older • Diagnosis of hypertension	**Initial Approval:** 6 months

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Aliskiren (Tekturna) Tekturna HCT	• For oral pellets: ○ Member is unable to swallow tablets • There was inadequate response, or inability to tolerate at least 2 formulary antihypertensive agents from any of the following therapeutic classes: ○ Thiazide-type diuretic ○ Calcium Channel Blocker ○ Angiotensin-converting-enzyme (ACE) Inhibitor ○ Angiotensin receptor blocker (ARB) • Member is not pregnant	**Renewal Approval**: 6 months ***Requires*:** • Positive response to treatment • Member is not pregnant
Divalproex Extended-Release (ER)[xxiii] Divalproex ER tablet Divalproex DR tablet	**Divalproex extended-release (ER) products should pay at point of sale when:** • Member has a seizure disorder **Prescriptions for divalproex extended-release (ER) tablets that do not pay at the point of sale require prior authorization (PA) and may be authorized for members who meet the following criteria:** • Member is 18 years of age or older • For women of childbearing age, member is utilizing effective contraception if other options are not effective or tolerated • Member meets one of the following: ○ Medication is being used for bipolar disorder and member is unable to adhere to or tolerate the delayed-release (DR) formulation	**Initial approval:** 1 year **Renewal:** 1 year ***Requires*:** Member is responding to treatment

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Medication is being used for migraine prophylaxis and two preferred agents have been tried and failed for the condition (for example amitriptyline, beta blockers (metoprolol, propranolol, or timolol), topiramate, or venlafaxine)	
Dry Eye Medications[xxiv] Cequa Restasis Xiidra	**May be approved when all of the following criteria is met:** • Cequa: ○ Member is 18 years of age or older • Restasis: ○ Member is 16 years of age or older • Xiidra: ○ Member is 17 years of age or older • Prescribed by, or in consultation with, an ophthalmologist or optometrist • Diagnosis of Keratoconjunctivitis Sicca (dry eye syndrome, dysfunctional tear syndrome), dry eye disease, or dry eyes due to Sjogren's Syndrome • Trial and failure, or intolerance, of at least two different forms of formulary artificial tears, used at least four times per day (for example, gels, ointments, or liquids)	**Initial Approval:** 6 months **Renewal:** One year **Quantity Level Limit:** 60 vials per 30 days
Dupixent[xxv]	**For Moderate to Severe Atopic Dermatitis, may be authorized when all of the following is met:** • Member is 12 years of age or older • Documented diagnosis of moderate to severe atopic dermatitis with baseline evaluation of condition: ○ Using Patient-Oriented Eczema Measure (POEM), with a score greater than or equal	**Initial Approval:** 4 months **Renewals:** 6 months

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	to 8; OR ○ Investigator's Global Assessment (IGA) with a score greater than or equal to 3 • 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: ○ Two preferred (medium to very high potency) topical corticosteroids (for example triamcinolone, clobetasol, mometasone, betamethasone, fluocinonide), or one preferred low potency topical corticosteroid, for sensitive areas, such as face, ○ Tacrolimus ○ One oral systemic therapy such as methotrexate, cyclosporine, azathioprine or mycophenolate **For Moderate to Severe Asthma, may be authorized when all of the following is met:** • Member is 12 years of age or older • Documented diagnosis of moderate to severe asthma with one of the following (submission of medical records required): ○ Eosinophilic phenotype, with pretreatment eosinophil count greater than or equal to 150/microL ○ Corticosteroid dependent asthma (has received greater than or equal to 5 mg/day oral prednisone or equivalent per day) • Prescribed by, or in consultation with a pulmonologist, allergist, or immunologist • Dupixent will be used as add on therapy to a medium or high dose Inhaled Corticosteroid (ICS), plus one additional controller (for example, Long-Acting Beta Agonist (LABA), or Long-Acting Muscarinic Antagonist (LAMA)	***Requires:*** **Atopic Dermatitis:** • Response to medication therapy (for example, reduction in lesions), Patient-Oriented Eczema Measure (POEM) of 0 to 2 (clear or almost clear), or Investigator's Global Assessment (IGA) of 0 or 1 (clear or almost clear) **Asthma of Eosinophilic Phenotype:** • Response to therapy (for example, by a decrease in exacerbations from baseline, improvement in

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Member has been compliant with medium to high dose Inhaled Corticosteroids (ICS) plus a Long-Acting Beta Agonist (LABA), Long-Acting Muscarinic Antagonist (LAMA), or other controller for at least three months and remains symptomatic • Asthma symptoms are uncontrolled, as defined by one of the following: • Daily use of rescue medications (for example, Short Acting Beta-2 Agonists) • Nighttime symptoms occurring one or more times a week • Minimum of two exacerbations in the last 12 months requiring additional medical treatment (For example, systemic corticosteroids, emergency department visits, or hospitalization) • Forced Expiratory Volume in less than one second (FEV_1) is less than 80% predicted • Dupixent will not be used with another monoclonal antibody **For Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP), may be authorized when all of the following is met:** • Member is 18 years of age or older • Documented diagnosis of chronic rhinosinusitis with nasal polyposis • Dupixent will be used as add-on therapy to intranasal corticosteroids • Prescribed by, or in consultation with an ear, nose, and throat (ENT) specialist or an allergist • Symptoms have persisted for at least 12 weeks and two out of four hallmark signs and symptoms are present: • Mucopurulent drainage	Forced Expiratory Volume in less than one second (FEV_1) from baseline, etc.) • Continued use of Dupixent as add on therapy to other asthma medications • Dupixent will not be used with another monoclonal antibody **<u>Corticosteroid Dependent Asthma:</u>** • Response to therapy (for example, by a decrease in dose of oral steroids from baseline, a decrease in exacerbations from baseline, improvement in Forced Expiratory

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Nasal obstruction • Decreased sense of smell • Facial pain, pressure, and/or fullness • Attestation prescriber has confirmed mucosal inflammation is present • Member's condition has been inadequately controlled by systemic corticosteroids and/or sinus surgery following intranasal corticosteroids	Volume in less than one second (FEV_1) from baseline, etc.) • Continued use of Dupixent as add on therapy to other asthma medications • Dupixent will not be used with another monoclonal antibody **<u>Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)</u>** • Response to therapy (for example, by a decrease in the bilateral endoscopic nasal polyps score (NPS) or nasal congestion/obstruction score (NC) from

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		baseline) • Continued use of Dupixent as add-on therapy to intranasal corticosteroids **Dosing:** **Asthma, moderate to severe:** Initial: 400 mg (given as two 200 mg injections) or 600 mg (given as two 300 mg injections) Maintenance: 200 mg (following 400 mg initial dose) or 300 mg (following 600 mg initial dose) once every other week **Asthma, oral**

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		corticosteroid dependent Initial: 600 mg (given as two 300 mg injections) Maintenance: 300 mg once every other week **Atopic dermatitis:** Initial: 600 mg (given as two 300 mg injections) Maintenance: 300 mg once every other week **Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)** 300mg once every other week

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Duration of Therapy Limits for Proton Pump Inhibitors (PPIs)[xxvi] Preferred: • Esomeprazole 20 mg capsule OTC (over-the-counter) • Lansoprazole 15 mg capsule Rx and OTC (prescription and over-the-counter) • Lansoprazole 30 mg capsule Rx	All Proton Pump Inhibitors (PPIs) (preferred and non-preferred) are subject to a duration of therapy limit. This limit is 180 days in a rolling 365-day period. Requests for a duration of therapy limit override for a non-preferred Proton Pump Inhibitor requires use of preferred Proton Pump Inhibitor (PPI) products. A maximum duration of therapy override request for a Proton Pump Inhibitor will be authorized when one of the following criteria is met: • Member has a documented upper gastrointestinal (GI) testing in the previous 2-year period • Member is dependent on a feeding tube for nutritional intake • Member resides in a long-term care facility • Member is unable to taper off a Proton Pump Inhibitor (PPI) without return of symptoms • Member is unable to transition to a histamine H2-receptor antagonist (H2 Blocker) • Member uses a Proton Pump Inhibitor (PPI) alone or in combination with a histamine H2-receptor antagonist (H2 Blocker) only as needed, but this is still more than 180 days in a year **Duration of Therapy Limit Exemptions for Proton Pump Inhibitors (PPIs)** A maximum duration of therapy override request for a Proton Pump Inhibitor will pay at the point of sale (without requiring a prior authorization) and will be authorized when one of the following are met: • Member is under 6 years of age	Duration of override approval, both initial and reauthorization, to exceed the 180-day duration of therapy limit: One year

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
(prescription) • First-Lansoprazole Suspension 3mg/mL (for members 12 years and younger) • Omeprazole delayed release 20 mg tablet OTC (over-the-counter) • Omeprazole 10 mg, 20 mg, 40 mg capsule Rx (prescription)	• Member is receiving pancreatic enzymes • Member receives a concomitant medication that increases the risk of upper gastrointestinal (GI) bleed (for example, anticoagulants, antiplatelets, Nonsteroidal Anti-inflammatory Drugs (NSAIDs)) • Member with one of the following diagnosis codes: ○ Angiodysplasia of Stomach and Duodenum (with OR without Mention of Hemorrhage) (K31.81*) ○ Atrophic Gastritis with Hemorrhage (K29.41) ○ Barrett's Esophagus (K22.7*) ○ Cerebral Palsy (G80*) ○ Chronic Pancreatitis (K86.0, K86.1) ○ Congenital Tracheoesophageal Fistula (Q39.1, Q39.2) ○ Cystic Fibrosis (E84.*) ○ Eosinophilic Esophagitis (K20.0) ○ Eosinophilic Gastritis (K52.81) ○ Gastrointestinal Hemorrhage (K92.2) ○ Gastrointestinal Mucositis (Ulcerative) (K92.81) ○ Malignant Mast Cell Tumors (C96.2*) ○ Multiple Endocrine Adenomas (D44.0, D44.2, D44.9) ○ Tracheoesophageal Fistula (J86.0) ○ Ulcer of Esophagus with OR without Bleeding (K22.1*) ○ Zollinger-Ellison Syndrome (E16.4) * Any number or letter or combination of UP TO FOUR numbers and letters of an assigned ICD-	

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
• Omeprazole magnesium 20.6 mg capsule OTC (over-the-counter) • First-Omeprazole Suspension 2 mg/mL (for members 12 years and younger) • Pantopra-zole 20 mg and 40 mg tablets Rx (prescript-tion) • Rabeprazole 20 mg tablet	10-CM diagnosis code	
Elmiron[xxvii]	**Elmiron will pay at the point of sale (without requiring a prior authorization) for 6 months**	**Initial Approval:**

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	when the following criteria is met: • Diagnosis of interstitial cystitis (ICD-10 N30.1*) **Prescriptions that do not pay at the point of sale require prior authorization and may be authorized for members who meet the following criteria:** • Diagnosis of bladder pain or discomfort associated with interstitial cystitis	• 6 months **Renewal:** • 6 months *Requires*: Improvement in symptoms (for example: pelvic/bladder pain, urinary frequency/urgency)
Emflaza[xxviii]	**Authorization criteria for members 2 years of age and older when all the following are met:** • Prescribed by or in consultation with a neurologist • Documentation indicating member has diagnosis of Duchenne Muscular Dystrophy (DMD) confirmed by one of the following: ○ Genetic testing demonstrating a mutation in the dystrophin gene, ○ Muscle biopsy evidence of total absence of dystrophin or abnormal dystrophin • Serum creatine kinase (CK) at least 10 times the upper limit of normal • Documentation member had a trial of prednisone for at least 6 months with unmanageable and clinically significant weight gain/obesity or psychiatric/behavioral issues (for example abnormal behavior, aggression, or irritability) • Documentation of baseline motor milestone scores by one of the following assessments: ○ 6-minute walk test (6MWT)	**Initial Approval:** 6 months **Renewal Approval:** **12 months** ***Requires*:** • Clinical benefit from therapy documented as an improvement in baseline motor milestone scores

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ North Star Ambulatory Assessment (NSAA) ○ Motor Function Measure (MFM) ○ Hammersmith Functional Motor Scale (HFMS) • Attestation of all the following: ○ Emflaza will not be given concurrently with live vaccinations ○ Member does not currently have an active infection (including Hepatitis B Virus (HBV)) • For members with history of Hepatitis B Virus (HBV) infection, prescriber agrees to monitor for Hepatitis B Virus (HBV) reinfection	• Attestation to the following: ○ Not given concurrently with live vaccinations ○ Absence of an active infection (including Hepatitis B Virus (HBV)). ○ If member has history of Hepatitis B Virus (HBV) infection, prescriber agrees to monitor for Hepatitis B Virus (HBV) reinfection
Entresto [xxix]	**May be approved when the following criteria are met:** • Diagnosis of heart failure and member meets one of the following: ○ 18 years of age and older with New York Heart Association (NYHA) Class II-IV chronic	**Initial Approval:** One year

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	heart failure with a reduced ejection fraction (HFrEF) of less than or equal to 40% ○ 1 year or older with symptomatic heart failure and systemic left ventricular systolic dysfunction • For members 18 or older with heart failure and a reduced ejection fraction (HFrEF) of less than or equal to 40%: ○ Member is tolerating an angiotensin receptor blocker (ARB) or an angiotensin-converting-enzyme inhibitor (ACEI) and Entresto will replace the angiotensin receptor blocker (ARB) and/or angiotensin-converting-enzyme inhibitor (ACEI) ○ Use in conjunction with other heart failure therapies (For example beta blockers, aldosterone antagonist, and combination therapy with hydralazine and isosorbide dinitrate) • For members 1 year or older with symptomatic heart failure and systemic left ventricular systolic dysfunction: ○ Member has tried and failed enalapril • Member is not pregnant • Attestation that Entresto will not be used concomitantly or within 36 hours of the last dose of an angiotensin-converting-enzyme inhibitor (ACEI), or a medication containing aliskiren (For example Tekturna or Tekturna-hydrochlorothiazide) • Attestation member does not have: ○ Severe hepatic impairment (Child Pugh Class C) ○ History of angioedema	**Renewal Approval:** One year ***Requires*:** • Response to treatment • Claims history review to verify use in conjunction with other heart failure therapies (For example beta blockers, aldosterone antagonist, and combination therapy with hydralazine and isosorbide dinitrate) for members 18 or older with heart failure and (HFrEF) of less than or equal to 40% • Member is not

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		pregnant **<u>Quantity Level Limit:</u>** • 24/26mg: 6 tablets per day (pediatric members only) • Other strengths: 2 tablets per day
Epidiolex[xxx]	**May be authorized when the following criteria are met:** • Member is at least 2 years of age • Prescribed by, or in consultation with a neurologist • Medication will be taken as adjunctive therapy to at least one other antiepileptic drug • Attestation that serum transaminases and total bilirubin levels have been obtained prior to initiation and will be taken periodically as appropriate (per Food and Drug Administration (FDA) approved labeling) • Dose must be appropriate for member's liver function and should not exceed 20mg/kg/day • **For Lennox-Gastaut syndrome:** ○ Documentation member has tried and failed or has intolerance or contraindication to Onfi® (clobazam) and two of the following: ▪ Valproic acid, topiramate, lamotrigine, and/or felbamate • **For Dravet syndrome:** ○ Documentation member has tried and failed or has intolerance or contraindication to Onfi® (clobazam), valproic acid, and one of the following: ▪ Topiramate, levetiracetam, zonisamide, lamotrigine, or felbamate	**<u>Initial Approval:</u>** 6 months **<u>Renewals:</u>** 1 year ***Requires*:** • Member has had decrease in seizure frequency from baseline • Serum transaminase level has not been greater than 3 times the upper limit of normal (ULN) while

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	*Note zonisamide and lamotrigine are not generally recommended in Dravet Syndrome treatment but will be recognized as previous therapy trials should they have been previously used.	accompanied by bilirubin greater than 2 times the ULN • Serum transaminase level has not been sustained at greater than 5 times the upper limit of normal (ULN) **Quantity Level Limit:** 20mg/kg/day. **All requests require current weight** to confirm correct dose not being exceeded
Erythromycin Ethylsuccinate Suspension [xxxi]	**May be authorized when one of the following criteria are met:** • Member has a diagnosis of gastroparesis characterized by delayed gastric emptying without the presence of mechanical obstruction, and ○ Member has had an inadequate response, intolerable side effects, or contraindication to metoclopramide, • Member has a bacterial infection other than gastroparesis, and ○ Member has had an inadequate response, intolerable side effects, or contraindication to both azithromycin and clarithromycin	**Initial Approval:** • Gastroparesis: 4 weeks • Bacterial infections: requested duration of therapy **Renewals:** 4 weeks

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		Requires: • Member continues to show improvement in symptoms from baseline and tolerates oral feeding
Erythropoiesis Stimulating Agents (ESAs)[xxxii] **Preferred Agents:** **Epogen** **Retacrit** **Non-Preferred Agents:** Procrit Aranesp Mircera	**Preferred Agents:** • Epogen and Retacrit are the preferred Erythropoiesis Stimulating Agents (ESA). **Non-Preferred Agents:** • Requests for Procrit require trial and failure of Epogen and Retacrit. • Requests for Aranesp and Mircera require trial and failure of Epogen, Retacrit and Procrit. **Documentation is required for both initial and renewal requests** **General Authorization Guidelines for All Indications:** • Member does not have uncontrolled hypertension • Member has adequate iron stores to support erythropoiesis demonstrated by one of the following: ○ Serum ferritin greater than or equal to 100 ng/mL, and transferrin saturation (iron saturation) greater than or equal to 20% ○ Reticulocyte hemoglobin content (CHr) greater than 29 pg	**Initial Approval:** • **Perioperative:** Up to 21 days of therapy per surgery • **All other indications:** 3 months **Renewal Approval:** • 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
	<u>Additional Criteria Based on Indication:</u> **Anemia due to Chronic Kidney Disease (CKD)** • Hemoglobin less than 10 g/dL within the last 2 weeks **Anemia due to Cancer Chemotherapy** • Anemia is because of concomitant myelosuppressive chemotherapy • Diagnosis of non-myeloid malignancy (for example, solid tumor) and expected outcome is not cure • There is a minimum of two additional months of planned chemotherapy • Hemoglobin less than 10 g/dL within the last 2 weeks **Anemia in Members with Human Immunodeficiency Virus (HIV) receiving zidovudine *(Procrit, Epogen, and Retacrit only)*** • Zidovudine dose less than or equal to 4200 mg/week • Endogenous erythropoietin levels ≤ 500 IU/L • Hemoglobin <10 g/dL within the last 2 weeks **Reducing transfusions in members undergoing elective, non-cardiac, nonvascular surgery *(Procrit, Epogen, and Retacrit only)*** • Hemoglobin greater than 10 g/dL, and less than or equal to 13 g/dL within 30 days prior to planned surgery date • Member is at high risk for perioperative blood loss	Anemia due to Chronic Kidney Disease: ○ Adults: Hemoglobin less than 11 g/dL for those on dialysis, or less than 10g/dL for those not on dialysis within the last 2 weeks ○ Pediatrics: Hemoglobin less than 12 g/dL in the last 2 weeks • Anemia due to cancer chemotherapy, or member with Human Immunodeficiency Virus: ○ Hemoglobin less

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Member is unable or unwilling to donate autologous blood preoperatively **Anemia associated with Myelodysplastic Syndrome (MDS) *(Procrit, Epogen, Retacrit, and Aranesp only)*** • Recent endogenous erythropoietin level less than or equal to 500 IU/L • Hemoglobin less than 10 g/dL within the last 2 weeks **Anemia in member receiving Hepatitis C treatment (Retacrit, Procrit, and Epogen only)** • Member is receiving combination therapy with ribavirin and interferon alpha • Hemoglobin less than 12 g/dL within the last 2 weeks	than 11 g/dL within the last 2 weeks • Anemia due to Myelodysplastic Syndrome: ○ Hemoglobin less than 12 g/dL in the last 2 weeks
Estradiol Vaginal Cream 0.01%[i]	**Estradiol Vaginal Cream 0.01% is approved when <u>one</u> of the following criteria is met:** • Member had inadequate response, intolerable side effects, or contraindication to Estradiol Vaginal Tablets • Member is 10 years of age or younger with a diagnosis of labial adhesion	**<u>Initial Approval:</u>** 6 months **<u>Renewal Approval</u>*:*** 6 months ***Requires*:** Attestation of response to therapy
Eucrisa[xxxiii]	**May be authorized when all of the following criteria is met:** • Member is at least two years of age • Diagnosis of mild to moderate atopic dermatitis with baseline evaluation of condition: ○ Using Patient-Oriented Eczema Measure (POEM), with a score greater than or equal to 3; OR	**<u>Initial Approval:</u>** 4 weeks **<u>Renewals:</u>** 3 months

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Investigator's Global Assessment (IGA) with a score greater than or equal to 2 • 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: ○ Two preferred (medium potency) topical corticosteroids (such as hydrocortisone, triamcinolone, mometasone, betamethasone, fluticasone); for sensitive areas, such as the face, one preferred low potency topical corticosteroid ○ Tacrolimus ○ One oral systemic therapy such as methotrexate (MTX), cyclosporine, azathioprine or mycophenolate	***Requires:*** • Response to medication therapy (for example, reduction in lesions), Patient-Oriented Eczema Measure (POEM) of 0 to 2 (clear or almost clear), or Investigator's Global Assessment (IGA) of 0 or 1 (clear or almost clear) **Quantity Limit:** 60 gm tube per month 100 gm tube per month
everolimus	**General Criteria:** ○ Prescribed by, or in consultation with oncologist	**Initial Approval:** 6 months

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
(Afinitor / Afinitor disperz) [xxxiv]	○ Member is 18 years of age or older ○ Age exception: Afinitor disperz for the following diagnosis: ○ Subependymal Giant Cell Astrocytoma (SEGA) ○ Tuberous Sclerosis Complex Associated Partial-Onset Seizures **In addition, may be authorized when one of the following criteria are met:** **Breast Cancer** • Human epidermal growth factor receptor 2 (HER2)-Negative breast cancer and Hormone receptor positive ○ For example, estrogen-receptor positive, or progesterone-receptor positive • Member status meets one of the following: ○ Postmenopausal ○ Premenopausal woman being treated with ovarian ablation/suppression ○ Male • Failure of treatment with letrozole, anastrozole, or tamoxifen • Used in combination with exemestane **Advanced Neuroendocrine Tumors** • Member meets one of the following criteria: ○ Progressive neuroendocrine tumor of pancreatic origin ○ Progressive, well-differentiated, non-functional neuroendocrine tumors of gastrointestinal tract or lung • Note: Afinitor tablets is not indicated for treatment of members with functional carcinoid tumors **Tuberous Sclerosis Complex** • Renal angiomyolipoma, not requiring immediate surgery	**Renewal:** 1 year ***Requires*:** Clinically significant improvement or stabilization of disease state

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	Subependymal giant cell tumor (SEGA) • Member is not a candidate for surgical resection **Advanced Renal Cell Carcinoma** • Member meets one of the following criteria: ○ Non-clear cell histology ○ Clear cell histology ○ Trial and failure with Sutent) or sorafenib (Nexavar) **Waldenstrom Macroglobulinemia -Lymphoplasmacytic Lymphoma** • Trial and failure with a first line chemotherapy regimen ○ For example, bendamustine-rituximab, bortezomib-dexamethasone-rituximab, rituximab-cyclophosphamide-dexamethasone, or others • **Soft Tissue Sarcoma** ○ Member has one of the following diagnosis: ▪ Perivacular epithelioid cell ▪ Recurrent Angiomyolipoma ▪ Lymphangioleiomyomatosis **Soft Tissue Sarcoma - Gastrointestinal Stromal Tumors (GIST)** • Member had trial and failure with imatinib, Sutent and Stivarga • Will be used in combination with imatinib, Sutent, or Stivarga **Classical Hodgkin Lymphoma** • Relapse or refractory disease ○ Failure to first line chemotherapy regimen ▪ ABVD (doxorubicin, bleomycin, vinblastine, dacarbazine), or BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone),	

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	or others **Thyroid Carcinoma** • Member has locally advanced or metastatic disease • Diagnosis is of follicular, Hürthle cell, or Papillary carcinoma **Thymomas and Thymic Carcinomas** • Trial and failure with at least one first line chemotherapy regimen ○ For example, cisplatin, doxorubicin, cyclophosphamide preferred for thymoma, or carboplatin-paclitaxel preferred for thymic carcinoma, or others **Bone cancer** • Member has relapsed, refractory or metastatic Osteosarcoma • Member had failure with at least one first line chemotherapy regimen • Used in combination with Nexavar **Afinitor Disperz tablets for oral suspension** **Subependymal Giant Cell Astrocytoma (SEGA) associated with Tuberous Sclerosis Complex (TSC)** • Age is 1 year or older • Member is not a candidate for surgical resection **Tuberous Sclerosis Complex (TSC) Associated Partial-Onset Seizures** • Age is 2 years or older • Treatment is adjunctive with antiepileptic medication	
Griseofulvin[xxxv]	Griseofulvin is approved when ONE of the following criteria is met: • Member had inadequate response, intolerable side effect, or contraindication to ONE of the	**Initial Approval**: 6 months

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	following agents: ○ fluconazole ○ itraconazole ○ ketoconazole ○ terbinafine OR • Member has a diagnosis of tinea capitis	**Renewal Approval**: 6 months
Growth Hormone	Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Serostim, somatropin, Zorbtive, Zomacton **See Detailed document:** Aetna Better Health of California Pharmacy Guidelines	
Gonadotropin Releasing Hormone (GnRH) Analogs[xxxvi] Firmagon Leuprolide acetate	Requests for non-preferred agents require trial of one preferred agent in addition to clinical criteria (exception for gender dysphoria/gender incongruence) **Endometriosis** • Prescribed by, or in consultation with a gynecologist or obstetrician • Member is at least 18 years of age • Meets one of the following criteria: ○ Trial and failure of at least one formulary hormonal cycle control agent (for example, Portia, Ocella, Previfem), or medroxyprogesterone, in combination with a non-steroidal anti-inflammatory drug (NSAID)	**Initial Approval:** **Endometriosis** 6 months **Uterine Leiomyoma (fibroids)** 3 months **Dysfunctional uterine bleeding** 2 months

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Lupaneta Pack Lupron Depot Lupron Depot-PED Eligard Orilissa Trelstar Triptodur Vantas Synarel Supprelin LA Zoladex	○ Member has severe disease or recurrent symptoms **Uterine Leiomyoma (fibroids)** • Prescribed by, or in consultation with a gynecologist or obstetrician • Member is at least 18 years of age • Prescribed to improve anemia and/or reduce uterine size prior to planned surgical intervention • Trial and failure of iron to correct anemia **Endometrial Thinning for Dysfunctional Uterine Bleeding** • Prescribed by, or in consultation with gynecologist or obstetrician • Member is at least 18 years of age • Prescribed to thin endometrium prior to planned endometrial ablation or hysterectomy within the next 4-8 weeks **Central Precocious Puberty** • Prescribed by, or in consultation with endocrinologist • Magnetic Resonance Imaging (MRI) or Computed Tomography (CT) Scan has been performed to rule out brain lesions or tumors • Onset of secondary sexual characteristics earlier than 8 years in females, and 9 years in males • Response to a Gonadotropin Releasing Hormone (GnRH) stimulation test (or if not available, other labs to support Central Precocious Puberty (CPP), such as luteinizing hormone level, estradiol and testosterone level) • Bone age advanced 1 year beyond chronological age	**Central Precocious Puberty** Supprelin LA: 12 months All others: 6 months **Cancer** 2 years **Gender Dysphoria** 6 months **<u>Renewal Approval:</u>** **Central Precocious Puberty** 6 months - 1 year (up to age 11 for females, and age 12 for males) ***Requires:*** • Clinical response to treatment (for example, pubertal slowing or decline, height velocity, bone age, estradiol, and

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Baseline height and weight **Advanced Prostate Cancer** • Prescribed by, or in consultation with oncologist or urologist • Member is at least 18 years of age **Advanced Breast Cancer** • Prescribed by, or in consultation with an oncologist • Member is at least 18 years of age and premenopausal at time of diagnosis **Advanced Ovarian Cancer** • Prescribed by, or in consultation with an oncologist • Member meets one of the following: ○ Cannot tolerate or does not respond to cytotoxic regimens ○ The drug requested is being used for post-operative management • Member is at least 18 years of age **Salivary Gland Cancer** • Prescribed by, or in consultation with an oncologist • Member has androgen receptor positive recurrent disease, with distant metastases • A performance status (PS) score of 0 – 3 by Eastern Cooperative Oncology Group (ECOG) standards **Gender Dysphoria/Gender Incongruence in adolescents** • Prescribed by a Pediatric Endocrinologist that has collaborated care with a Mental Health Provider	testosterone level) **Endometriosis** (Lupron Depot/Lupaneta only): 6 months ***Requires*** • Treatment is for recurrence after initial course of therapy • Total duration of treatment for both initial and recurrent symptoms will not be longer than 12 months • Add-back therapy (norethindrone) will be used concurrently **Uterine Leiomyoma (fibroids) or Dysfunctional Uterine**

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Member shows a persistent, well-documented diagnosis of gender non-conformity or dysphoria that worsened with puberty • Exhibits signs of puberty with a minimum Tanner stage 2 • Member has made a fully informed decision and has given consent, and parent/guardian consents to treatment, or member has been emancipated • The member's comorbid conditions are reasonably controlled • Member has been educated on any contraindications and side effects to therapy • Member has been informed of fertility preservation options prior to treatment **Gender Dysphoria/Gender Incongruence in Adults** • Member is 18 years of age or older • Prescribed by an Endocrinologist that has collaborated care with a Mental Health Provider • Member shows a persistent, well-documented diagnosis of gender dysphoria/incongruence • The member has the capacity to make a fully informed decision and consents to treatment • Mental health concerns, if present, are reasonably well controlled • Member has been informed of fertility preservation options prior to treatment	**Bleeding** Long-term use is not recommended **Gender Dysphoria** 12 months ***Requires:*** Lab results to support response to treatment (for example, follicle-stimulating hormone (FSH), luteinizing hormone (LH), weight, height, tanner stage, bone age)
Hepatitis C	**Preferred agent: Mavyret** Treatment Policy for the management of Chronic Hepatitis C is available at: https://www.aetnabetterhealth.com/california/providers/pharmacy/prior-auth	

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Hereditary Angioedema (HAE) Agents	Berinert, Cinryze, Firazyr, Kalbitor, Ruconest, Takhzyro https://www.aetnabetterhealth.com/california/providers/pharmacy/prior-auth	
Hetlioz[xxxvii]	**Authorization criteria for members 18 years of age and older:** • Prescribed by, or in consultation with a sleep specialist (board-certified by the American Board of Sleep Medicine) • Diagnosis of non-24 sleep-wake disorder ○ Requires at least 14 days of documentation of progressively shifting sleep-wake times with sleep diaries (may submit actigraphy if available) (submit documentation) • Member is completely blind with no light perception • No other concomitant sleep disorder (for example, sleep apnea, insomnia) • Member did not achieve increases in nighttime sleep or decreases in daytime sleep that resulted in a change of entrainment status after a 3 month continuous trial of melatonin or has a documented intolerance or contraindication to the use of melatonin therapy (recommended dose for non-24-hour sleep wake disorder is melatonin 5-10 mg once daily)	**Initial Approval:** 6 months **Renewals:** 1 year ***Requires:*** Attestation that circadian rhythms are entrained to normal 24-hour cycle **Quantity Level Limit:** 30 capsules every 30 days

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
High Dose Proton Pump Inhibitors (PPIs)[xxxviii] Preferred: • Esomeprazole 20 mg capsule OTC (over-the-counter) • Lansoprazole 15 mg capsule Rx and OTC (prescription and over-the-counter) • Lansoprazole 30 mg capsule Rx (prescription)	**High Dose Proton Pump Inhibitors (PPIs) will be authorized when the following criteria are met:** • Provider submits rationale for high dose (for example, member has unsatisfactory or partial response to once daily dosing, night-time symptoms, severe erosive esophagitis, stricture, Zollinger-Ellison) • Requests for high dose non-preferred Proton Pump Inhibitors (PPIs) require use of a preferred Proton Pump Inhibitor (PPI) at high dose	**Initial Approval:** • One year **Renewal:** • One year ***Requires:*** • Response to therapy • Rationale for continuing high dose and 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
• First-Lansoprazole Suspension 3mg/mL (for members 12 years and younger) • Omeprazole delayed release 20 mg tablet OTC (over-the-counter) • Omeprazole 10 mg, 20 mg, 40 mg capsule Rx (prescription) • Omeprazole magnesium		

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
20.6 mg capsule OTC (over-the-counter) • First-Omeprazole Suspension 2 mg/mL (for members 12 years and younger) • Pantopra-zole 20 mg and 40 mg tablets Rx (prescript-tion) • Rabeprazole 20 mg tablet		
HP Acthar[xxxix]	**Submission of appropriate medical records and clinical/chart notes is required.** **May be authorized when the following criteria has been met:**	**Initial Approval**: 1 month

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	Infantile Spasm: • Member is two years of age or under • Prescribed by or in consultation with neurologist or epileptologist • Diagnosis of Infantile Spasm (West syndrome) • Confirmation of diagnosis by an electroencephalogram • Documentation of current body surface area NOTE: All other indications have not been supported by clinical trials by the manufacturer and are considered experimental and investigational, and hence not medically necessary and will not be covered	**Renewal:** Treatment beyond 4 weeks for same episode is not recommended, and is not medically necessary, as prolonged use may lead to adrenal insufficiency or recurrent symptoms, which make it difficult to stop treatment **Dosing:** Infantile spasms: 150u/m^2 into twice daily doses of 75u/m^2
Hydroxyprogesterone caproate injection **Makena Auto-Injector** [xl]	**Approved when all the following criteria is met:** • Member is currently pregnant with singleton gestation • Prescribed by, or in consultation with provider of obstetrical care • Member has history of spontaneous preterm singleton delivery ○ For example, delivery of infant less than 37 weeks gestation	**Initial Approval:** Until 37 weeks gestation Injections start no earlier than 16 weeks 0 days and no later than 23 weeks 6 days **Subcutaneous**

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		Administration: Auto-Injector 275mg weekly **Intramuscular Administration:** Injection 250mg weekly
Idiopathic Pulmonary Fibrosis Agents[xli] Esbriet Ofev	**Documentation is required to support approval, when all the following criteria are met:** • Member is 18 years of age or older • Prescribed by, or in consultation with, a pulmonologist • Diagnosis of idiopathic pulmonary fibrosis (IPF) confirmed by one of the following: ○ High resolution computed tomography (HRCT) demonstrating usual interstitial pneumonia (UIP) ○ Surgical lung biopsy with usual interstitial pneumonia (UIP) • Forced vital capacity (FVC) greater than or equal to 50% predicted • Carbon Monoxide Diffusion Capacity (DLCO) greater than or equal to 30% • Baseline liver function tests (LFTs) prior to initiating treatment • Member is not a current smoker • Other known causes of interstitial lung disease have been ruled out (for example, domestic and occupational environmental exposures, connective tissue disease, or drug toxicity)	**Initial Approval:** 3 months **Renewal:** 6 months ***Requires:*** Documentation of all the following: • Stable Forced Vital Capacity (FVC) (recommend discontinuing if there is greater than 10% decline in Forced

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		Vital Capacity (FVC) over 12-month period) • Liver function tests (LFTs) are being monitored • Member is not a current smoker • Compliance and adherence to treatment **Quantity Level Limit:** Ofev: 2 caps per day Esbriet: 9 caps per day or 3 tabs per day
Imatinib[xlii] **(Gleevec)**	**General Criteria:** ○ Prescribed by or in consultation with an oncologist ○ Member is 18 years of age or older ○ Exceptions: pediatric members with newly diagnosed Philadelphia Chromosome	**Initial Approval:** **1 year** **Renewal Approval:**

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	Positive Acute Lymphoblastic Leukemia (Ph+ALL), who will receive imatinib in combination with chemotherapy, newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML), or Desmoid Tumors **In addition, Imatinib can be authorized for members who meet one of the following criteria:** • Adult and pediatric members with newly diagnosed chronic myeloid leukemia (CML) • Pediatric members with newly diagnosed Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) in combination with chemotherapy • Relapsed or refractory Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) • Myelodysplastic/Myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements, as determined by an Food and Drug Administration (FDA) approved test • Aggressive systemic mastocytosis (ASM) with one of the following: ○ Food and Drug Administration (FDA) approved test showing member is without D816V c-Kit mutation ○ Member's c-Kit mutational status is unknown • Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) • Unresectable, recurrent, or metastatic Dermatofibrosarcoma protuberans (DFSP) in adults • Kit-positive (CD117) unresectable and/or metastatic positive gastrointestinal stromal tumors (GIST) • Adjuvant treatment after complete gross resection of Kit-positive (CD117) gastrointestinal stromal tumors (GIST) • Bone cancer: Chordoma	**1 year** ***Requires:*** • Member does not show evidence of progressive disease while on therapy • Member does not have unacceptable toxicity from therapy

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Pigmented Villonodular Synovitis / Tenosynovial Giant Cell Tumor (PVNS/TGCT) • Steroid-Refractory Chronic Graft-Versus-Host Disease (GVHD) • Metastatic or Unresectable Melanoma as second-line therapy for tumors with activating mutations of c-Kit • Adults and adolescents 12 and older for aggressive fibromatosis (desmoid tumor) that is unresectable or not susceptible to radiotherapy • Post-transplant relapse for chronic myeloid leukemia (CML) if member has not failed imatinib prior to transplant • AIDS-Related Kaposi Sarcoma as subsequent systemic therapy for relapsed/refractory disease	
Immune Globulins	Gamunex-C, Gammagard, Gammagard SD, Gammaked, Flebogamma DIF, Asceniv, Bivigam, Cutaquig, Cuvitru, Gamastan, Gammaplex, Hizentra, Hyqvia, Octagam, Privigen, Panzyga, Xembify See detailed document: Aetna Better Health of California Pharmacy Guidelines	
Increlex[xliii]	**For Members that Meet the Following Criteria:** • Prescribed by or in consultation with a pediatric endocrinologist • Member is 2 years of age and not older than 19 years of age • Documentation showing member has no evidence of the following: ○ Epiphyseal closure	**Initial Approval:** 6 months **Renewal Approval:** • 6 months - If at least doubling of

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Active or suspected neoplasia • Documentation supporting one of the following diagnoses: ○ Growth hormone (GH) gene deletion with development of neutralizing antibodies to Growth hormone (GH) ○ Severe, Primary Insulin-like growth factor 1 (IGF-1) deficiency ▪ Height standard deviation score less than or equal to -3 ▪ Basal Insulin-like growth factor 1 (IGF-1) standard deviation score less than or equal to -3 ▪ Normal or elevated growth hormone levels (greater than 10ng/mL on standard growth hormone stimulation tests) • Member shows no evidence of secondary forms of Insulin-like growth factor 1 (IGF-1) deficiency, such as growth hormone deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of corticosteroids • Increlex will not be approved as a substitute to growth hormone for growth hormone indications	pretreatment growth velocity • 1 year - If growth velocity is greater than or equal to 2.5 cm/yr ***Requires:*** • Documentation of growth charts • Epiphyses are open (confirmation of open growth plates in members 10 years of age or older) • Member has no active or suspected neoplasia • Member is not on concurrent growth hormone therapy **Quantity Limit:** 0.24

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		mg/kg/day
Injectable Osteoporosis Agents	Forteo, Prolia, Zoledronic acid, Tymlos and Evenity **See Detailed document:** Aetna Better Health of California Pharmacy Guidelines	
Inlyta (axitinib)[xliv]	**General Criteria:** ○ Prescribed by or in consultation with an oncologist ○ Member is 18 years of age or older **In addition, Inlyta may be authorized when one of the following criteria is met:** ○ Advanced renal cell carcinoma (RCC) meets one of the following: ○ Member has renal cell carcinoma (RCC) with clear cell histology ○ Member has renal cell carcinoma (RCC) with non-clear cell histology AND ▪ There was a trial and failure with Sutent (sutinib), Cometriq (cabozantinib), or Afinitor (everolimus) ○ Differentiated thyroid carcinoma (for example, papillary, follicular, and Hürthle cell) meets all the following: ○ Unresectable recurrent, persistent locoregional, or distant metastatic disease ○ Progressive and/or symptomatic iodine-refractory disease ○ Nexavar (sorafenib) and Lenvima (lenvatinib) are not available or are not clinically appropriate	**Initial Approval:** 1 year **Renewal Approval:** 3 years ***Requires:*** Member has been on Inlyta and does not show evidence of progressive disease while on therapy **Quantity Level Limit:** 20mg/day
Interleukin 5	**May be authorized for the treatment of severe eosinophilic asthma when the following are**	**Initial Approval:**

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
(IL-5) Antagonists[xlv] Nucala Cinqair Fasenra	**met:** • Member is at least: ○ 12 years old (Nucala, Fasenra) ○ 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: ○ Greater than or equal to 150 cells/mcL within 6 weeks of dosing (Nucala, Fasenra) ○ Greater than or equal to 300 cells/mcL at any time in the past 12 months (Nucala, Fasenra) ○ Greater than or equal to 400 cells/mcL at baseline (Cinqair) • Member has been compliant with one of the following regimens for at least 3 months: ○ Medium or high dose inhaled corticosteroids (ICS) plus long-acting beta agonist (LABA) ○ Other controller medications (for example, Leukotriene receptor antagonists (LTRA), or theophylline) if intolerant to a long-acting beta agonist (LABA) • Asthma symptoms are poorly controlled on one of the above regimens as defined by any of the following: ○ At least two exacerbations in the last 12 months requiring additional medical treatment (systemic corticosteroids, emergency department visits, or hospitalization) ○ Daily use of rescue medications (short-acting inhaled beta-2 agonists) ○ Nighttime symptoms occurring more than once a week • Members with history of exacerbations must have an adequate 2-month compliant trial of	6 months **<u>Renewal for Severe Eosinophilic Asthma:</u>** 1 year ***Requires:*** • Demonstration of clinical improvement (for example, decreased use of rescue medications, or systemic corticosteroids, reduction in number of emergency department visits, or hospitalizations) • Compliance with asthma controller medications **Dosing for Severe Eosinophilic Asthma:**

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	tiotropium (requires prior authorization (PA)). • Member will not receive in combination with Xolair or another Interleukin-5 (IL-5) inhibitor **Criteria for Eosinophilic Granulomatosis with Polyangiitis (EGPA): (Nucala Only)** • Member is at least 18 years old • Prescribed by, or after consultation with a pulmonologist or allergist/immunologist • Diagnosis is for at least 6 months, with history of relapsing or refractory disease • Member has been on stable dose of oral prednisolone or prednisone greater than or equal to 7.5 mg/day but less than or equal to 50 mg/day for at least 4 weeks. • Member has a Five Factor Score (FFS) of less than 2. • Member had a trial and failure, or contraindication to cyclophosphamide. **Note: Not covered for treatment of other eosinophilic conditions or relief of acute bronchospasm or status asthmaticus**	Nucala: 100mg every 4 weeks Cinqair: 3mg/kg every 4 weeks Fasenra: 30mg every 4 weeks for first 3 doses, then once every 8 weeks **Renewal for Eosinophilic Granulomatosis with Polyangiitis (EGPA):** 1 year ***Requires:*** • Member response to treatment • Tapering of oral corticosteroid dose **Dosing for Eosinophilic Granulomatosis with Polyangiitis (EGPA):**

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		Nucala: 300mg every 4 weeks as 3 separate 100mg injections
Insulin Pens[xlvi] **Formulary** **Rapid Acting**: Admelog Admelog Solostar **Rapid Acting:** Apidra Solostar Humalog KwikPen Novolog FlexPen Admelog Solostar Fiasp FlexTouch **Short Acting:** Humulin R KwikPen	**General criteria for all members:** • Diagnosis of Type I or Type II Diabetes Mellitus **(For Plans with age restriction on formulary pens)** • Documentation to support member meets one of the following: ○ A school-aged child requiring multiple daily injections ○ Visual impairment ○ Physical disability or dexterity problems and unable to draw up syringe ○ Environmental factors which prevent use of vial formulation **OR** • Documentation to support inadequate response, intolerable side effects, or contraindication to two formulary insulins within the same class (for example, rapid, regular, or basal) **Toujeo Solostar and Toujeo Max Solostar only:** • Documentation to support inadequate (three 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** Documentation to support required units of basal insulin exceeds 100 units/day	**Initial Approval:** 1 year **Renewal:** 1 year

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Intermediate Acting: Humulin N KwikPen Humulin 70/30 KwikPen **Basal Insulin:** Basaglar KwikPen Lantus Solostar Levemir Flextouch Toujeo Solostar Toujeo Max Solostar Tresiba FlexTouch		
Interferons[xlvii] ***α-Interferon*** Alferon N Intron A	**Chronic Hepatitis B** *(Intron A, Pegasys)* • Prescribed by, or in consultation with, an Infectious Disease physician, Gastroenterologist, Hepatologist, or Transplant physician • Diagnosis of Chronic Hepatitis B	**Initial Approval:** ***Hepatitis B*** Intron A • Adults: 16 weeks • Children: 24 weeks

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Pegasys ***γ-Interferon*** Actimmune	• Current lab results to support one of the following: ○ Documentation of Alanine Aminotransferase (ALT) greater than or equal to 2 times the Upper Limit of Normal (ULN) ○ Significant histologic disease and documentation of elevated Hepatitis B Virus Deoxyribonucleic Acid (DNA) level above 2,000 IU/mL (Hepatitis B e-antigen (HBe-Ag negative)) or above 20,000 IU/mL (HBe-Ag positive) • Compensated Liver disease • Age restriction for *Pegasys* ○ Pediatrics: 3 years of age or older, non-cirrhotic and Hepatitis B e-antigen (HBe-Ag) positive ○ Adults: 18 years of age or older • Age restriction for *Intron A*: ○ 1 year of age or older **Follicular Non-Hodgkin's Lymphoma (Stage III/IV)** (Intron A) • Member is 18 years of age or older • Prescribed by, or in consultation with Hematologist/Oncologist • Given in conjunction with anthracycline-containing combination chemotherapy **Acquired Immune Deficiency Syndrome (AIDS)-related Kaposi's sarcoma** *(Intron A [powder for solution ONLY])* • Member is 18 years of age or older • Prescribed by, or in consultation with Infectious Disease physician, or Human Immunodeficiency Virus specialist	Pegasys ○ 48 weeks ***Osteopetrosis*** ○ 12 months ***Chronic Granulomatous Disease*** ○ 12 months ***Hairy-cell Leukemia*** ○ 6 months ***Kaposi's sarcoma*** ○ 16 weeks ***Follicular Non-Hodgkin's Lymphoma (Stage III/IV)*** ○ 6 months ***Condylomata Acuminate*** Intron A

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	Hairy-cell Leukemia *(Intron A)* • Member is 18 years of age or older • Prescribed by, or in consultation with Hematologist/Oncologist • Member meets one of the following: ○ Demonstrated less than a complete response to cladribine or pentostatin ○ Relapsed after less than 2 years of demonstrating a complete response to cladribine or pentostatin **Chronic Granulomatous Disease** *(Actimmune)* • Member is one year of age or older • Prescribed by, or in consultation with Immunologist, or Infectious Disease specialist **Malignant Osteopetrosis** *(Actimmune)* • For treatment of severe, malignant Osteopetrosis • Prescribed by, or in consultation with Hematologist, or Endocrinologist **Condylomata acuminata – genital or venereal warts** *(Intron A, Alferon N)* • Member is 18 years of age or older • For intra-lesional use • Lesions are small and limited in number • Trial and failure of topical treatments or surgical technique (for example, imiquimod cream, podofilox, cryotherapy, laser surgery, electrodessication, surgical excision)	○ 3 weeks Alferon N ○ 8 weeks **Renewal Approval:** ***Hepatitis B*** Intron A ○ Additional 16 weeks if still Hepatitis B e-antigen (HBe-Ag)-positive ○ Indefinite for Hepatitis B e-antigen (HBe-Ag)-negative ***Chronic Granulomatous Disease*** • 12 months, if no evidence of disease progression ***Osteopetrosis*** • 12 months, if no evidence of disease progression ***Condylomata***

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		acuminate Intron A • 3 weeks ○ Treatment is administered at week 12 to week 16 Alferon N • 8 weeks ○ There is at least 3 months between treatments unless lesions grow, or new lesions appear ***All other indications*** • 12 months • For Hairy-Cell Leukemia it is not recommended to continue if disease has progressed

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Intravaginal Progesterone Products[xlviii] Crinone First-progesterone suppositories	**Crinone 8% Gel and First-Progesterone are Approved when ALL the following criteria are met:** • Prescribed by, or in consultation with, a provider of obstetrical care • Member is not on Makena (17-hydroxyprogesterone) • Member is pregnant with singleton gestation and meets either of the following: ○ History of spontaneous preterm birth (delivery of an infant less than 34 weeks gestation) ○ Cervical length less than 25 mm before 24 weeks of gestation **Crinone is approved for the treatment of secondary amenorrhea when ALL the following criteria are met:** • Prescribed by, or in consultation with a provider of obstetrical care • Member has had an inadequate response, or intolerable side effects to, progesterone capsules • Crinone 8% Gel can be approved for use when 4% gel has been tried and failed	**Initial Approval:** Approve as requested until 35 weeks gestation Begin progesterone use no earlier than 16 weeks, 0 days and no later than 23 weeks, 6 days Crinone 4% and 8%: For the treatment of amenorrhea: up to a total of 6 doses Requests for additional quantities will require review Progesterone products will not be covered for uses related to infertility
Janus	**General Authorization Guideline for All Indications:**	**Initial Approval:**

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Associated Kinase Inhibitors[xlix] Inrebic Jakafi	• Prescribed by, or in consultation with hematologist/oncologist • Member has been screened for tuberculosis ○ If screening was positive for latent tuberculosis, member has received treatment for latent tuberculosis prior to initiating therapy • There is no evidence showing member has a serious current active infection **Additional Criteria Based on Indication:** **Myelofibrosis:** • Member is at least 18 years of age • Baseline platelet count is at least 50 X 10^9/L • Diagnosis is primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis • Intermediate or high-risk disease is defined as having two or more of the following risk factors: ○ Age greater than 65 years ○ Constitutional symptoms (weight loss greater than 10% from baseline and/or unexplained fever, or excessive sweats persisting for more than 1 month) ○ Hemoglobin less than 10g/dL ○ White Blood Cell count greater than or equal to 25 x 10^9/L ○ Peripheral Blood blasts greater than 1% ○ Platelet count less than 100 X 10^9/L ○ Red Cell Transfusion ○ Unfavorable karyotype [for example, complex karyotype, or sole, or two abnormalities	6 months **Renewal:** 1 year ***Requires:*** **For Myelofibrosis:** • Spleen size reduction of greater than or equal to 35% OR • Symptom improvement (greater than or equal to 50% reduction in total symptom score from baseline) OR • Absence of disease progression • Additional criteria for Inrebic includes documentation that liver function tests, and thiamine levels

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	that include trisomy 8, 7/7q-, i(17q), inv(3), 5/5q-, 12p- or 11q23 rearrangement] • Additionally, for Inrebic: ○ Member had a trial and failure, or intolerance with Jakafi ○ Documentation showing no signs of severe hepatic impairment (baseline total bilirubin level greater than 3-times the upper limit of normal) ○ Documentation of serum thiamine levels taken at baseline and periodically during therapy to avoid Wernicke's encephalopathy NOTE: Inrebic is only indicated for Myelofibrosis **Polycythemia Vera** • Member is at least 18 years of age • Inadequate response or intolerance to hydroxyurea • Diagnosis of Polycythemia vera required by meeting all 3 major criterions, or the first 2 major criterions plus minor criterion below: Major Criteria ○ Hemoglobin greater than 16.5 g/dL in men, greater than 16.0 g/dL in women OR Hematocrit greater than 49% in men, greater than 48% in women OR Increased red cell mass ○ Bone marrow biopsy showing hypercellularity for age with trilineage growth (panmyelosis), including prominent erythroid, granulocytic, and megakaryocytic proliferation with pleomorphic, mature megakaryocytes (differences in size) ○ Presence of Janus Kinase 2 (JAK2) V617F mutation, or Janus Kinase 2 (JAK2) exon	are being monitored periodically during therapy **For Polycythemia Vera:** • Hematologic improvement (decreased hematocrit, platelet count or white blood cell count) OR • Reduction in palpable spleen length OR • Improvement in symptoms (for example, pruritus, night sweats, bone pain) **For Acute Graft-Versus-Host Disease:** • Response to treatment OR • Symptoms are

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	12 mutation Minor criterion ○ Subnormal serum erythropoietin level **Acute Graft-Versus-Host Disease:** • Member is at least 12 years of age • There was Inadequate response to steroids after an allogenic hematopoietic stem cell transplant • Diagnosis of grade 2 to 4 disease, based on Mount Sinai Acute GVHD International Consortium (MAGIC) criteria	recurring during or after taper, and retreatment is needed
Jardiance[l]	Jardiance is approved when the following criteria is met: • Member has an estimated glomerular filtration rate (eGFR) of greater than or equal to 45mL/min/1.73m^2 and one of the following: ○ Trial and failure of Steglatro or Segluromet ○ Diagnosis of Diabetes Mellitus Type 2 with established cardiac disease	**Initial Approval:** 1 year **Renewal:** 1 year
Juxtapid[li]	**Medical Records Required with Requests** **May be authorized when all the following criteria are met:** • Member is 18 years of age or older • Prescribed by, or in consultation with Cardiologist, Endocrinologist, or Lipid Specialist • Females of reproductive potential have a negative pregnancy test prior to starting treatment • Used as an adjunct to a low-fat diet and exercise	**Initial Approval:** **3 months** **Renewal Approval:** **6 months** ***Requires:*** • Member is continuing a low-fat diet and

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Diagnosis of homozygous familial hypercholesterolemia (HoFH) as evidenced by one of the following: ○ Genetic confirmation of 2 mutant alleles at the Low-Density Lipoprotein Receptor (LDLR), Apolipoprotein B100 (APO-B100), or Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) ○ History of untreated Low-Density Lipoprotein (LDL) greater than 500 mg/dL, or treated Low-Density Lipoprotein (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 years ▪ Heterozygous familial hypercholesterolemia (HeFH) in both parents • Current lipid panel/Low-Density Lipoprotein (LDL) from past 90 days • Member had a failure or contraindication to a 90-day trial of a Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitor (for example, Repatha or Praluent) • Attestation to the following: ○ Member does not have significant hepatic impairment (Child-Pugh B or C) ○ Will be used in conjunction with other lipid lowering therapies such as statins, ezetimibe, bile acid sequestrants, or Low-Density Lipoprotein (LDL) apheresis	exercise regimen • Current lipid Panel within the past 90 days showing Low-Density Lipoprotein (LDL) reduction from baseline • Claims history to support compliance or adherence to Juxtapid and adjunctive lipid lowering therapies • Prescriber attestation of monitoring liver related tests, and dosing adjusted according to prescribing information • Females of reproductive potential are

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		currently using contraception **Quantity Level Limits:** • Juxtapid: 1 tablet per day
Korlym[lii]	• Member is 18 years of age or older • Documentation (submit chart notes) that diagnosis is of endogenous Cushing syndrome with all the following: ○ Uncontrolled hyperglycemia due to glucose intolerance or type 2 diabetes mellitus ○ Member failed surgery or is not a candidate for surgery ○ There was failure to achieve adequate glycemic control despite individualized diabetic management • Prescribed by or in consultation with endocrinologist • Baseline labs for hemoglobin A1c (HbA1c) • Prescriber attestation to all the following: ○ Female members of childbearing potential are not pregnant ○ Female members do not have history of unexplained vaginal bleeding, endometrial hyperplasia with atypia, or endometrial carcinoma ○ Member does not require concurrent long-term corticosteroid use for serious medical conditions or illnesses (for example immunosuppression after organ transplant) • Other accepted and approved indications for mifepristone are not covered using the Korlym product	**Initial Approval:** 6 months **Renewal Approval:** 12 months ***Requires:*** • Documentation of improved glycemic control as evidenced by Hemoglobin A1c (HbA1c) labs lower than baseline • Female members of childbearing potential are currently using non-hormonal contraception

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		Quantity Level Limit: • Maximum dose 1200 mg per day
Lidocaine 5% Ointment[liii]	• **Approvable when one of the following criteria is met:** o Diagnosis is for one of the following: ▪ Production of anesthesia of accessible mucous membranes of oropharynx ▪ Anesthetic lubricant for intubation o There was inadequate response, intolerable side effects, or contraindication to *lidocaine 4% cream*, and use is for one of the following: ▪ For temporary relief of pain associated with minor burns, including sunburn, abrasions of skin, and insect bites ▪ For FDA-approved or compendia-supported diagnosis	**Approval:** 3 months **Quantity Level Limit**: 50 grams per 30 days
Lidocaine Topical Patch Lidocaine 5% Patch[liv] ZTLido 1.8% Patch	**Lidocaine 5% Patch or ZTLido 1.8% Patch may be authorized for:** • Member that is 18 years of age or older • Diagnosis is for post herpetic neuralgia • Documentation or Pharmacy claims history supporting trial and failure with topical lidocaine 4% patch • Documentation or Pharmacy claims history supporting trial and failure, or intolerance, to two oral formulary alternatives o For example, gabapentin, tricyclic antidepressants • For ZTLido: • Documentation or Pharmacy claims history to support trial and intolerance, or	**Initial Approval:** 3 months **Renewal Approval:** 12 months **Quantity Level Limit**: 90 patches per 30 days

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	contraindication to Lidocaine 5% patch **Lidocaine 5% Patch may be authorized for:** • Member that is 18 years of age or older • Diagnosis of diabetic peripheral neuropathy • Documentation of Pharmacy claims history supporting trial and failure with topical lidocaine 4% patch • Documentation or Pharmacy claims history supporting trial and failure, or intolerance to two oral formulary alternatives ○ For example, duloxetine, venlafaxine, gabapentin, tricyclic antidepressants Documentation or Pharmacy claims history supporting therapy with a diabetic medication	
linezolid [lv]	The requested drug will be covered with prior authorization when the following criteria are met: • The patient is being converted from intravenous (IV) linezolid (Zyvox) as prescribed or directed by an Infectious Disease specialist for a NON-Tuberculosis (TB) bacterial infection **OR** • The patient has any of the following: A) an infection caused by vancomycin-resistant Enterococcus faecium including cases with concurrent bacteremia, B) a nosocomial (institution-acquired) pneumonia caused by Staphylococcus aureus (methicillin-susceptible and -resistant isolates) or Streptococcus pneumoniae, C) community-acquired pneumonia caused by Streptococcus pneumoniae, including cases with concurrent bacteremia, or Staphylococcus aureus (methicillin-susceptible isolates only), D) a complicated skin and skin structure infection including diabetic foot infections, without concomitant osteomyelitis, caused by Staphylococcus aureus	**Approval Duration**: Requests for pulmonary extensively drug resistant (XDR) or treatment-intolerant/ nonresponsive multidrug-resistant (MDR) tuberculosis AND as part of a combination regimen with Pretomanid and Sirturo (bedaquiline): 12 months

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	(methicillin-susceptible and -resistant isolates), Streptococcus pyogenes, or Streptococcus agalactiae, E) an uncomplicated skin and skin structure infection caused by Staphylococcus aureus (methicillin-susceptible isolates only) or Streptococcus pyogenes **AND** • The infection is proven or strongly suspected to be caused by susceptible bacteria **AND** • The patient has experienced an inadequate treatment response, intolerance, or contraindication to alternative therapies OR the bacteria are NOT susceptible to any other antibiotics **OR** • The requested drug is being prescribed for pulmonary extensively drug resistant (XDR) or treatment-intolerant/ nonresponsive multidrug-resistant (MDR) tuberculosis **AND** • The requested drug is being prescribed as part of a combination regimen with Pretomanid and Sirturo (bedaquiline)	All other approvable requests: 28 days
Lucemyra[lvi] (lofexidine)	**May be authorized when the following criteria are met:** • Member is 18 years of age or older • Symptoms of opioid withdrawal are experienced due to abrupt opioid discontinuation • Opioids have been discontinued • Member meets one of the following criteria: ○ Trial and failure, or contraindication to clonidine, or member has a clinically significant	**Initial Approval**: 14 days per episode of treatment (224 total tablets) **Dosing**:

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	adverse effect ○ Medication was initiated in an inpatient setting • Member is on a behavioral modification plan for substance abuse counseling (psychosocial support) • Member is not currently taking benzodiazepines, alcohol, barbiturates, or other sedating agents	Three 0.18 mg tablets taken orally four times daily for 7 days Approvable for a maximum of 224 tablets per 14-day supply for a 1-month period **Quantity Level Limit (QLL)**: Maximum dose 0.72 mg/dose (4 tablets) or 2.88 mg/day (16 tablets per day) or 224 tablets
Lyrica CR and Pregabalin[lvii]	**Lyrica CR is approved only for post-herpetic neuralgia and diabetic peripheral neuropathy. Requests may be authorized when a member has tried and failed the immediate-release formulation and the criteria below have been met** **Authorization criteria for Partial Onset Seizures:** • Documentation of weight for members between 1 month to 16 years of age **Authorization Criteria for Neuropathic Pain Associated with Spinal Cord Injury (SCI):** • Member is 18 years of age or older	**Initial Approval:** 4 months **Renewal:** 12 months ***Requires:*** Positive response to

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Member had inadequate treatment response, intolerance or contraindication to gabapentin **Authorization Criteria for Post-Herpetic Neuralgia:** • Member is 18 years of age or older • Member had inadequate treatment response, intolerance or contraindication to gabapentin **Authorization Criteria for Cancer Related Neuropathic Pain:** • Member is 18 years of age or older • Member had inadequate treatment response, intolerance or contraindication to two of the following: ○ gabapentin ○ tricyclic antidepressants ○ venlafaxine ○ duloxetine **Authorization Criteria for Fibromyalgia:** • Member is 18 years of age or older • Member had inadequate treatment response, intolerance or contraindication to a tricyclic antidepressant and one other formulary agent: ○ Duloxetine or gabapentin **Authorization Criteria for Diabetic Peripheral Neuropathy:** • Member is 18 years of age or older • Member had inadequate treatment response, intolerance or contraindication to duloxetine and one other formulary agent used for neuropathy:	therapy **<u>Quantity Level Limits:</u>** Immediate-release: 3 capsules/day (approvals for titrations outside this range will be limited to 2 - 3 months) Solution: 600mg/day Extended-release: • 82.5mg & 165mg tablets – 3/day • 330mg tablet – 2/day

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ tricyclic antidepressants ○ venlafaxine ○ gabapentin	
Monoamine Depletors[lviii] Ingrezza Austedo Tetrabenazine	**Medical Records required for all Indications** **Tardive Dyskinesia (Ingrezza, Austedo)** • Member is 18 years of age or older • Diagnosis of moderate to severe tardive dyskinesia • Prescribed by, or in consultation with a neurologist or psychiatrist • Abnormal Involuntary Movement Scale (AIMS) score greater than or equal to 6 • Provider has attempted an alternative method to manage condition ○ For example, dose reduction, discontinuation of offending medication, or switching to alterative agent such as atypical antipsychotic ▪ Documentation of atypical antipsychotic used ▪ Time frame of stability on the atypical antipsychotic **Additional Criteria for Austedo:** • Member does not have any of the following: ○ Hepatic dysfunction ○ Active suicidal thoughts or behaviors ○ Untreated or undertreated depression ○ Congenital long QT syndrome, or arrhythmias associated with a prolonged QT interval **Additional Criteria for Ingrezza:**	**Initial Approval:** 3 months **Renewal Approval:** 6 months **Tardive Dyskinesia *Requires:*** • Documentation of improvement in AIMS score (decrease from baseline by at least 2 points). • Provider is monitoring for all the following: ○ Emergent or worsening depression ○ Suicidal thoughts and behaviors

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Member does not have any of the following: ○ Active Suicidal thoughts and behaviors ○ Untreated or undertreated depression ○ Congenital long QT syndrome, or arrhythmias associated with a prolonged QT interval **Huntington's Chorea (Austedo, Tetrabenazine)** • Member is 18 years of age or older. • Diagnosis is confirmed by neurologist consult and genetic testing • Unified Huntington's Disease Rating Scale (UHDRS), total maximal chorea score of 8 or greater • Member had inadequate response, or intolerable side effects to amantadine • Member does not have any of the following: ○ Hepatic dysfunction ○ Active suicidal thoughts or behaviors ○ Untreated or undertreated depression ○ Congenital long QT syndrome, or arrhythmias associated with a prolonged QT interval	○ EKG, for members at risk for QT prolongation ○ Hepatic dysfunction (for Austedo only) **Huntington's Chorea *Requires:*** • Documentation of improvement in Total Maximal Chorea score (3 points or greater) from baseline • Provider is monitoring all the following: ○ Emergent or worsening depression ○ Suicidal thoughts and behaviors

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		○ EKG, for members at risk for QT prolongation ○ Hepatic dysfunction **<u>Quantity Level Limits:</u>** • Ingrezza 30/30 • Austedo 120/30 • Tetrabenazine 120/30
Multaq[lix]	**Multaq may be authorized when the following criteria are met:** • Member is 18 years of age or older • Diagnosis of paroxysmal or persistent atrial fibrillation and ○ Member is currently in normal sinus rhythm, or ○ Member plans to undergo cardioversion to normal sinus rhythm • Prescribed by, or in consultation with a cardiologist • Attestation member does not have any contraindications as outlined per the prescribing information including, but not limited to the following: ○ Symptomatic heart failure with recent decompensation requiring hospitalization ○ New York Heart Association (NYHA) Class IV chronic heart failure • Member had inadequate response, intolerable side effect, or contraindication to one of the	**<u>Initial Approval</u>:** 3 months **<u>Renewal Approval</u>:** 6 months ***Requires:*** • Attestation that member has positive response to treatment

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	following formulary alternatives: ○ amiodarone ○ propafenone ○ flecainide ○ sotalol	• Monitoring of electrocardiogram (ECG) every 3 months to make sure atrial fibrillation (AF) has not become permanent **Quantity Level Limits:** 60/30 days
Multiple Sclerosis	Copaxone, Glatiramer acetate, Glatopa, Rebif/Rebidose, Extavia, Avonex, Betaseron, Aubagio, Plegridy, Tecfidera, Gilenya, Mayzent, Mavenclad, Mitoxantrone, Tysabri, Lemtrada, Ocrevus, Vumerity https://www.aetnabetterhealth.com/california/providers/pharmacy/prior-auth	

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Nexavar (sorafenib)[lx]	**General Criteria:** ○ Prescribed by or in consultation with an oncologist ○ Member is 18 years of age or older **In addition, Nexavar may be authorized when one of the following criteria are met:** • Advanced renal cell carcinoma (RCC) with clear cell histology: ○ Trial of a preferred first-line Tyrosine Kinase Inhibitor (such as Sutent (sunitinib), Votrient (pazopanib)) ▪ **Note:** Sorafenib is no longer recommended for Non-Clear Cell Renal Cell Carcinoma • Hepatocellular carcinoma ○ Disease is metastatic or member is otherwise not eligible for transplant • Treatment of differentiated thyroid carcinoma (for example, papillary, follicular, and Hürthle cell), that is refractory to radioactive iodine treatment • Metastatic medullary thyroid carcinoma (MTC) that is persistent or recurrent: ○ Member has symptomatic or progressive disease ○ Trial of Caprelsa (vandetanib) or Cometriq (cabozantinib) • Bone Cancer ○ Recurrent Chordoma ▪ Trial of Gleevec (imatinib), Sutent (sunitinib), or Sprycel (dasatinib) ○ Osteosarcoma, dedifferentiated chondrosarcoma, or high-grade Undifferentiated Pleomorphic Sarcoma (UPS) ▪ Member has relapsed/refractory or metastatic disease ▪ Trial of a first-line regimen containing cisplatin and doxorubicin	**Initial Approval:** 1 year **Renewal Approval**: 3 years ***Requires*** • Member does not show evidence of progressive disease while on therapy • Member does not have unacceptable toxicity from therapy

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Angiosarcoma • Advanced or unresectable desmoid tumors (aggressive fibromatosis) • Gastrointestinal stromal tumor (GIST) ○ Disease progression occurred while on Gleevec (imatinib), Sutent (sunitinib), or Stivarga (regorafenib) • Solitary fibrous tumor/hemangiopericytoma • Relapsed or refractory acute myeloid leukemia (AML) ○ Nexavar will be used in combination with Vidaza (azacitidine) or Dacogen (decitabine) ○ Member has *FLT3*-ITD mutation positive	
Non-Stimulant Attention Deficit Hyperactivity Disorder (ADHD) Medications[lxi] **Preferred**: Guanfacine ER **Non-Preferred**: Atomoxetine Clonidine ER	Intuniv (guanfacine ER), Kapvay (clonidine ER) and atomoxetine (Strattera) are all indicated for the treatment of attention deficit/hyperactivity disorder (ADHD). Intuniv and Kapvay were studied in pediatric patients (6-17 years). Atomoxetine (Strattera) was studied in both pediatric and adult patients (≥ 6 years). Intuniv and Kapvay may be used as an adjunctive therapy to stimulant medications but should not be used together. **Member must meet ALL following criteria for approval:** • Diagnosis of attention deficit/hyperactivity disorder/attention deficit disorder (ADHD/ADD) • If request is for Clonidine ER, member must meet ALL the following: ○ Member is 6 to 17 years of age ○ Inadequate response, intolerable side effect, or contraindication to guanfacine ER (Intuniv)	**Initial Approval:** 1 year **Renewal Approval:** 1 year ***Requires:*** Response to therapy

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• If request is for atomoxetine: ○ Member is 6 years of age or older ○ Member must meet one of the following: ▪ Inadequate response, intolerable side effect or contraindication to formulary extended-release amphetamine agent AND formulary extended-release methylphenidate agent ▪ Member is a poor candidate for stimulants (for example, member or a household member has history of drug abuse, tic disorder, cardiovascular issues) ○ If member is less than 18 years of age: Inadequate response, intolerable side effect, or contraindication to guanfacine ER **Children age 5 and under:** • Guanfacine ER, clonidine ER, and atomoxetine 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 first line treatment.	
Nuedexta[lxii]	**May be authorized when all of the following criteria are met:** • Member is 18 years of age or older • Medication is prescribed by, or in consultation with, a specialist (for example, a psychiatrist, psychologist, neuropsychologist, or neurologist)	**Initial Approval:** 3 months **Renewal:** 1 year

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Diagnosis of pseudobulbar affect (PBA) • Documentation that member has at least one underlying neurologic condition associated with pseudobulbar affect (PBA) • Member has had a cognitive assessment to evaluate for the presence of pseudobulbar affect (PBA) (for example, Center for Neurologic Study-Lability Scale (CNS-LS) greater than or equal to 13 or The Pathological Laughter and Crying Scale (PLACS) greater than or equal to 13) • Member does not have any contraindications to therapy (for example, QT prolongation, Atrioventricular (AV) block, or monoamine oxidase inhibitor (MAOI) therapy in the previous 14 days) • Member has tried and failed selective serotonin reuptake inhibitors (SSRIs) or tricyclic antidepressants (TCAs) • Dose adjustments to desipramine, paroxetine, and digoxin will be made if co-administered with Nuedexta	***Requires***: Decreased frequency of pseudobulbar affect (PBA) episodes **Quantity Level Limit:** 2 capsules per day
Ondansetron Oral Solution[lxiii]	**Ondansetron Oral Solution will pay at the point of sale (without requiring prior authorization) when the following criteria is met:** • Member is 3 years of age or younger **Prescriptions that do not pay at the point of sale require prior authorization and may be authorized for members who meet one of the following:** • Member is 3 years of age or younger • Trial of ondansetron tablet or ondansetron orally disintegrating tablet (ODT)	**Initial Approval:** One year **Renewals:** One year
Onychomycosi	**May be authorized when all the following criteria is met:**	**Initial and Renewal**

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
s[lxiv] Jublia Kerydin	• For Jublia ○ Member is 18 years of age or older • For Kerydin ○ Member is 6 years of age or older • Diagnosis of onychomycosis of toenail is due to one of the following organisms: ○ *Trichophyton rubrum* ○ *Trichophyton mentagrophytes* • Attest to confirmation of onychomycosis of toenail with one of the following tests: ○ Positive potassium hydroxide preparation test ○ Positive fungal culture ○ Nail biopsy • Member had trial and failure, or contraindication, with two formulary antifungal agents (for example, itraconazole, oral terbinafine, or ciclopirox) • Treatment is due to one of the following medical conditions: • Diabetes Mellitus • Human Immunodeficiency Virus • Immunosuppressed members • Peripheral Vascular Disease • Pain caused by onychomycosis Not approved for cosmetic use	**Approvals:** 48 weeks **Quantity Level Limit:** • Jublia - 8mL per month • Kerydin - 10mL per month
Opioid Guideline	**See detailed document:** Aetna Better Health of California Pharmacy Guidelines	

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Oral Liquids **Antidepressants:** Citalopram Solution 10mg/5ml Escitalopram Solution 5mg/5ml Nortriptyline Solution 10mg/5ml Sertraline Solution 20mg/5ml **Antivirals:** Acyclovir Suspension 200/5ml Tamiflu/	An oral liquid may be authorized for members over 12 years of age when the following criteria is met: • Medical necessity of an oral liquid due to an inability to use an oral solid dosage form (medical necessity includes but not limited to dysphagia, ulcers, stomatitis, feeding tube)	

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Oseltamivir Suspension 6mg/ml **Corticosteroids:** Prednisone Solution 5mg/5ml **Ulcer Drugs:** Carafate Suspension 1gm/10ml Dicyclomine Solution 10mg/5ml Famotidine Suspension 40mg/5ml First-Lansoprazole Suspension		

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
3mg/ml First-Omeprazole Suspension 2mg/ml **Urinary Anti-infective:** Nitrofurantoin Suspension 25mg/5ml		
Otezla[lxv]	**Psoriatic Arthritis** **Member must meet all the following criteria:** • Diagnosis of moderate to severe Psoriatic Arthritis • Age is 18 years or older • Prescribed by or in consultation with a Rheumatologist • Documentation of active Psoriatic Arthritis with a three months trial of one of the following: ○ Methotrexate (leflunomide or sulfasalazine, if methotrexate is contraindicated) ○ Anti-tumor necrosis factor antagonists such as Humira or Enbrel. **Plaque Psoriasis** **Member must meet all the following criteria:** • Diagnosis of moderate to severe Plaque Psoriasis • Age is 18 years or older	**Initial Approval:** 4 months **Renewal Approval:** 12 months ***Requires:*** Response to treatment **Quantity Level Limit:** 60 tablets per 30 days after initial 5-day titration

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Prescribed by or in consultation with a dermatologist • Documentation to support an adequate 3-month trial and failure, or intolerance with methotrexate or cyclosporine, or there is a true contraindication to both. • Attestation to one of the following: ○ More than 10% of body surface area affected ○ Less than 10% body surface area affected, but involves sensitive areas (for example: hands, feet, face or genitals) that interferes with daily activities ○ Psoriasis Area and Severity Index score of more than 10 • Trial and failure for 2 months with phototherapy ○ PUVA (psoralen ultraviolet type A), UVB (ultraviolet type B) **Oral Ulcers Associated with Behçet's Disease** **Member must meet all the following criteria:** • Diagnosis of Behçet's disease with active recurrent oral ulcers • Age is 18 years or older • Prescribed by or in consultation with a rheumatologist, dermatologist, or another specialist • Documentation of previous trial and failure with at least one Non-Biologic Disease-Modifying Anti-Rheumatic Drug such as methotrexate, leflunomide, sulfasalazine or hydroxychloroquine	
Oxbryta[lxvi]	**May be authorized with documentation of all the following:** • Diagnosis of sickle cell disease • Member is 12 years of age or older	**Initial approval**: 6 months

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Prescribed by or in consultation with a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease • Failure of a 3-month trial of hydroxyurea or clinical rationale as to why it cannot be used • Baseline hemoglobin level between 5.5 and 10.5g/dL within the past 3 months • Member has had 1 or more vaso-occlusive crises in the past 12 months • Member is not receiving regular red-cell transfusion therapy, has not received a transfusion in the past 60 days, and has not been hospitalized for vaso-occlusive crisis within 14 days • Adakveo will not be used concurrently	**Renewal:** 12 months ***Requires:*** • Documentation showing there has been a sustained hemoglobin increase from baseline of more than 1g/dL **Quantity Level Limits:** 3 tablets per day
Proprotein Convertase Subtilisin/ Kexin Type 9 Inhibitors (PCSK9 Inhibitors)[lxvii] Repatha Praluent	**Medical Records Required with Request** **Authorization Criteria for all indications:** • Prescribed by, or in consultation with, a Cardiologist, Endocrinologist, or Lipid Specialist • Member had a trial and failure, or contraindication with Repatha • Current lipid panel results within the past 90 days • Will be used in combination with maximum tolerated dosed statin and other lipid lowering therapies such as ezetimibe or bile acid sequestrants • Member meets one of the following: ○ Trial and failure of 2 high intensity statins for 90 days ▪ For example, atorvastatin greater than or equal to 40 mg and rosuvastatin greater	**Initial Approval:** 3 months **Renewal Approval:** 6 months ***Requires:*** • Current Lipid Panel within past 3 months • Claims history to support compliance

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	than or equal to 20 mg, at maximum tolerated doses and in combination with other lipid lowering therapies such as ezetimibe or bile acid sequestrants ○ Member had intolerance to at least 2 different statins as defined by one of the following: ▪ Documentation supporting skeletal muscle related symptoms ♦ For example, myopathy, myositis or abnormal biomarkers such as alanine aminotransferase/aspartate aminotransferase (ALT/AST) 3 times the upper limit of normal, elevation of creatinine kinase 10 times the upper limit of normal, or elevation of creatine kinase 4 times the upper limit of normal with evidence of rhabdomyolysis) ▪ Documentation that dose reduction was attempted for resolution of symptoms and for biomarker abnormalities rather than discontinuation of statin therapy altogether ▪ Documentation member has been re-challenged at lower dose or with different statin ▪ Member has condition that is contraindicated for statin therapy ♦ For example, chronic active liver disease, persistent elevation of serum transaminases **Additional Criteria based on Indication** **<u>Repatha or Praluent</u>** **Atherosclerotic Cardiovascular Disease:** • Member is 18 years of age or older • There is supporting evidence of high cardiovascular disease risk ○ For example, history of acute coronary syndrome, myocardial infarction, stable or	or adherence • Low-Density Lipoprotein reduction from baseline **<u>Quantity Level Limit</u>:** **<u>Praluent</u>** • Atherosclerotic Cardiovascular Disease ○ 2 syringes per 28 days • Heterozygous Familial Hypercholesterolemia ○ 2 syringes per 28 days **<u>Repatha</u>** • Atherosclerotic Cardiovascular Disease ○ 2 syringes per 28

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	unstable angina, coronary or other revascularization (percutaneous coronary intervention/coronary artery bypass grafting), stroke, transient ischemic attack, peripheral arterial disease presumed to be of atherosclerotic origin). • Lab results to support a Low-Density Lipoproteins level greater than or equal to 70 mg/dL (treated) **<u>Repatha or Praluent</u>** **Heterozygous Familial Hypercholesterolemia** • Member is 18 years of age or older • There is evidence of one of the following: ○ Low-Density Lipoprotein (LDL)-C is greater than 190 mg/dL either pretreatment or highest on treatment ○ Physical evidence of tendon xanthomas or evidence of these signs in a 1st or 2nd degree relative Deoxyribonucleic acid (DNA) based evidence of a Low-Density Lipoprotein receptor mutation, Apolipoprotein B100 (APO-B100), or Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) mutation ○ Who/Dutch Lipid Network Criteria result with a score of greater than 8 points • Lab results to support a current low-density lipoprotein level greater than or equal to 70 mg/dL on treatment. **<u>Repatha</u>** **Homozygous Familial Hypercholesterolemia:** • Member is 13 years of age or older • There is evidence of one of the following:	days • Heterozygous Familial Hypercholesterolemia: ○ 2 syringes per 28 days ○ May be increased to 3 (140mg) syringes OR 1 (420mg) syringe per 28 days if LDL is >70 after initial trial **<u>Repatha</u>** • Homozygous Familial Hypercholesterolemia ○ 3 (140mg) syringes OR 1 (420mg) syringe per 28 days

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Genetic confirmation of two mutant alleles at low-density lipoprotein receptor, or Apolipoprotein B100 (APO-B100), or Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9), ○ History of untreated Low-Density Lipoprotein level over 500mg/dL, or treated Low-Density Lipoprotein level over 300mg/dL and member is on maximum dosed statin with evidence of one of the following: ▪ Presence of cutaneous xanthoma before the age of 10 ▪ Evidence of Heterozygous Familial Hypercholesterolemia in both parents • Low-Density Lipoprotein reduction was less than 50% on current lipid lowering therapy ○ For example, high intensity statin + ezetimibe or bile acid sequestrants	
Platelet Inhibitors[lxviii] Brilinta Zontivity	**May be approved when all the following criteria are met:** **<u>Brilinta:</u>** • Diagnosis of Acute Coronary Syndrome (for example, unstable angina, ST-Elevation Myocardial Infarction (STEMI), or Non-ST-Elevation Myocardial Infarction (NSTEMI)) • Aspirin dose does not exceed 100 mg per day • Member does not have any of the following:	**Approve for members stabilized in hospital** **<u>Initial Approval</u>** Brilinta 12 months History of stent thrombosis or re-

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Active pathological bleed ○ History of intracranial hemorrhage ○ Planned Coronary Artery Bypass Grafting (CABG) **Zontivity:** • Member has a history of Myocardial Infarction, or Peripheral Artery Disease • Will be used with aspirin and/or clopidogrel • Member does not have any of the following: ○ History of stroke (Transient Ischemic Attack) ○ Intracranial hemorrhage ○ Active pathological bleeding (for example, peptic ulcer)	stenosis may be approved indefinitely Zontivity: 12 months **Renewal Approval** 12 months ***Requires*:** Member is not at high risk of bleeding, or has significant overt bleeding **Quantity Level Limit** Brilinta: 2 tablets per day Zontivity: 1 tablet per day
Progestin-only Intrauterine Devices (IUD)[lxix] **Preferred:** Liletta	**Liletta is the formulary preferred agent. Requests for non-preferred agents will be approved when ONE of the following criteria is met:** • Member has tried and failed or has a documented contraindication to Liletta that is not present with the requested progestin-only intrauterine device (IUD) • Request is for Mirena and medication is being used to treat heavy menstrual bleeding	**Approval:** 1 year **Quantity Level Limits:** Lilleta, Kyleena, and Mirena – 1 IUD every 5 years

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Non-Preferred: Kyleena Mirena Skyla		Skyla – 1 Intrauterine Device (IUD) every 3 years
Promacta[lxx]	**For all indications:** • Attestation that Provider to monitor the following labs at baseline and regularly throughout therapy, per frequency outlined in package insert: ○ Ocular examination ○ Complete blood count with differentials ○ Platelet count ○ Liver function tests **Chronic immune thrombocytopenia (ITP) - Relapsed or Refractory:** • Member is at least 1 year of age • Medication is prescribed by or in consultation with a hematologist • Member had insufficient response to corticosteroids or immunoglobulins • Documentation that Promacta is being used to prevent major bleeding in member with platelet count less than 30,000/mm^3 and NOT to achieve platelet counts in normal range (150,000-450,000/mm^3) **Hepatitis C-associated Thrombocytopenia:** • Member is at least 18 years of age • Medication is prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist	**Initial Approval:** 4 weeks **Dosing Restrictions by Indication:** • Chronic ITP: ○ 75mg/day • Hepatitis C-associated Thrombocytopenia: ○ 100mg/day • Aplastic Anemia: ○ 150mg/day **Renewal Approval:** • Chronic ITP (idiopathic thrombocytopenic purpura) with

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Member has chronic hepatitis C with baseline thrombocytopenia (documentation of platelet count less than 75,000/mm^3) that prevents initiation of interferon-based therapy when interferon is required NOTE: If member is not receiving interferon-based therapy for treatment of Hepatitis C, Promacta should NOT be approved **Severe Aplastic Anemia:** • Member meets one of the following: ○ Age is at least 17 years old for treatment of refractory aplastic anemia ○ Age is at least 2 years old for first-line treatment of severe aplastic anemia in combination with standard immunosuppressive therapy • Medication is prescribed by or in consultation with a hematologist • Diagnosis of severe aplastic anemia is confirmed by documentation of both the following: ○ Bone marrow cellularity less than 25% (or 25 to 50% if less than 30 percent of residual cells are hematopoietic) ○ At least two of the following: ▪ Absolute Neutrophil Count (ANC) less than 500/mm^3 ▪ Platelet count less than 20,000/mm^3 ▪ Absolute Reticulocyte Count (ARC) less than 20,000/mm^3 OR • Anemia is refractory to previous first line treatment, including hematopoietic cell transplantation or immunosuppressive therapy with combination of cyclosporine A and antithymocyte globulin (ATG)	documented platelet increase to greater than 50,000/mm^3 to less than 200,000/mm^3: ○ 6 months at current dose • Chronic ITP (idiopathic thrombocytopenic purpura) without documented platelet increase to greater than 50,000/mm^3: ○ 4 additional weeks with dose increase to 75mg/day • Hepatitis C-associated Thrombocytopenia with documented platelet increase to

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Documentation member has a platelet count less than 30,000/mm^3 **Limitations of Use:** Promacta is not indicated for treatment of myelodysplastic syndrome and is not a covered benefit	greater than 50,000/mm^3: ○ Duration of antiviral treatment • Hepatitis C-associated Thrombocytopenia without documented platelet increase to greater than 50,000/mm^3: ○ 4 additional weeks with dose increase up to a maximum of 100mg/day • Aplastic anemia with documented platelet increase to greater than or equal to 50,000/mm^3: ○ 6 months at

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		current dose • Aplastic Anemia without documented platelet increase to greater than or equal to 50,000/mm^3: • 4 additional weeks with dose increase up to maximum of 150mg/day
Pulmonary Arterial Hypertension[lxxi] **PREFERRED AGENTS** **Oral:** sildenafil tadalafil Tracleer Letairis	**Authorization Guideline for All Agents:** • Prescribed by, or in consultation with pulmonologist or cardiologist • Evidence of right heart catheterization with mean Pulmonary Arterial Pressure (mPAP) greater than or equal to 25 mmHg • Medical records supporting diagnosis of Pulmonary Arterial Hypertension World Health Organization Group I with Functional Class II to IV symptoms • Member meets one of the following criteria: ○ Negative vasoreactivity test ○ Contraindication to vasoreactivity test ♦ For example, low blood pressure, low cardiac index, or presence of severe Functional Class IV symptoms ○ Positive vasoreactivity test with inadequate response, or intolerance, to one calcium channel blocker:	**Initial Approval**: 6 months **Renewal**: 1 year ***Requires*:** Medical records and lab results to support response to therapy; maintain or achieve a low risk profile ○ For example,

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Opsumit **Injectable:** epoprostenol **NON-PREFERRED AGENTS:** **Oral:** Adempas Orenitram Revatio Uptravi **Inhaled:** Tyvaso Ventavis **Injectable:** Flolan Remodulin treprostinil Veletri	♦ For example, amlodipine, nifedipine ER, or diltiazem ○ Contraindication to use of calcium channel blockers Note: Adempas may include World Health Organization Group IV and does not require trial of calcium channel blocker **Additional Drug Specific Criteria:** **Brand Revatio** (sildenafil) **oral suspension** • Documentation to support inability to swallow, and necessity of brand suspension formulation **tadalafil** • Documentation to support trial and failure of, or intolerance to sildenafil **Adempas** (riociguat) • Member meets one of the following diagnoses: ○ Diagnosis of Pulmonary Arterial Hypertension, World Health Organization Group I (as described above) and member tried and failed all preferred oral agents: ♦ Phosphodiesterase 5 Inhibitors (sildenafil and tadalafil) ♦ Endothelin Receptor Antagonists (Tracleer, Letairis and Opsumit) ○ Diagnosis of Chronic Thromboembolic Pulmonary Hypertension, World Health Organization Group IV and one of the following: ♦ Recurrent or persistent Chronic Thromboembolic Pulmonary Hypertension, after surgical treatment ♦ Inoperable Chronic Thromboembolic Pulmonary Hypertension	improvement in 6-minute walk distance, functional class, or reducing time to clinical worsening **Quantity Level Limit:** Adempas: 90 tablets per 30 days Opsumit: 30 tablets per 30 days Orenitram: Determine by tolerability: 90 tablets per 30 days Sildenafil: 90 tablets per 30 days Brand Revatio oral suspension: 180 mL per 30 days Tadalafil: 60 tablets per 30 days Tracleer: 60 tablets per 30 days

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	Uptravi (selexipag), **Orenitram** (treprostinil) • Member does not have severe hepatic impairment (Child-Pugh class C) • For members with World Health Organization Functional Class II and III symptoms: ○ There was a trial and failure with all preferred oral agents: ♦ Phosphodiesterase 5 Inhibitors (sildenafil and tadalafil) ♦ Endothelin Receptor Antagonists (Tracleer, Letairis and Opsumit) • For members with World Health Organization Functional Class IV symptoms: ○ There was a trial and failure with one Prostacyclin Analog such as epoprostenol **Tyvaso** (treprostinil), **Ventavis** (Iloprost), **Remodulin** (treprostinil), treprostinil • Member has World Health Organization Functional Class III-IV symptoms (for example, Tyvaso and Ventavis) or Functional Class II-IV symptoms (for example, Remodulin) • For members with World Health Organization Functional Class II and III symptoms: ○ There was a trial and failure with all preferred oral agents: ♦ Phosphodiesterase Type 5 Inhibitors (sildenafil and tadalafil) ♦ Endothelin Receptor Antagonists (Tracleer, Letairis, and Opsumit) • For members with World Health Organization Functional Class IV symptoms: ○ There was a trial and failure with one Prostacyclin Analog such as epoprostenol **Coverage Limitation:** Any contraindications to treatment including but not limited to the following: • Pregnancy: Endothelin Receptor Antagonists and Adempas • Concurrent use of nitrate or nitric oxide donors (for example, isosorbide mononitrate,	Letairis: 30 tablets per 30 days Uptravi: 60 tablets per 30 days (may be higher during titration phase) Tyvaso: 54 mcg (9 breaths) per treatment session, 4 times daily Flolan/Veletri: 56 vials per 28 days Remodulin/treprostinil: 1 vial per 30 days

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	isosorbide dinitrate, nitroglycerin): Phosphodiesterase Type 5 Inhibitors and Adempas • Child Pugh class C hepatic impairment: Orenitram, Uptravi • Heart Failure with severe left ventricular dysfunction: Veletri/epoprostenol • Pulmonary veno-occlusive disease: tadalafil, sildenafil, Letairis, Opsumit, epoprostenol, Tracleer **Coverage Exclusions:** • Requests for Viagra (sildenafil) for Pulmonary Arterial Hypertension must be redirected to Revatio (sildenafil). • Requests for Cialis (tadalafil) for Pulmonary Arterial Hypertension must be redirected to tadalafil. **Additional Information:** • Pediatric case requests have an accepted off-label use and will require to further be sent to medical director for review **WHO Functional Classification of Pulmonary Hypertension** (modified after New York Heart Association (NYHA) FC) Class I: • No limitation of physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain, or near syncope. Class II: • Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity causes undue dyspnea or fatigue, chest pain, or near syncope. Class III:	

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes undue dyspnea or fatigue, chest pain, or near syncope. Class IV: • Inability to carry out any physical activity without symptoms. Dyspnea and/or fatigue may be present at rest and discomfort is increased by any physical activity.	
Pyrimethamine (Daraprim)[lxxii]	**Documentation Requirement Includes Physician Progress Notes, and Lab Work per Below Criteria** **Toxoplasmosis Encephalitis – Primary Prophylaxis** • Member must meet all of the following: ○ Prescribed by, or in consultation with an Infectious Disease specialist ○ Diagnosis of Human Immunodeficiency Virus (HIV) with cluster differentiation 4 (CD4) count less than 100 cells/microL ○ Seropositive for anti-toxoplasma immunoglobulin G anti-bodies (IgG) ○ Intolerance or contraindication to trimethoprim-sulfamethoxazole ▪ For non-life-threatening reactions, National Acquired Immuno-Deficiency Syndrome (AIDS) Guideline recommends re-challenge ○ Pyrimethamine to be given in combination with leucovorin • Note: Discontinue treatment if cluster differentiation 4 (CD4) is greater than 200 cells/microL for more than 3 months, in response to antiretroviral therapy **Toxoplasmosis Encephalitis – Treatment, Human Immunodeficiency Virus (HIV) Associated** • Member must meet all of the following:	**Initial Approval:** **Toxoplasmosis, Primary Prophylaxis** • Approve 3 months **Toxoplasmosis, Acute Treatment** • Approve 6 weeks **Acquired and Congenital Toxoplasmosis, Treatment - Non-Human Immunodeficiency Virus (HIV) Related** • Approve 6 weeks **Renewals:** **Toxoplasmosis, Chronic**

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	○ Prescribed by, or in consultation with an Infectious Disease specialist, or Human Immunodeficiency Virus (HIV) specialist ○ Diagnosis of Human Immunodeficiency Virus (HIV) with cluster differentiation 4 (CD4) count less than 100 cells/microL ○ Seropositive for anti-toxoplasma immunoglobulin G anti-bodies (IgG) ○ Magnetic resonance imaging (MRI), or Computed Tomography (CT) results, to support Central Nervous System (CNS) lesions ○ Treatment will be in combination with a sulfonamide and leucovorin **Toxoplasmosis Encephalitis, Chronic Maintenance Therapy (Secondary Treatment / Secondary Prophylaxis)** • Member must meet all of the following: ○ Prescribed by, or in consultation with an Infectious Disease specialist, or Human Immunodeficiency Virus (HIV) specialist ○ Member has successfully completed 6 weeks of initial therapy ○ There is documented improvement in clinical symptoms ○ Magnetic Resonance Imaging (MRI), or Computed Tomography (CT) indicates improvement in ring enhancing lesions, prior to start of maintenance therapy ○ Antiretroviral Therapy has been initiated ○ Treatment is in combination with a sulfonamide and leucovorin • Note: Discontinue treatment if cluster differentiation 4 (CD4) is greater than 200 cells/microL for more than 6 months, in response to Antiretroviral Therapy **Acquired and Congenital Toxoplasmosis, Treatment (Non-Human Immunodeficiency Virus (HIV) Related)**	**Maintenance Therapy** • Approve 6 months **Toxoplasmosis, Primary Prophylaxis** • Compliance to treatment • Lab results to support Cluster Differentiation 4 (CD4) Count • Approve 3 months • Note: Restart Primary Prophylaxis, if cluster differentiation 4 (CD4) count decreases to less than 100 to 200 cells/microL **<u>Quantity Level Limit (QLL):</u>**

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	• Member must meet all of the following: ○ Prescribed by, or in consultation with an Infectious Disease specialist ○ Pyrimethamine will be used in combination with a sulfonamide and leucovorin	• Induction: 90/30 • Maintenance: 60/30
Ranolazine (Ranexa)[lxxiii]	**For members who meet all of the following:** • Member is 18 years of age or older • Diagnosis of chronic angina • Member had an inadequate trial and failure to one formulary agent from each of the following three drug classes: ○ Beta blockers ○ Calcium channel blockers ○ Long acting nitrates • Or has a documented contraindication or intolerance to beta blockers, calcium channel blockers, **AND** long-acting nitrates	**Initial Approval:** 1 year **Renewal:** 1 year **Quantity Level Limit:** 2 tablets/day
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
Revlimid[lxxiv] **(lenalidomide)**	**General Criteria:** ○ Prescribed by or in consultation with an oncologist ○ Member is 18 years of age or older **In addition, Revlimid may be authorized when one of the following criteria is met:**	**Initial Approval:** 1 year **Renewal Approval:**

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Multiple myeloma • Mantle cell lymphoma, after relapse or progression with two prior therapies, one of which includes Velcade (bortezomib) • Myelodysplastic Syndrome, member meets one of the following: ○ Symptomatic anemia associated with the 5q-deletion cytogenetic abnormality ○ Symptomatic anemia without the 5q-deletion, and serum erythropoietin levels greater than 500 mU/mL or history of failure, contraindication, or intolerance to a preferred erythropoietin • Diffuse Large B-cell Lymphoma with one of the following: ○ Used as maintenance therapy for ages 60 – 80 years ○ Used as second-line therapy or as therapy for relapsed/refractory disease • Follicular lymphoma • Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma with one of the following: ○ Used for post first-line chemoimmunotherapy maintenance ○ Used for relapsed or refractory disease • Systemic light chain amyloidosis, in combination with dexamethasone • Hodgkin's Lymphoma, as subsequent therapy for relapsed/refractory disease • Adult T-cell leukemia/lymphoma, second-line or subsequent therapy • Peripheral T-cell lymphoma, second-line or subsequent therapy for relapsed or refractory disease • Marginal Zone Lymphoma, including Mucosa-Associated Lymphoid Tissue Lymphoma, nodal marginal zone lymphoma, and splenic marginal zone lymphoma ○ Disease has been previously treated and therapy will be given in combination with	1 year ***Requires*** • Member does not show evidence of progressive disease while on therapy • Member does not have unacceptable toxicity from therapy

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	rituximab • Myelofibrosis-associated anemia with serum erythropoietin levels greater than or equal to 500 mU/mL, or failure with a preferred erythropoiesis stimulating agent • Acquired Immune Deficiency Syndrome (AIDS)-Related B-cell lymphoma, as second-line or subsequent therapy • Castleman's Disease, as second-line or subsequent therapy for disease that has progressed following therapy for relapsed/refractory or progressive disease • Mycosis fungoides/Sezary syndrome	
Second/Third Generation Tyrosine Kinase Inhibitors (TKI) for Chronic Myeloid Leukemia (CML) and Acute Lymphoblastic Leukemia (ALL)[lxxv] **Second**	Imatinib, a first-generation Tyrosine Kinase Inhibitor (TKI), is the preferred agent for Chronic Myeloid Leukemia (CML) and Acute Lymphoblastic Leukemia (ALL) with prior authorization Imatinib should NOT be used in patients who had treatment failure with a second or third generation Tyrosine Kinase Inhibitor (TKI) Tasigna and Sprycel - Second generation Tyrosine Kinase Inhibitors (TKIs), are formulary preferred with prior authorization **General Criteria:** ○ Prescribed by or in consultation with an oncologist ○ Member is 18 years of age or older ○ Exception for Tasigna: Diagnosis of Chronic myeloid leukemia (CML) in chronic phase for 1 year of age or older ○ Exception for Sprycel: Diagnosis of Chronic myeloid leukemia (CML) in chronic phase and newly diagnosed Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) in those 1 year of age or older	**Initial Approval:** 1 year **Renewal Approval:** 3 years ***Requires*** • Member does not show evidence of progressive disease while on therapy • Member does not have unacceptable toxicity from therapy

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Generation: Sprycel (dasatinib) Tasigna (nilotinib) Bosulif (bosutinib) **Third Generation:** Iclusig (ponatinib)	**In addition, Tasigna or Sprycel may be authorized when one the following criteria is met:** • Newly diagnosed Chronic Myeloid Leukemia (CML) in chronic phase: ○ Low to intermediate risk group determined by EUTOS, Euro [Hasford], or Sokal scores, requires trial of imatinib; or ○ High risk group determined by EUTOS, Euro [Hasford], or Sokal scores • Newly diagnosed Philadelphia chromosome positive (Ph+), or BCR-ABL1 positive Acute Lymphoblastic Leukemia (ALL) • Chronic Myeloid Leukemia (CML) in chronic or advanced phase, or Philadelphia chromosome positive (Ph+), or BCR-AB1 positive Acute Lymphoblastic Leukemia: Intolerance, disease progression, or resistance to prior therapy of imatinib • Follow-up treatment for Chronic Myeloid Leukemia (CML) with allogeneic hematopoietic cell transplant **In addition, Bosulif may be authorized when ONE the following criteria is met:** • Newly diagnosed Philadelphia chromosome positive (Ph+) Chronic Myeloid Leukemia (CML) in chronic phase: ○ Low or intermediate risk group determined by EUTOS, Euro [Hasford], or Sokal scores, requires trial of imatinib, AND Tasigna or Sprycel ○ High risk group determined by EUTOS, Euro [Hasford], or Sokal scores, requires trial of Tasigna or Sprycel • Chronic Myeloid Leukemia (CML) in chronic phase or in advanced phase, or Philadelphia chromosome positive (Ph+), or BCR-ABL1 positive Acute Lymphoblastic Leukemia (ALL), and intolerance, disease progression, or resistance to imatinib and Tasigna or Sprycel	

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Follow-up treatment for Chronic Myeloid Leukemia after allogeneic hematopoietic cell transplant **In addition, Iclusig may be authorized when one of the following criteria is met:** • Chronic Myeloid Leukemia (CML) in chronic phase, or advanced phase, or Philadelphia chromosome positive (Ph+), or BCR-ABL1 positive Acute Lymphoblastic Leukemia (ALL) *(note: not indicated in newly diagnosed chronic phase CML)* ○ T315I-positive OR ○ Disease has not responded to 2 or more Tyrosine Kinase Inhibitor (TKI) therapies (for example, imatinib, Tasigna, Sprycel, or Bosulif), or other Tyrosine Kinase Inhibitor (TKI) therapy is not indicated. • Follow-up treatment for Chronic Myeloid Leukemia (CML) after allogeneic hematopoietic cell transplant	
Soliris[lxxvi] **(eculizumab)**	**Atypical hemolytic uremic syndrome** Authorization of 6 months may be granted for treatment of atypical hemolytic uremic syndrome not caused by Shiga toxin when all of the following criteria are met: • ADAMTS 13 activity level above 5% • Absence of Shiga toxin **Paroxysmal nocturnal hemoglobinuria** Authorization of 6 months may be granted for treatment of paroxysmal nocturnal hemoglobinuria (PNH) when all of the following criteria are met: • The diagnosis of PNH was confirmed by detecting a deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-APs) as demonstrated by either of the following:	**Initial Approval:** **Atypical hemolytic uremic syndrome:** 6 months **Paroxysmal nocturnal hemoglobinuria:** 6 months **Generalized myasthenia gravis (gMG):** 6 months **Neuromyelitis Optica Spectrum Disorder (NMOSD):** 6 months

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ At least 5% PNH cells ○ At least 51% of GPI-anchored protein deficient poly-morphonuclear cells • Flow cytometry is used to demonstrate GPI-anchored proteins deficiency **Generalized myasthenia gravis (gMG)** Authorization of 6 months may be granted for treatment of generalized myasthenia gravis (gMG) when all of the following criteria are met: 1. Anti-acetylcholine receptor (AchR) antibody positive 2. Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV 3. MG activities of daily living (MG-ADL) total score ≥6 4. Meets both of the following: a. Member has had an inadequate response to at least two immunosuppressive therapies listed below: i. azathioprine ii. cyclosporine iii. mycophenolate mofetil iv. tacrolimus v. methotrexate vi. cyclophosphamide b. Member has inadequate response to chronic IVIG AND rituximab **Neuromyelitis Optica Spectrum Disorder (NMOSD)** Authorization of 6 months may be granted for treatment of neuromyelitis optica spectrum disorder (NMOSD) when all of the following criteria are met: • Anti-aquaporin-4 (AQP4) antibody positive	**Renewal Approval Requires**: **Atypical hemolytic uremic syndrome** Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen and demonstrate a positive response to therapy (for example, normalization of lactate dehydrogenase (LDH) levels, platelet counts). **Paroxysmal nocturnal hemoglobinuria** Authorization of 12 months may be granted for continued treatment in

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Member exhibits one of the following core clinical characteristics of NMOSD: • Optic neuritis • Acute myelitis • Area postrema syndrome (episode of otherwise unexplained hiccups or nausea and vomiting) • Acute brainstem syndrome • Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions • Symptomatic cerebral syndrome with NMOSD-typical brain lesions • The member will not be treated with rituximab and eculizumab concomitantly	members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen and demonstrate a positive response to therapy (for example, improvement in hemoglobin levels normalization of lactate dehydrogenase [LDH] levels). **Generalized myasthenia gravis (gMG)** Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen and

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		demonstrate a positive response to therapy (for example, improvement in MG-ADL score, changes compared to baseline in Quantitative Myasthenia Gravis (QMG) total score). **Neuromyelitis optica spectrum disorder (NMOSD)** Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen and demonstrate a positive response to therapy (for example, reduction in number of relapses).

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Somatostatin Analogs[lxxvii] **Preferred agents:** Octreotide Sandostatin Long Acting Release (LAR) **Non-preferred agents:** Signifor Signifor Long Acting Release (LAR) Somatuline	**Criteria for approval of Non-Preferred agents:** • Must meet general clinical and indication-based criteria • Member had inadequate response, intolerable side effects, or contraindication to Sandostatin Long Acting Release (LAR) **General Authorization Criteria for ALL Indications:** • Member is 18 year of age or older (unless prescribed for pediatric chemotherapy-induced diarrhea) • Sandostatin Long Acting Release (LAR) and Somatuline Depot: ○ Baseline testing for the following: ▪ A1c or fasting glucose ▪ Thyroid-stimulating hormone ▪ Electrocardiography • Signifor and Signifor Long Acting Release (LAR): ○ Baseline testing for the following: ▪ A1c, or fasting plasma glucose ▪ Electrocardiography ▪ Potassium ▪ Magnesium ▪ Thyroid-stimulating hormone ▪ Liver function tests	**Initial Approval:** 6 months **Renewal:** • Acromegaly, Cushing's, Carcinoid and VIPomas: One year • All other indications: 6 months ***Requires:*** **Documentation of the following for all indications:** • A1c or fasting glucose • Electrocardiography • Monitor for cholelithiasis and discontinue if

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Depot	▪ Attestation that gallbladder ultrasound has been completed **Additional Criteria Based on Indication:** • **Acromegaly** (Octreotide, Sandostatin Long Acting Release, Somatuline Depot, Signifor Long Acting Release): o Prescribed by, or in consultation with, an endocrinologist o Member has one of the following: ▪ Persistent disease following radiotherapy and/or pituitary surgery ▪ Surgical resection is not an option as evidenced by one of the following: a) Majority of tumor cannot be resected b) Member is a poor surgical candidate based on comorbidities c) Member prefers medical treatment over surgery, or refuses surgery o Baseline insulin-like growth factor-1 (IGF-1) meets one of the following criteria: ▪ Greater than or equal to 2 times the upper limit of normal for age ▪ Remains elevated despite a 6-month trial of maximally tolerated dose of cabergoline (unless member cannot tolerate, or has contraindication to cabergoline) • **Carcinoid Tumor or Vasoactive Intestinal Polypeptide Secreting Tumor (VIPomas)** (Octreotide, Sandostatin Long Acting Release, Somatuline Depot) - To reduce frequency of short-acting somatostatin analog rescue therapy: o Prescribed by, or in consultation with, oncologist or endocrinologist • **Cushing's Syndrome** (Signifor): o Member has persistent disease after pituitary surgery, or surgery is not an option o Member had inadequate response, intolerable side effects, or contraindication to	complications of cholelithiasis are suspected • Thyroid-stimulating hormone • Response to therapy **Documentation of additional requirements per indication or drug:** • Acromegaly: Decreased or normalized insulin-like growth factor-1 (IGF-1) levels • Cushing's: o Decreased or normalized cortisol levels • Signifor: o Liver function tests **Quantity Level Limits:**

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	cabergoline ○ NOTE: Member does not need a trial of octreotide or Sandostatin Long Acting Release for approval • **Hepato-renal syndrome** (Octreotide): ○ Prescribed by hepatologist or nephrologist ○ Must be used in combination with midodrine and albumin • **Gastro-entero-pancreatic neuroendocrine tumor** (Octreotide, Sandostatin Long Acting Release, Somatuline Depot): ○ Prescribed by, or in consultation with, oncologist or endocrinologist ○ Member has persistent disease after surgical resection, or is not a candidate for surgery **Octreotide may be reviewed for medical necessity and approved for the following:** • Chemotherapy induced diarrhea in pediatrics, when prescribed by, or in consultation with, oncologist • Dumping Syndrome in adults 18 years of age or older • Enterocutaneous fistula in adults 18 years of age or older • Hyperthyroidism due to thyrotropinoma in adults 18 years of age or older • Short bowel syndrome (associated diarrhea) in adults 18 years of age or older • Portal hypertension and/or upper gastrointestinal bleed related to variceal bleeding, in adult members with esophageal varices that are 18 years of age or older	• Octreotide: Max dose 1500mcg/day • Sandostatin (LAR): Maximum dose 40mg every 4 weeks ○ 10mg and 30mg vials: 1 vial per 28 days ○ 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
Spinraza[lxxviii] (nusinersen)	**May be authorized when all the following criteria are met:** • Member has a diagnosis of spinal muscular atrophy confirmed by genetic testing • Prescribed by, or in consultation with a neurologist	**Initial Approval:** 2 months

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Documentation that member has Type I, Type II, or Type III Spinal Muscular Atrophy • Member is 15 years of age or younger at initiation of treatment • Member is confirmed to have at least 2 copies of the Survival Motor Neuron-2 (SMN2) gene • Genetic test confirms presence of one of the following chromosome 5q mutations or deletions: ○ Homozygous deletions of Survival Motor Neuron-1 (SMN1) gene ○ Homozygous mutation in the Survival Motor Neuron-1 (SMN1) gene ○ Compound heterozygous mutation in the Survival Motor Neuron-1 (SMN1) gene (deletion of Survival Motor Neuron-1 (SMN1) exon 7 (allele 1), and mutation of Survival Motor Neuron-1 (SMN1) (allele 2)) • Member is not dependent on any of the following: ○ Invasive ventilation for more than 16 hours per day, or tracheostomy ○ Non-invasive ventilation for at least 12 hours per day • Baseline motor milestone score is obtained using one of the following assessments: ○ Hammersmith Functional Motor Scale Expanded (HFMSE) ○ Hammersmith Infant Neurologic Exam Part 2 (HINE-2) ○ Revised Upper Limb Module (RULM) test ○ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) ○ Six-minute walk test • Baseline labs to rule out coagulation abnormalities and thrombocytopenia: ○ Platelet count ○ Prothrombin time (PT), and activated partial thromboplastin time (aPTT)	**Renewal Approval:** 4 months **Requires:** • Response to therapy as demonstrated by medical records of one of the following: ○ Maintained, or improved motor milestone score, using the same exam as performed at baseline (refer to specific exam below) ○ Achieved, and maintained any new motor milestones, when otherwise would be unexpected to

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Baseline labs to rule out renal toxicity: ○ Quantitative spot urine protein testing <u>Notes:</u> There is currently insufficient evidence to support initiation of Spinraza after the age of 15 years. Spinraza will not be approved for spinal muscular atrophy without confirmation of the chromosome 5q mutation or deletion testing.	do so, using the same exam as performed at baseline **<u>Additional Requirements per Exam Performed:</u>** • **Hammersmith Infant Neurologic Exam Part 2 (HINE-2)** ○ One of the following: ▪ Improvement, or maintenance of previous improvement, of at least a 2 point increase in ability to kick ▪ Improvement, or

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		maintenance of previous improvement, of at least a 1-point increase, in any other milestone (for example, head control, rolling, sitting, crawling), excluding voluntary grasp • **Hammersmith Functional Motor Scale Expanded (HFMSE)** ○ Improvement, or maintenance of previous improvement, of at least a 3-point

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		increase in score from baseline • **Revised Upper Limb Module (RULM)** ○ Improvement, or maintenance of previous improvement, of at least a 2-point increase in score from baseline • **Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)** ○ Improvement, or maintenance of previous improvement, of at least a 4-point increase in score

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		from baseline • **6-Minute Walk Test (6MWT)** ○ Maintained, or improved score from baseline • The following laboratory tests showing improvement from pretreatment baseline status: ○ Platelet count ○ Coagulation tests such as prothrombin time (PT), activated partial thromboplastin time (aPTT) ○ Quantitative spot urine protein test

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		Quantity Level Limit: *Initial:* • 12 mg (5 mL) per administration ➢ Total of 4 loading doses. First 3 doses are given at 14-day intervals. The 4th dose is given 30 days after the 3rd dose. *Maintenance:* Given once every 4 months
Spiriva Respimat[lxxix]	**Incruse Ellipta** is the formulary preferred agent for the treatment of chronic obstructive pulmonary disease (COPD) and does not require prior authorization **Spiriva Respimat may be authorized when:** • Member is 6 years of age or older with a diagnosis of asthma • Member is currently taking an inhaled corticosteroid (ICS), and will continue with an inhaled corticosteroid (ICS) when Spiriva is initiated • There was a trial and failure with at least two formulary agents: o Inhaled corticosteroid o Inhaled corticosteroid with a long-acting beta-2 agonist	**Initial Approval:** 12 months **Renewal Approval:** 12 months ***Requires:*** Member is currently taking an inhaled corticosteroid (ICS), and

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Montelukast or zafirlukast NOTE: Spiriva HandiHaler, and Incruse Ellipta are not Food and Drug Administration (FDA) approved for asthma	will continue to take the inhaled corticosteroid (ICS) along with the Spiriva Respimat
Sucraid[lxxx]	**May be authorized when the following criteria is met**: • Prescribed by a gastroenterologist, endocrinologist, or genetic specialist • Member does not have secondary (acquired) disaccharidase deficiencies • Documentation to support the diagnosis of congenital sucrose-isomaltase deficiency has been submitted: ○ Diagnosis of congenital sucrose-isomaltase deficiency has been confirmed by low sucrose activity on duodenal biopsy and other disaccharidases normal on same duodenal biopsy ○ If small bowel biopsy is clinically inappropriate, difficult, or inconvenient to perform, the following diagnostic tests are acceptable alternatives (all must be performed and results submitted): ▪ Stool pH less than six; AND ▪ Breath hydrogen increase greater than 10 parts per million (ppm) following fasting sucrose challenge; AND ▪ Negative lactose breath test • Attestation dose will not exceed 8,500 units per meal or snack for those weighing 15kg or less and 17,000 units for those weighing more than 15kg	**Initial Approval:** 2 months **Renewal:** 12 months *Requires*: Documentation to support a response to treatment with Sucraid (weight gain, decreased diarrhea, increased caloric intake, decreased gassiness, abdominal pain).
Sutent	**General Criteria:**	**Initial Approval:**

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
(sunitinib)[lxxxi]	• Prescribed by or in consultation with an oncologist • Member is 18 years of age or older **In addition, Sutent may be authorized when one the following criteria is met:** • Treatment of Gastrointestinal Stromal Tumor (GIST) after disease progression while on or intolerance to imatinib • Treatment of advanced Renal Cell Carcinoma (RCC) • Adjuvant treatment for member at high risk of Recurrent Renal Cell Carcinoma (RCC) following nephrectomy ○ Clear cell histology and stage III disease • Unresectable, locally advanced, or metastatic pancreatic neuroendocrine tumors (pNET) • Angiosarcoma Solitary fibrous tumor/hemangiopericytoma • Alveolar Soft Part Sarcoma (ASPS) ○ Differentiated thyroid carcinoma (for example, papillary, follicular, and Hürthle cell) meets all the following: ○ Unresectable recurrent, persistent locoregional, or distant metastatic disease ○ Progressive and/or symptomatic iodine-refractory disease ○ Nexavar (sorafenib) and Lenvima (lenvatinib) are not available, or are not clinically appropriate • Metastatic medullary thyroid carcinoma (MTC) that is persistent or recurrent: ○ Member has symptomatic or progressive disease ○ Trial of Caprelsa (vandetanib) or Cometriq (cabozantinib) • Locally advanced, advanced, or recurrent thymic carcinomas: ○ Trial and failure of a first-line systemic therapy (for example carboplatin/paclitaxel or	1 year **Renewal Approval**: 3 years ***Requires:*** • Member does not show evidence of progressive disease while on therapy • Member does not have unacceptable toxicity from therapy

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	cisplatin/doxorubicin/ cyclophosphamide with prednisone) • Recurrent chordoma	
Synagis[lxxxii]	**May be authorized for members in the following groups when the criteria is met:** **A. Preterm Infants without Chronic Lung Disease (CLD):** • Gestational Age (GA) less than 29 weeks, 0 days • 12 months of age or younger at the start of Respiratory Syncytial Virus (RSV) season **B. Preterm Infants with Chronic Lung Disease (CLD):** • Gestational Age (GA) less than 32 weeks, 0 days • Member meets ONE of the following: o Is less than 12 months of age at the start of Respiratory Syncytial Virus (RSV) season AND has required greater than 21% oxygen for greater than 28 days after birth o Is between 12 and 24 months of age at the start of Respiratory Syncytial Virus (RSV) season AND continues to require medical support (for example, supplemental oxygen, chronic systemic corticosteroid therapy, diuretic therapy, or bronchodilator therapy) within 6 months of the start of Respiratory Syncytial Virus (RSV) season **C. Infants with Hemodynamically Significant Congenital Heart Disease:** Member meets one of the following: o Is between 12 and 24 months of age at the start of Respiratory Syncytial Virus (RSV) season AND has undergone cardiac transplantation during Respiratory Syncytial Virus (RSV) season	**Initial Approval:** 1 dose per month for a maximum of 5 doses per season **Note:** infants born during Respiratory Syncytial Virus (RSV) season may require fewer than 5 doses** ***Requires:*** Current weight to confirm correct vial size at 15mg/kg dose

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	○ Is less than 12 months of age at the start of Respiratory Syncytial Virus (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 **D. Children with Anatomic Pulmonary Abnormalities or Neuromuscular Disorder:** ○ Is 12 months of age or younger at the start of Respiratory Syncytial Virus (RSV) season ○ Disease or congenital anomaly impairs ability to clear secretions from the upper airway because of ineffective cough **E. Immunocompromised Children:** ○ Is 24 months of age or younger at the start of Respiratory Syncytial Virus (RSV) season ○ Child is profoundly immunocompromised during Respiratory Syncytial Virus (RSV) season **F. Children with Cystic Fibrosis** Member meets one of the following: ○ Is 12 months of age or younger and has clinical evidence of chronic lung disease (CLD) and/or nutritional compromise in the first year of life ○ Is 24 months of age or younger with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on	

PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	chest radiography or chest computed tomography that persist when stable) or weight for length less than the 10th percentile. **The following groups are not at increased risk of Respiratory Syncytial Virus (RSV) and should NOT receive Synagis:** • Infants and children with hemodynamically insignificant heart disease (for example, 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 above criteria is met) • Children with Down Syndrome (unless qualifying heart disease or prematurity) • Children who had met the criteria above but experienced break through Respiratory Syncytial Virus (RSV) hospitalization during the current season.	
Tadalafil (Cialis)[lxxxiii]	**Tadalafil 2.5mg and 5mg may be approved for members who meet all the following:** • Diagnosis of benign prostatic hyperplasia (BPH) • Inadequate response, intolerable side effects or contraindication to both of the following: ○ Two alpha blockers ▪ For example, alfuzosin, tamsulosin, doxazosin, terazosin ○ Finasteride for at least 6 months • Member is not using any form of organic nitrate (for example, nitroglycerin, isosorbide dinitrate, isosorbide mononitrate or amyl nitrate) or Adempas	**Initial Approval:** 3 months **Renewal Approval:** 12 months ***Requires:*** • Demonstration of improvement in

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	NOTE: Use of tadalafil for treatment of erectile dysfunction including penile rehabilitation is not a covered benefit	symptoms ○ Improvement of International Prostate Symptom Score (I-PSS), or American Urological Association (AUA) Symptom Index score from baseline • Member continues to not use organic nitrates or Adempas **Quantity Level Limit:** 30/30 days
Tarceva[lxxxiv] (erlotinib)	**General Criteria:** ○ Prescribed by or in consultation with an oncologist ○ Member is 18 years of age or older **In addition, Tarceva may be authorized when one the following criteria is met:** • Locally advanced or metastatic pancreatic cancer in combination with gemcitabine	**Initial Approval:** 1 year **Renewal Approval:** 3 years

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	(Gemzar) • Advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) with one of the following: ○ Epidermal Growth Factor Receptor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutation ○ Trial and failure, or adverse effect to at least one chemotherapy regimen (for example: platinum-based chemo regimen containing cisplatin or carboplatin) • Central Nervous System Cancer ○ Member is positive for the sensitizing Epidermal Growth Factor Receptor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutation, and meets one of the following: ▪ Brain metastases as result of recurrent Non-Small Cell Lung Cancer (NSCLC) ▪ Leptomeningeal or spinal metastases from Non-Small Cell Lung Cancer (NSCLC) • Advanced Renal Cell Carcinoma (RCC): ○ Non-clear cell histology ○ Trial and failure with Sutent (sunitinib), Cometriq (cabozantinib), or Afinitor (everolimus) • Advanced, recurrent, or metastatic vulvar cancer when used as a single agent • Recurrent chordoma ○ Trial of Gleevec (imatinib), Sutent (sunitinib), or Sprycel (dasatinib)	***Requires*:** • Member does not show evidence of progressive disease while on therapy Member does not have unacceptable toxicity from therapy
Tavalisse[lxxxv]	**May be authorized when the following criteria are met:** • Member is 18 years of age or older • Diagnosis of chronic immune thrombocytopenia (ITP) • Medication is prescribed by or in consultation with a hematologist • Insufficient response to a previous treatment (such as corticosteroid, splenectomy, intravenous immunoglobulin [IVIG], anti-D immunoglobulin, Thrombopoietin (TPO)	**Initial approval:** 4 months **Renewals:** 6 months

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	Receptor Agonists (Promacta®, Nplate®), or Rituxan®) • Documentation of a baseline platelet count: less than 30 x 10^9/L • After obtaining baseline assessments, provider agrees to: ○ Monitor complete blood counts (CBCs), including platelet counts, monthly until a stable platelet count (at least 50 x 10^9/L) is achieved. Thereafter, continue to monitor complete blood counts (CBCs), including neutrophils, regularly ○ Monitor liver function tests (LFTs) (for example, alanine aminotransferase [ALT], aspartate aminotransferase [AST] and bilirubin) monthly ○ Monitor blood pressure every 2 weeks until establishment of a stable dose, then monthly thereafter • No concomitant use with a strong CYP3A4 inducer (for example, phenobarbital, carbamazepine)	*Requires*: • After 12 weeks, platelet count increases to a level sufficient to avoid clinically important bleeding. • Provider continues to monitor complete blood counts (CBCs), including neutrophils, blood pressure, liver function tests (LFTs) **Quantity Level Limit**: 2 tablets/day
Testosterone agents[lxxxvi] **Preferred:** Testosterone enanthate	**Non-Preferred products require trial and failure of two preferred formulary agents in addition to meeting the clinical criteria** **<u>Testosterone Replacement Therapy (TRT):</u>** • Diagnosis of hypogonadism in males with consistent symptoms supported by one of the following: ○ Documentation of two pretreatment serum total testosterone levels confirmed on two	**Initial Approval:** • 6 months **Renewal:** • Delayed Puberty: 6 months

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Testosterone cypionate Testosterone gel Testosterone packets Testosterone solution 30mg/act **Branded Products Non-Preferred** Androderm Androgel Aveed Axiron Delatestryl Depo-Testosterone Fortesta Jatenzo Natesto	separate mornings with results below normal range (less than 264ng/dL or less than the reference range for the lab) ○ Documentation of one pretreatment free or bioavailable testosterone level (less than the reference range for the lab), and ▪ Member has a condition that may alter sex-hormone binding globulin (for example obesity, diabetes mellitus, hypothyroidism, etc.), or ▪ Documentation that member's initial testosterone concentrations were at or near the lower limit of normal ○ Diagnosis of one of the following: ▪ Bilateral Orchiectomy ▪ Genetic disorder due to hypogonadism (for example, Klinefelter syndrome) ▪ Panhypopituitarism • Diagnosis of hypogonadism is not made during, or recovery from an acute illness, or when member is engaged in short-term use of certain medications (for example opioids and glucocorticoids) • Attestation member does not have either of the following: ○ Prostate cancer ○ Male breast cancer • Attestation that serum testosterone, prostate specific antigen (PSA), hemoglobin, hematocrit, liver functions tests, and lipid concentrations will be monitored periodically as appropriate **Female to Male Transsexualism (FtM TS):** **Member must meet all the following:**	All others: 12 months ***Requires:*** • All indications (except breast cancer): Hematocrit less than 54% • Testosterone Replacement Therapy (TRT) and Female to Male Transsexualism (FtM TS): Documentation testosterone remains within the normal male range • Delayed Puberty: Documentation showing measurements of height/weight, Tanner stage of pubertal

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Striant Testim Testopel Vogelxo Xyosted	• Age of 16 years or older • An evaluation from a mental health professional shows there is a persistent, well-documented diagnosis of gender dysphoria • Co-morbid mental health concerns have been or are actively being addressed • Member made a fully informed decision and has given consent, and the parent and/or guardian consents to treatment for those under 18 years of age • NOTE: Per the World Professional Association for Transgender Health (WPATH) Standards of Care psychotherapy is not an absolute requirement for hormone therapy **Delayed Puberty:** • Member is at least 14 years of age • Prescriber is a pediatric endocrinologist or urologist • Serial physical evaluations have been made over time (six months or more) to help confirm the diagnosis ○ Examination must include measurements of height/weight, Tanner stage of pubertal development, bone age, and testicular size • Prescriber has determined there are few to no signs of puberty and pubertal delay is severe or the member's psychosocial concerns cannot be resolved without treatment **Palliative treatment of inoperable breast cancer in women:** • Prescribed by oncologist **Acquired Immunodeficiency Syndrome (AIDS) -Associated wasting syndrome**: • Diagnosis of Human Immunodeficiency Virus/Acquired Immunodeficiency Virus (HIV/AIDS) • Attestation of a loss of at least 10% of body weight	development, bone age, and testicular size continue to be taken and there is still evidence of small testes • For Testosterone Replacement Therapy (TRT): ○ Attestation member has not developed prostate or male breast cancer(s) ○ Prostate specific antigen (PSA), hemoglobin, liver functions tests, and lipid concentration continue to be monitored • Breast cancer:

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		• Member is responding to therapy without disease progression • HIV/AIDS-wasting: member has seen and maintained increased weight from baseline **Quantity Level Limit:** Testosterone solution 30mg/act: 6 mL/day
Topical Hyaluronic Acid Agents 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	**Intial 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
Tranexamic Acid Tablets[lxxxvii]	• Member is 12 years of age or older • Treatment is for cyclic heavy menstrual bleeding • Prescriber attestation that member has no fibroids, or fibroids are less than 3 cm in size • There was inadequate response, intolerable side effect, or contraindication to one oral Non-Steroidal Anti-inflammatory Drug (NSAID) • Member had inadequate response, intolerable side effect, or contraindication to one of the following: ○ Oral hormonal cycle control combinations ○ Oral progesterone ○ Progesterone-containing intrauterine device (IUD) ○ Medroxyprogesterone depot • Member does not have history of thrombosis or thromboembolism (including retinal vein or artery occlusion) Approved for treatment and prevention of acute bleeding episodes, such as dental surgery, in members with hemophilia.	**Initial Approval:** 90 days **Renewal Approval:** 6 months ***Requires:*** • Reduction in menstrual blood loss **Quantity Level Limit:** • Menstrual bleeding: 30 tablets per 30 days • Hemophilia: 84 tablets per 30 days
Transmucosal Immediate Release	Transmucosal immediate release fentanyl (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.	**Initial Approval:** 1 year **Renewals:** 1 year

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Fentanyl (TIRF) Agents[lxxxviii] Abstral (fentanyl) sublingual tablets fentanyl citrate lozenge Fentora (fentanyl) buccal tablets Lazanda (fentanyl citrate) nasal spray Subsys (fentanyl) sublingual spray	Transmucosal immediate release fentanyl (TIRF) agents are available only through a restricted TIRF Risk Evaluation and Mitigation Strategy (REMS) Access program. The preferred formulary product is the generic fentanyl citrate with prior authorization (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 • Member is on a long-acting opioid around-the-clock for treatment of cancer pain • Attestation member is not on a benzodiazepine or gabapentinoids (gabapentin or pregabalin), but if concomitant use is deemed necessary therapy will be tapered and/or member will be monitored closely for adverse effects • Member must be considered opioid-tolerant and is considered opioid-tolerant if the member has received at least <u>one week</u> of treatment on <u>one</u> of the following medications: ○ Oral morphine sulfate at doses of at least 60 mg/day ○ Fentanyl transdermal patch at doses of at least 25 mcg/hour ○ Oral oxycodone at doses of at least 30 mg/day ○ Oral hydromorphone at doses of at least 8 mg/day ○ Oral oxymorphone at doses of at least 25 mg/day	Requires: • Improvement in breakthrough cancer pain • Continued use of a long-acting opioid around-the-clock while on treatment **Quantity Level Limit (QLL)**: Abstral: 4 tablets/day Actiq: 4 lozenges/day Fentora: 4 tablets/day Lazanda: 1 bottle/day Subsys: 8 sprays/day

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Oral hydrocodone at doses of at least 60 mg/day ○ An alternative opioid at an equianalgesic dose for at least one week (for example, oral methadone at doses of at least 20 mg/day) And • For all non-formulary agents, member had inadequate response or intolerable side effects with generic fentanyl citrate lozenge. **Note: transmucosal immediate release fentanyl (TIRF) products 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.	
Tykerb (lapatinib)[lxxxix]	**General Criteria:** • Prescribed by or in consultation with an oncologist • Member is 18 years of age or older **In addition, Tykerb may be authorized when one of the following criteria is met:** • Recurrent or metastatic breast cancer, human epidermal growth factor receptor 2 positive (HER2+) in combination with an aromatase inhibitor (for example, anastrozole, letrozole, or exemestane) ○ Member meets one of the following: ▪ Postmenopausal or premenopausal, and receiving ovarian ablation or suppression ▪ Will receive testicular steroidogenesis suppression (for male members) • Recurrent or metastatic breast cancer that is human epidermal growth factor receptor 2 positive (HER2+) ○ Used in combination with capecitabine (Xeloda) or trastuzumab (Herceptin)	**Initial Approval:** 1 year **Renewal Approval**: 3 years ***Requires*:** • Member does not show evidence of progressive disease while on therapy • Member does not have unacceptable toxicity from therapy

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	▪ Disease progression while on trastuzumab prior to initiation of either combination regimen • Recurrent chordoma o Trial of Gleevec (imatinib), Sutent (sunitinib), or Sprycel (dasatinib) o Disease is epidermal growth factor receptor positive (EGFR+) • Subsequent therapy of advanced or metastatic colon or rectal cancer: o Disease is not appropriate for intensive therapy o Treatment will be in combination with trastuzumab • Central Nervous System cancers meet one of the following: o Recurrence of tumors in adult intracranial and spinal ependymoma (excluding subependymoma) ▪ Treatment is in combination with temozolomide o Brain metastases in recurrent breast cancer ▪ Treatment is in combination with capecitabine	
Viscosupplements[xc] **Preferred Agents:** **Gel-One** **Hyalgan** **Non-Preferred**	**Preferred Agents:** Hyalgan and Gel-one are the preferred viscosupplements for Osteoarthritis **Non-Preferred Agents will not be covered** **Authorization Criteria:** • Member had inadequate response, intolerable side effects, or contraindications to all the following: o Conservative non-pharmacologic therapy ▪ For example, physical therapy, land based or aquatic based exercise, resistance	**Initial Approval:** • 1 series **Renewal:** • 1 series • No more than 2 series of injections are allowed per lifetime

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Agents: Euflexxa Supartz FX Synvisc Synvisc-One Monovisc Orthovisc Gel-Syn GenVisc 850 Hymovis Visco-3 Durolane	training, or weight loss ○ Adequate trial of pharmacologic therapy, one of which must be oral or topical non-steroidal anti-inflammatory drugs (NSAIDs) ▪ For example, acetaminophen, duloxetine, or topical capsaicin ○ Intra-articular steroid injections • Member reports pain which interferes with functional activities ○ For example, ambulation, or prolonged standing • Pain is not attributed to other forms of joint disease • Member has not had surgery on the same knee in the past 6 months • Treatment is not requested for any of the following indications: ○ Temporomandibular joint disorders ○ Chondromalacia of patella (chondromalacia patellae) ○ Pain in joint, lower leg (patellofemoral syndrome) ○ Osteoarthrosis and allied disorders (joints other than knee) ○ Diagnosis of osteoarthritis of the hip, hand, shoulder, et cetera • Documentation to meet one of the following criteria: ○ Radiographic evidence of mild to moderate osteoarthritis of the knee ▪ For example, severe joint space narrowing, subchondral sclerosis, osteophytes ○ Symptomatic osteoarthritis of the knee according to the American College of Rheumatology clinical and laboratory criteria, which requires knee pain, and at least **five** of the following: ▪ Bony enlargement ▪ Bony tenderness	***Requires:*** • 6 months has elapsed since previous treatment • Documentation to support improved response to previous series ○ For example, a dose reduction with non-steroidal anti-inflammatory drugs (NSAIDs), or other analgesics

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	▪ Crepitus (noisy, grating sound) on active motion ▪ Erythrocyte sedimentation rate (ESR) less than 40 mm/hour ▪ 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 white blood cells less than 2000/mm3)	
Votrient[xci]	**General Criteria:** • Prescribed by or in consultation with an oncologist • Member is 18 years of age or older **In addition, Votrient may be authorized when one of the following criteria is met:** • Advanced Renal Cell Carcinoma (RCC) • Advanced or metastatic Soft Tissue Sarcoma (STS) and one of following: o Angiosarcoma o Pleomorphic rhabdomyosarcoma o Retroperitoneal/intra-abdominal soft tissue sarcoma o Soft tissue sarcoma of the extremity, superficial trunk, head or neck o Gastrointestinal stromal tumor (GIST) and disease progression after imatinib (Gleevec), sunitinib (Sutent), and regorafenib (Stivarga) • Metastatic Dermatofibrosarcoma Protuberans (DFSP) • Recurrent or metastatic uterine sarcoma that has progressed with prior cytotoxic therapy (for example doxorubicin, docetaxel/gemcitabine, doxorubicin/ifosfamide)	**Initial Approval:** 1 year **Renewal:** 3 years ***Requires:*** • Member does not show evidence of progressive disease while on therapy • Member does not have unacceptable toxicity from therapy

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	• Epithelial, ovarian, Fallopian tube, or primary peritoneal cancer must meet the following: ○ Disease is stage 2 to 4 ○ Member received primary treatment with chemotherapy (for example carboplatin with paclitaxel) and/or surgery and achieved complete clinical remission • Differentiated thyroid carcinoma (for example, papillary, follicular, and Hürthle cell) meets all the following: ○ Unresectable recurrent, persistent locoregional, or distant metastatic disease ○ Progressive and/or symptomatic iodine-refractory disease ○ Nexavar (sorafenib) and Lenvima (lenvatinib) are not available or are not clinically appropriate • Metastatic medullary thyroid carcinoma (MTC) that is persistent or recurrent: ○ Member has symptomatic or progressive disease ○ Trial of Caprelsa (vandetanib) or Cometriq (cabozantinib)	
Wakefulness Agents[xcii] Armodafinil Modafinil Sunosi Wakix	Armodafinil is the preferred formulary agent and requires prior authorization. Modafinil is non-formulary and may be authorized if the member meets criteria and has a documented trial and failure of armodafinil. Sunosi requires a documented trial and failure of both armodafinil and modafinil where indicated (narcolepsy and sleep apnea). Wakix requires a documented trial and failure of both armodafinil and modafinil where indicated (narcolepsy).	**Initial Approval:** 6 months **Renewal:** 1 year ***Requires:*** • Response to treatment • For Obstructive Sleep

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	May be authorized for members at least 17 years old for *excessive daytime sleepiness associated with narcolepsy* when the following is met: • Prescribed by, or in consultation with, a sleep specialist • Multiple sleep latency test (MSLT) or maintenance of wakefulness test (MWT) performed after polysomnography supports diagnosis of narcolepsy **May be authorized for members 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 Obstructive Sleep Apnea (OSA) • Member remains symptomatic despite optimization of Continuous Positive Airway Pressure (CPAP) or Bilevel Positive Airway Pressure (BIPAP) therapy, and compliance for at least 1 month • Continuous Positive Airway Pressure (CPAP) or Bilevel Positive Airway Pressure (BIPAP) will be continued after modafinil or armodafinil is started • Daytime fatigue is significantly impacting, impairing, or compromising the member's ability to function normally **Note: Wakix is not indicated for Obstructive Sleep Apnea (OSA). **May be authorized for members at least 17 years old for *excessive daytime sleepiness associated with Shift-Work Disorder (SWD)* when the following is met:**	Apnea (OSA): member must be compliant with Continuous Positive Airway Pressure (CPAP) or Bilevel Positive Airway Pressure (BIPAP) For Shift-Work Disorder (SWD): member must still be a shift-worker

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	• Prescribed by, or in consultation with, a sleep specialist • Sleep log and actigraphy monitoring have been completed for at least 14 days and show a disrupted sleep and wake pattern • Disruption is not due to another sleep disorder, medical condition, poor sleep hygiene, or substance abuse disorder Symptoms have been present for 3 or more months • The sleepiness is significantly impacting, impairing, or compromising the member's ability to function normally **Note: Sunosi and Wakix are not indicated for Shift-Work Disorder (SWD)	
Weight Reduction Medications[xciii] **Preferred:** Benzphetamine Phentermine Phendimetrazine Phendimetrazine XR Diethylpropion, Diethylpropion ER	**General Criteria for All Medications:** • Member has Body Mass Index (BMI) greater than or equal to 30kg/m^2 (obese)**; OR** • Member has Body Mass Index (BMI) greater than or equal to 27kg/m^2 (overweight) and ONE of the following obesity-related risk factors: ○ Coronary heart disease ○ Dyslipidemia ○ Hypertension ○ Diabetes ○ Sleep apnea ○ Osteoarthritis • Member is not pregnant and/or breastfeeding • Member is not receiving other medications for weight loss or has history of an eating disorder (for example anorexia, bulimia) • Member had failure with a weight loss treatment plan (for example low calorie diet,	**Initial Approval:** Saxenda: 4 months Xenical, Alli, Qsymia: 6 months All others: 3 months **First Renewal:** 6 months ***Requires:***

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
Orlistat (OTC Alli) Qsymia Contrave **Non-Preferred:** Saxenda Orlistat (Xenical)	increased physical activity and behavioral therapy) for a minimum of 6 months • Member will continue with low calorie diet, increased physical activity and behavioral therapy with requested drug **In addition, for Qsymia:** • Member is 18 years of age or older • Member meets ONE of the following: o Had an inadequate response, intolerable side effects, or a contraindication to orlistat (Alli) OR a sympathomimetic (for example, phentermine, diethylpropion, benzphetamine) o Had a good response to a sympathomimetic, however has taken the medication for the maximum recommended duration **In addition, for Contrave:** • Member is 18 years of age or older • Member meets ONE of the following: o Had an inadequate response, intolerable side effects, or a contraindication to orlistat (Alli) OR a sympathomimetic (for example, phentermine, diethylpropion, benzphetamine) o Had a good response to a sympathomimetic, however has taken the medication for the maximum recommended duration • Member is not using chronic opioids concurrently. • Member does not have seizure disorder or history of seizures • Member is not currently using monoamine oxidase inhibitors (MAOIs) • Comorbid mental health conditions have been ruled out or are stable/being adequately	• Documentation of weight loss of greater than or equal to 5% of baseline weight • Member's BMI is greater than or equal to 24 kg/m^2 **Additional Renewal:** 6 months ***Requires:*** • Member has maintained at least 67% of their initial weight loss • Member's BMI is greater than or equal to 24 kg/m^2 QLL: Xenical: 3 capsules per day

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	treated **In addition, for Saxenda:** • Member is 18 years of age or older • Member has had inadequate efficacy or intolerable side effects with trials of at least 3 formulary agents OR has contraindications to all formulary agents • Member is not concurrently on Victoza, other Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists, or insulin • Member does not have a personal or family history of Medullary Thyroid Carcinoma (MTC) or Multiple Endocrine Neoplasia Syndrome Type 2 (MEN 2) **Note: Saxenda is indicated for weight management only and should not be approved for treatment of type 2 diabetes mellitus **In addition, for Xenical:** • Member has had inadequate efficacy or intolerable side effects with a trial of three formulary agents OR has contraindications to all formulary agents • Member does not have any of the following: ○ Chronic malabsorption syndrome ○ Cholestasis • Member must be able to adhere to a low-fat diet (less than 30% of calories from fat)	Saxenda: 5 pens (15mL) per 30 days Formulary agents also have quantity and age limits. Refer to formulary for detailed information.
Xifaxan[xciv]	**Xifaxan 200mg may be authorized when the following are met:** • Treatment is for Traveler's Diarrhea • Member is 12 years of age or older • Member had inadequate response, intolerable side effect, or contraindication to azithromycin or a fluoroquinolone	**Initial Approval:** Traveler's Diarrhea: 3 days Hepatic Encephalopathy: 12 months

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	Xifaxan 550mg may be authorized when one of the following is met: • Treatment is for Irritable Bowel Syndrome with Diarrhea: • Member is 18 years of age or older • Member had inadequate response or intolerable side effect to at least 2 of the following agents: ○ Loperamide, bile acid sequestrants, antispasmodics, or tricyclic antidepressants • Treatment is for Hepatic Encephalopathy: • Member is 18 years of age or older and meets <u>one</u> of the following: ○ There was an inadequate response to a recent 3-month trial of lactulose and member will continue use of lactulose concomitantly with Xifaxan (review claim history) ○ There was an intolerable side effect to lactulose. (Provide date and type of adverse event experienced; unpleasant taste is not considered an intolerance to lactulose)	Irritable Bowel Syndrome with Diarrhea: One-time authorization of 14 days **<u>Renewal Approval</u>:** Hepatic Encephalopathy: 12 months ***Requires:*** Decreased symptoms or blood ammonia levels Irritable Bowel Syndrome with Diarrhea: 14 days; Maximum 3 treatment courses per year ***Requires:*** Symptom resolution during previous treatment course **<u>Quantity Level Limit</u>:** Irritable Bowel Syndrome with Diarrhea: 3 tablets

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		per day Traveler's Diarrhea: 3 tablets per day; Maximum 1 treatment course per 90 days Hepatic Encephalopathy: 2 tablets per day
Xolair[xcv]	**May be authorized when all of the following are met:** • Member six years of age and older • Diagnosis of moderate to 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 (for example: dust mite, animal dander, cockroach, etc.) • Documentation to support Immunoglobulin E (IgE) is between 30 and 1300 IU/mL • Member has been compliant with medium to high dose inhaled corticosteroids (ICS) + a long-acting beta agonist (LABA) for at least three months or other controller medications (for example: LTRA (Leukotriene Receptor Antagonists) or theophylline) if intolerant to a long-acting beta agonist (LABA) • Asthma symptoms are poorly controlled on one of the above regimens as defined by any of the following: ○ Daily use of rescue medications (short-acting inhaled beta-2 agonists) ○ Nighttime symptoms occurring more than once a week	**Initial Approval:** **Asthma:** 6 months **Chronic urticaria:** 3 months **Renewal:** **Asthma:** 1 year *Requires* Demonstration of clinical improvement (for example: decreased use

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ At least two exacerbations in the last 12 months requiring additional medical treatment (systemic corticosteroids, emergency department visits, or hospitalization) • Member will not receive in combination with Interleukin-5 (IL-5) antagonists (Nucala, Fasenra, or Cinqair) or Dupixent **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: ○ H1 antihistamine + Leukotriene inhibitor (montelukast or zafirlukast) ○ H1 antihistamine + H2 antihistamine (ranitidine or cimetidine) ○ H1 antihistamine + Doxepin ○ First generation + second generation antihistamine ***Note: Off-label use for Allergic Rhinitis or food allergy is not covered*** **Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus **	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 (for example: decreased itching) **<u>Dosing Restriction:</u>** **Asthma:** Per manufacturer, Do not exceed 375mg every 2 weeks

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
		Urticaria: Initial dose of 150mg per 4 weeks. Dose may be increased to 300mg per 4 weeks if necessary.
Xyrem[xcvi]	Documentation such as progress notes, lab results or other clinical information is required to support member has met all approval criteria below. **May be authorized for members 7 years of age or older when all the following criteria are met:** • Diagnosis of one of the following: ○ Severe Narcolepsy with cataplexy ○ Severe Narcolepsy with excessive daytime sleepiness • Member does not have succinic semialdehyde dehydrogenase deficiency (inborn error of metabolism variably characterized by mental retardation, hypotonia, and ataxia) • Prescribed by, or in consultation with a neurologist or sleep specialist that is board-certified by the American Board of Sleep Medicine • Member has no concomitant fills for Central Nervous System (CNS) depressants ○ Please note, Central Nervous System (CNS) depressant drugs may include, but are not limited to the following:	**Initial Approval:** 6 months **Renewal Approval:** 6 months ***Requires:*** • There are no concomitant fills for Central Nervous System (CNS) depressants • Adherence to medication as demonstrated by prescription claims history

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	▪ Alcohol ▪ Sedative hypnotics ▪ Narcotic analgesics ▪ Benzodiazepines ▪ Sedating antidepressants ▪ Sedating antipsychotics ▪ Sedating antiepileptic drugs ▪ General anesthetics ▪ Muscle relaxants • Polysomnography indicates the following: o At least 6 hours of sleep time occurred during the overnight polysomnogram o Other conditions of sleepiness have been ruled out • Multiple sleep latency test (MSLT) indicates the following: o Mean sleep latency is of 8 minutes or less o There are 2 or more sleep onset rapid eye movement periods (SOREMPs) (within 15 minutes of sleep onset) o If a sleep onset rapid eye movement period (SOREMP) is identified on polysomnography, then multiple sleep latency test (MSLT) can show one sleep onset rapid eye movement period (SOREMP) • Cataplexy:	• Response to therapy is indicated by a decrease in symptoms as demonstrated by Epworth Sleepiness Scale (ESS) and/or Maintenance of Wakefulness Test (MWT) **Quantity Level Limit:** 9 grams per day or 18 mL per day or 540 mL per 30 days

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PA Guideline	Requirements	Duration of Approval if Requirements Are Met
	○ Members that are 17 years of age or older require: ▪ Trial and failure, intolerance, or contraindication to Modafinil for a period of 60-days (prior authorization required) • Excessive Daytime Sleepiness: ○ Trial and failure, intolerance, or contraindication to 2 Central Nervous System (CNS) stimulants such as amphetamine, dextroamphetamine, or methylphenidate ▪ Dosage trial is for a period of 60 days at maximum tolerated dose ○ Members that are 17 years of age or older require: ▪ Trial and failure, intolerance, or contraindication to Modafinil ▪ Dosage trial is for a period of 60-days (prior authorization required) • Prescriber and member must both be enrolled in the Xyrem Risk Evaluation and Mitigation Strategy (REMS) Program	

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