# Aetna Better Health® of Florida

## Pharmacy Prior Authorization

## Non-Formulary and Prior Authorization Guidelines

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

| PA Guideline | Requirements | Duration of Approval if Requirements Are Met |
|---|---|---|
| **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 Prior Authorization 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 |
| **Step Therapy** | Medications requiring Step Therapy first go through trial and failure of formulary agent prior to approval<br><br>If prerequisite medications have been filled within specified time frame, prescription will automatically process at the pharmacy<br><br>Prior Authorization will be required for prescriptions that do not process automatically at pharmacy | **Initial Approval:**<br>One year<br><br>**Renewal Approval:**<br>One year<br><br>***Requires:***<br>Member response to treatment |
| **Quantity Level Limits** | Requests that exceed established Quantity Level Limits will require prior authorization<br><br>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<br><br>Approval of Quantity Level Limit exceptions are considered after medication specific prior authorization guideline and medical necessity review | **Initial Approval:**<br>One year<br><br>**Renewal Approval:**<br>One year |

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| | **Authorization Criteria for Quantity Limit Exceptions:**<br>• **Quantities that Exceed Food and Drug Administration (FDA) Maximum Dose:**<br>  ○ 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 | |

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| | ○ Request meets one of the following:<br>▪ Dose is included in drug compendia or evidence-based clinical practice guidelines for same indication<br>▪ Published randomized, double blind, controlled trial, demonstrating safety and efficacy of requested dose is submitted with request<br>• **Quantities that do not Exceed Food and Drug Administration (FDA) Maximum Dose (Dose Optimization):**<br>○ Request meets one of the following:<br>▪ There was inadequate response or intolerable side effect to optimized dose<br>▪ There is a manufacturer shortage of higher strengths<br>▪ Member is unable to swallow tablet/capsule due to size, and dosage form cannot be crushed<br>▪ Effect of medication is wearing off between doses<br>▪ Member cannot tolerate entire dose in one administration<br>• **Quantities for Medications that do not have Established Food and Drug Administration (FDA) Maximum Dose:**<br>○ 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<br>○ Requested dose is considered medically necessary | |
| **Anthelmintic**[i] | **Praziquantel pays at Point of Sale when one of the following infections is present:** | **Initial Approval:** |

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| Praziquantel (Biltricide) | • Flukes<br>  ○ Clonorchiasis<br>  ○ Opisthorchiasis<br>  ○ Paragonimiasis<br>  ○ Fasciolopsis<br>• Tapeworms<br>  ○ Schistosomiasis<br>  ○ Taeniasis<br>  ○ Cysticercosis/Neurocysticercosis<br>**Prescriptions for praziquantel that do not pay at Point of Sale may be approved for members who meet one of the following:**<br>• Trial and failure with ivermectin or pyrantel<br>• Infection falls either under Fluke or Tapeworm:<br>  ○ Flukes<br>  ▪ Clonorchiasis<br>  ▪ Opisthorchiasis<br>  ▪ Paragonimiasis<br>  ▪ Fasciolopsis<br>  ○ Tapeworms<br>  ▪ Schistosomiasis<br>  ▪ Taeniasis | Roundworm: 21 days<br>All others: 3 days<br><br>**Exceptions to Initial Approval**:<br>Cysticercosis/Neurocysticercosis: Up to 15 days |

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| | ▪ Cysticercosis/Neurocysticercosis | |
| **Anticoagulants - Oral**[ii]<br><br>Savaysa | **Savaysa may be authorized for members who meet all of the following:**<br>• Age is 18 years or older<br>• Diagnosis is for one of the following:<br>○ Non-valvular atrial fibrillation<br>▪ There is no moderate-to-severe mitral stenosis or mechanical heart valve<br>▪ Documentation of a $CHA_2DS_2$-VASc score of 1 or more (greater than or equal to 1 in males or greater than or equal to 2 in females)<br>▪ Creatinine clearance is less than 95 milliliters per minute<br>○ Treatment of Deep Vein Thrombosis and Pulmonary Embolism<br>• There was 5 – 10 days of initial therapy with parenteral anticoagulant | **Initial Approval:**<br>• Atrial fibrillation: 1 year<br>• Treatment of Deep Vein Thrombosis or Pulmonary Embolism:<br>○ 3 months<br>**Renewal Approval:**<br>• Atrial fibrillation:<br>○ 1 year<br>• Treatment of Deep Vein Thrombosis or Pulmonary Embolism:<br>○ 3 months<br>• American College of Chest Physicians (CHEST) recommends 3-month duration for most acute Venous Thromboembolism treatment |

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| | | **Quantity Level Limit:**<br>Savaysa: 1 tablet per day |
| **Cablivi**[iii] | **Member meets all the following criteria:**<br>• Age is 18 years or older<br>• Medication is prescribed by, or in consultation with a hematologist<br>• Diagnosis is for acquired thrombotic thrombocytopenic purpura (aTTP)<br>• Diagnosis is confirmed by one of the following:<br>  ○ Member has severe thrombocytopenia with microangiopathic hemolytic anemia (MAHA), confirmed by red blood cell fragmentation on peripheral blood smear<br>  ▪ For example, schistocytes<br>  ○ Testing shows ADAMTS13 activity levels of less than 10%<br>• Medication will be given in combination with plasma exchange and immunosuppressive therapy<br>  ○ For example, systemic glucocorticoids, rituximab<br>• Cablivi will be discontinued if member experiences more than 2 recurrences of aTTP while on treatment with Cablivi | **Initial Approval:**<br>30 days<br>**Renewal Approval:**<br>28 days<br>***Requires:***<br>Additional therapy up to a maximum of 28 additional days will be considered when provider submits the following:<br>• Documentation of remaining signs of persistent underlying disease<br>  ○ For example, suppressed |

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| | | ADAMTS13 activity levels<br>• Documentation date of prior episode and date of new episode<br>• Medication will be given in combination with plasma exchange and immunosuppressive therapy<br>  ○ For example, systemic glucocorticoids, rituximab<br>• Member has not experienced more than 2 recurrences while on Cablivi<br>**Quantity Level Limit:** |

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| | | Total treatment duration per episode is limited to 58 days beyond last therapeutic plasma exchange |
| **Cinacalcet**[iv] **(Sensipar)** | **Secondary Hyperparathyroidism due to Chronic Kidney Disease on Dialysis:**<br>• Member is at least 18 years of age<br>• Serum calcium greater than or equal to 8.4mg/dL, prior to initiation of therapy<br>• Intact parathyroid hormone (iPTH) greater than or equal to 300pg/mL, prior to initiation of therapy<br>• Inadequate response or intolerable side effect to at least one type of phosphate binder<br>• Member meets one of the following criteria:<br>  ○ Inadequate response or intolerable side effect to calcitriol or paricalcitol<br>  ○ Serum phosphate greater than or equal to 5.5mg/dL, or serum calcium greater than or equal to 9.5mg/dL, and there is persistently elevated parathyroid hormone (PTH), despite maximum therapies to decrease phosphate<br>**Parathyroid Cancer:**<br>• Member is at least 18 years of age<br>• Serum calcium is greater than or equal to 12.5mg/dL, prior to initiation of therapy<br>**Primary Hyperparathyroidism:**<br>• Member is at least 18 years of age | **Initial Approval:**<br>6 months<br><br>**Renewal Approval:**<br>1 year<br>***Requires:***<br>Serum Calcium 8.4-12.5mg/dL<br><br>**Dosing information:**<br>• Dialysis member with secondary hyperparathyroidism: Up to 300 mg/day |

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| | • Member is not a candidate for parathyroidectomy<br>• Serum calcium greater than or equal to 12.5mg/dL, prior to initiation of therapy | • Hypercalcemia associated with parathyroid carcinoma or primary hyperparathyroidism: Up to 360 mg/day |
| **Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists**[v]<br><br>Aimovig<br><br>Emgality 100mg<br><br>Emgality 300mg | **May be authorized when member meets the following criteria:**<br>• Prescribed by, or in consultation with neurologist for preventative treatment of migraines, treatment of acute migraines, or treatment of cluster headaches<br>• Age is 18 years or older<br>• **Chronic Migraine** (Aimovig):<br>○ Headache occurring on 15 or more days per month with at least 8 migraine days per month for more than 3 months<br>• **Episodic Migraine** (Aimovig):<br>○ Headache occurring less than 15 days per month with 4 to 14 migraine days per month<br>• For Chronic and Episodic migraines, there is documented inadequate response, or intolerable side effects, to at least two medications for migraine prophylaxis from two different classes, for at least 2 months: | **Initial Approval**:<br>3 months<br><br>**Renewal Approval:**<br>6 months<br><br>***Requires:***<br>• Documentation of reduction in migraine headache days from baseline<br>• Aimovig 140mg monthly injection |

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| | ○ Beta-Blockers: Propranolol, metoprolol, atenolol, timolol, nadolol<br>○ Anticonvulsants: Valproic acid, or divalproex, topiramate<br>○ Antidepressants: Amitriptyline, nortriptyline, venlafaxine, duloxetine<br>• **Episodic Cluster Headaches:** (Emgality)<br>○ Headaches occurring at maximum 8 attacks per day, or minimum one attack every other day<br>○ Trial and failure with verapamil for preventive treatment or sumatriptan (nasal or subcutaneous) for acute treatment<br>• Aimovig 140mg monthly injection, requires trial and failure with the 70mg injection<br>• Medication will not be used in combination with another Calcitonin Gene-Related Peptide Receptor (CGRP) antagonist, or with Botulinum toxin (Botox) | requires trial and failure with the 70mg injection<br>• Medication will not be used in combination with another Calcitonin Gene-Related Peptide Receptor (CGRP) antagonist, or with Botulinum toxin (Botox)<br><br>**Quantity Level Limits:**<br>**Aimovig**:<br>• 1mL per 30 days<br>**Emgality for Cluster Headaches:**<br>• 3mL for 1st 30 days then 1mL per 30 days |

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| **Direct Renin Inhibitors**[vi]<br><br>**Aliskiren (Tekturna) Tekturna HCT** | • Member is 6 years of age or older<br>• Diagnosis of hypertension<br>• For oral pellets:<br>  ○ Member is unable to swallow tablets<br>• There was inadequate response, or inability to tolerate at least 2 formulary antihypertensive agents from any of the following therapeutic classes:<br>  ○ Thiazide-type diuretic<br>  ○ Calcium Channel Blocker<br>  ○ Angiotensin-converting-enzyme (ACE) Inhibitor<br>  ○ Angiotensin receptor blocker (ARB)<br>• Member is not pregnant | **Initial Approval:**<br>6 months<br><br>**Renewal Approval**:<br>6 months<br><br>***Requires*:**<br>• Positive response to treatment<br>• Member is not pregnant |
| **Dry Eye Medications**[vii]<br><br>Cequa<br>Tryvaya | **May be approved when all the following criteria are met:**<br>• Cequa and Tryvaya:<br>  • Member is 18 years of age or older<br>• Prescribed by, or in consultation with, an ophthalmologist or optometrist<br>• Diagnosis of Keratoconjunctivitis Sicca (dry eye syndrome, dysfunctional tear syndrome), dry eye disease, or dry eyes due to Sjogren's Syndrome<br>• 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:**<br>6 months<br><br>**Renewal Approval:**<br>6 months<br><br>**Quantity Level Limit:**<br>• Tryvaya: 2 bottles per 30 days<br>• Others: 60 vials per 30 |

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| | | days |
| **Egrifta**[viii] | **Egrifta is approved when the following criteria are met:**<br>• Diagnosis of human immunodeficiency virus (HIV)-associated lipodystrophy<br>• Documentation of waist circumference greater than or equal to 95 cm for males, or greater than or equal to 94 cm for females at start of therapy<br>• Member is currently receiving anti-retroviral therapy<br>• Baseline evaluation within the past 3 months of the following:<br>  ○ Hemoglobin A1c (HbA1c)<br>  ○ Insulin-like growth factor 1 (IGF-1)<br>• Attestation Hemoglobin A1c (HbA1c) will be monitored every 3 to 4 months<br>• Member is at risk for medical complications due to excess abdominal fat<br>• Member does not have active malignancy<br>• Member does not have disruption of the hypothalamic-pituitary gland axis or head trauma<br>• Women of childbearing age are not pregnant and are using appropriate contraception | **Initial Approval:**<br>6 months<br><br>**Renewal Approval:**<br>6 months<br><br>***Requires*:**<br>Documentation of a positive clinical response:<br>• Hemoglobin A1c (HbA1c) within normal range (for the lab)<br>• Insulin-like growth factor 1 (IGF-1) within normal range (for the lab)<br>• Decrease in waist circumference |
| **Epidiolex**[ix] | **May be authorized when the following criteria are met:**<br>• Member is at least 1 years of age | **Initial Approval:**<br>6 months |

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| | • Prescribed by, or in consultation with a neurologist<br>• Medication will be taken as adjunctive therapy to at least one other antiepileptic drug<br>• 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)<br>• Dose must be appropriate for member's liver function and should not exceed 20mg/kg/day<br>• **For Lennox-Gastaut syndrome:**<br>  ○ Documentation member has tried and failed or has intolerance or contraindication to Onfi® (clobazam) and two of the following:<br>  ▪ Valproic acid, topiramate, lamotrigine, and/or felbamate<br>• **For Dravet syndrome:**<br>  ○ Documentation member has tried and failed or has intolerance or contraindication to Onfi® (clobazam), valproic acid, and one of the following:<br>  ▪ Topiramate, levetiracetam, zonisamide, lamotrigine, or felbamate<br>• **For seizures associated with tuberous sclerosis complex:**<br>  ○ Documentation member has tried and failed or has intolerance or contraindication any two antiepileptic agents | **Renewal Approval:**<br>1 year<br>***Requires*:**<br>• Member has had decrease in seizure frequency from baseline<br>• Serum transaminase level has not been greater than 3 times the upper limit of normal (ULN) while accompanied by bilirubin greater than 2 times the ULN<br>• Serum transaminase level has not been sustained at greater than 5 times the upper |

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| | *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. | limit of normal (ULN)<br><br>**Quantity Level Limit:**<br>• Lennox-Gastaut Syndrome and Dravet Syndrome: 20 mg/kg/day<br>• Tuberous Sclerosis Complex: 25 mg/kg/day<br><br>**All requests require current weight** to confirm correct dose not being exceeded |
| **Griseofulvin**[x] | Griseofulvin is approved when ONE of the following criteria is met:<br>• Member had inadequate response, intolerable side effect, or contraindication to ONE of the following agents:<br>  ○ fluconazole<br>  ○ itraconazole<br>  ○ ketoconazole<br>  ○ terbinafine | **Initial Approval**: 6 months<br><br>**Renewal Approval**: 6 months |

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

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| PA Guideline | Requirements | Duration of Approval if Requirements Are Met |
|---|---|---|
| | | Progesterone products will not be covered for uses related to infertility |
| **Multaq**[xii] | **Multaq may be authorized when the following criteria are met:**<br>• Member is 18 years of age or older<br>• Diagnosis of paroxysmal or persistent atrial fibrillation and<br>  ○ Member is currently in normal sinus rhythm, or<br>  ○ Member plans to undergo cardioversion to normal sinus rhythm<br>• Prescribed by, or in consultation with a cardiologist<br>• Attestation member does not have any contraindications as outlined per the prescribing information including, but not limited to the following:<br>  ○ Symptomatic heart failure with recent decompensation requiring hospitalization<br>  ○ New York Heart Association (NYHA) Class IV chronic heart failure<br>• Member had inadequate response, intolerable side effect, or contraindication to one of the following formulary alternatives:<br>  ○ amiodarone<br>  ○ propafenone<br>  ○ flecainide<br>  ○ sotalol | **Initial Approval:**<br>3 months<br><br>**Renewal Approval:**<br>6 months<br><br>***Requires:***<br>• Attestation that member has positive response to treatment<br>• Monitoring of electrocardiogram (ECG) every 3 months to make sure atrial fibrillation (AF) has not become permanent<br><br>**Quantity Level Limits:** |

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| PA Guideline | Requirements | Duration of Approval if Requirements Are Met |
|---|---|---|
| | | 60/30 days |
| **Injectable Osteoporosis** | InJectable Osteoporosis FL MMA | |
| **Oxervate**[xiii] | **May be authorized when member meets the following criteria:**<br>• Diagnosis is for treatment of stage 2 or Stage 3 neurotrophic keratitis<br>• Member is 2 years of age or older<br>• Member experienced persistent epithelial defects (PED), or corneal ulceration for at least 2 weeks<br>• There was trial and failure with one or more conventional non-surgical treatments<br>  ○ For example: preservative free artificial tears<br>• Documentation of decreased corneal sensitivity (less than or equal to 4 cm using the Cochet-Bonnet aesthesiometer) within the area of epithelial defects (PED) or corneal ulcer, and outside the area of the defect in at least one corneal quadrant<br>• The member has not received a previous 8-week course of Oxervate in the affected eye<br>• All other indications are considered experimental/investigational and not medically necessary | **Approval Duration:**<br>8 weeks total per eye<br><br>**Recommended Dosing:**<br>One drop in the affected eye(s), 6 times per day at 2-hour intervals, for 8 weeks |

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| PA Guideline | Requirements | Duration of Approval if Requirements Are Met |
|---|---|---|
| **Platelet Inhibitors**[xiv]<br><br>Zontivity | **May be approved when the following criteria are met:**<br>• Member has a history of Myocardial Infarction, or Peripheral Artery Disease<br>• Will be used with aspirin and/or clopidogrel<br>• Member does not have any of the following:<br>  ○ History of stroke (Transient Ischemic Attack)<br>  ○ Intracranial hemorrhage<br>  ○ Active pathological bleeding (for example, peptic ulcer) | **Approve for members stabilized in hospital**<br><br>**Initial Approval:**<br>12 months<br><br>**Renewal Approval:**<br>12 months<br><br>***Requires*:**<br>Member is not at high risk of bleeding, or has significant overt bleeding<br><br>**Quantity Level Limit:**<br>Zontivity: 1 tablet per day |

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| **Duration of Therapy Limits for Proton Pump Inhibitors (PPIs)**[xv]<br><br>Preferred:<br>• Esomeprazole 20 mg capsule OTC (over the counter)<br>• Lansoprazole 15 mg capsule Rx and OTC (prescription and over the counter)<br>• Lansoprazole 30 mg capsule Rx (prescription)<br>• First-Lansoprazole | 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.<br><br>Requests for a duration of therapy limit override for a non-preferred Proton Pump Inhibitor requires use of preferred Proton Pump Inhibitor (PPI) products.<br><br>A maximum duration of therapy override request for a Proton Pump Inhibitor will be authorized when one of the following criteria is met:<br>• Member has a documented upper gastrointestinal (GI) testing in the previous 2-year period<br>• Member is dependent on a feeding tube for nutritional intake<br>• Member resides in a long-term care facility<br>• Member is unable to taper off a Proton Pump Inhibitor (PPI) without return of symptoms<br>• Member is unable to transition to a histamine H2-receptor antagonist (H2 Blocker)<br>• 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<br><br>**Duration of Therapy Limit Exemptions for Proton Pump Inhibitors (PPIs)**<br>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: | Duration of override approval, both initial and reauthorization, to exceed the 180-day duration of therapy limit: One year |

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| | | |
|---|---|---|
| Suspension 3mg/mL (for members 12 years and younger)<br>• Omeprazole delayed release 20 mg tablet OTC (over the counter)<br>• Omeprazole 10 mg, 20 mg, 40 mg capsule Rx (prescription)<br>• Omeprazole magnesium 20.6 mg capsule OTC (over the counter) | • Member is under 6 years of age<br>• Member is receiving pancreatic enzymes<br>• Member receives a concomitant medication that increases the risk of upper gastrointestinal (GI) bleed (for example, anticoagulants, antiplatelets, Nonsteroidal Anti-inflammatory Drugs (NSAIDs))<br>• Member with one of the following diagnosis codes:<br>o Angiodysplasia of Stomach and Duodenum (with OR without Mention of Hemorrhage) (K31.81*)<br>o Atrophic Gastritis with Hemorrhage (K29.41)<br>o Barrett's Esophagus (K22.7*)<br>o Cerebral Palsy (G80*)<br>o Chronic Pancreatitis (K86.0, K86.1)<br>o Congenital Tracheoesophageal Fistula (Q39.1, Q39.2)<br>o Cystic Fibrosis (E84.*)<br>o Eosinophilic Esophagitis (K20.0)<br>o Eosinophilic Gastritis (K52.81)<br>o Gastrointestinal Hemorrhage (K92.2)<br>o Gastrointestinal Mucositis (Ulcerative) (K92.81)<br>o Malignant Mast Cell Tumors (C96.2*)<br>o Multiple Endocrine Adenomas (D44.0, D44.2, D44.9)<br>o Tracheoesophageal Fistula (J86.0)<br>o Ulcer of Esophagus with OR without Bleeding (K22.1*)<br>o Zollinger-Ellison Syndrome (E16.4) | |

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| PA Guideline | Requirements | Duration of Approval if Requirements Are Met |
|---|---|---|
| • First-Omeprazole Suspension 2 mg/mL (for members 12 years and younger)<br>• Pantoprazole 20 mg and 40 mg tablets Rx (prescription)<br>• Rabeprazole 20 mg tablet | * Any number or letter or combination of UP TO FOUR numbers and letters of an assigned ICD-10-CM diagnosis code | |

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|---|---|---|
| **High Dose Proton Pump Inhibitors (PPIs)**[xvi]<br><br>**Preferred agents:**<br>• Esomeprazole 20 mg capsule OTC (over the counter)<br>• Lansoprazole 15 mg capsule Rx and OTC (prescription and over the counter)<br>• Lansoprazole 30 mg capsule Rx (prescription)<br>• First-Lansoprazole | **High Dose Proton Pump Inhibitors (PPIs) will be authorized when the following criteria are met:**<br>• 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)<br>• Requests for high dose non-preferred Proton Pump Inhibitors (PPIs) require use of a preferred Proton Pump Inhibitor (PPI) at high dose | **Initial Approval:**<br>One year<br><br>**Renewal Approval:**<br>One year<br>***Requires:***<br>• Response to therapy<br>• Rationale for continuing high dose and failure to once daily dosing after completion of high dose course |

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| | | |
|---|---|---|
| Suspension 3mg/mL (for members 12 years and younger)<br>• Omeprazole delayed release 20 mg tablet OTC (over the counter)<br>• Omeprazole 10 mg, 20 mg, 40 mg capsule Rx (prescription)<br>• Omeprazole magnesium 20.6 mg capsule OTC (over the counter) | | |

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| PA Guideline | Requirements | Duration of Approval if Requirements Are Met |
|---|---|---|
| • First-Omeprazole Suspension 2 mg/mL (for members 12 years and younger)<br>• Pantoprazole 20 mg and 40 mg tablets Rx (prescription)<br>• Rabeprazole 20 mg tablet | | |
| **Reyvow**[xvii] | **May be authorized when the following criteria is met:**<br>• Prescribed by, or in consultation with a neurologist, or headache specialist<br>• Member is 18 years of age or older<br>• Diagnosis of migraine with or without aura according to the International Classification of Headache Disorders (ICHD-III) diagnostic criteria<br>• Headache pain is moderate to severe intensity<br>• Documented inadequate response or intolerable side effects with at least two triptans for at least one month each, or member has a contraindication to triptan use | **Initial Approval:**<br>3 months<br><br>**Renewal Approval:**<br>6 months<br>***Requires:***<br>• Response to therapy |

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|---|---|---|
| | • Prescriber attestation that member acknowledges and agrees to not drive or operate machinery until at least 8 hours after taking each dose | ○ for example, decrease in pain severity; decreased symptoms of photophobia, phonophobia, or nausea and or vomiting<br>• Prescriber attestation that member acknowledges and agrees to not drive or operate machinery until at least 8 hours after taking each dose<br><br>**Quantity Level Limit:**<br>4 tablets per 30 days |
| **Somatostatin Analogs**[xviii] | **General Authorization Criteria for ALL Indications:**<br>• Member is 18 year of age or older (unless prescribed for pediatric chemotherapy- | **Initial Approval:**<br>6 months |

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| PA Guideline | Requirements | Duration of Approval if Requirements Are Met |
|---|---|---|
| Sandostatin LAR<br>Signifor<br>Signifor LAR<br>Somavert<br>Somatuline depot | induced diarrhea)<br>• Sandostatin LAR and Somatuline Depot:<br>  ○ Baseline testing for the following:<br>  ▪ A1c or fasting glucose<br>  ▪ Thyroid-stimulating hormone<br>  ▪ Electrocardiography<br>• Somavert:<br>  ○ Baseline testing shows member's liver function tests (LFTs) are less than 3x the upper limit of normal (ULN)<br>• Signifor and Signifor Long-Acting Release:<br>  ○ Baseline testing for the following:<br>  ▪ A1c, or fasting plasma glucose<br>  ▪ Electrocardiography<br>  ▪ Potassium<br>  ▪ Magnesium<br>  ▪ Thyroid-stimulating hormone<br>  ▪ Liver function tests<br>  ▪ Attestation that gallbladder ultrasound has been completed<br>**Additional Criteria Based on Indication:**<br>• **Acromegaly**<br>Somatuline Depot, Signifor, Signifor Long-Acting Release, Somavert, Sandostatin | **Renewal Approval:**<br>• Acromegaly, Cushing's, Carcinoid and VIPomas: One year<br>• All other indications: 6 months<br>***Requires:***<br>Documentation of the following for all indications for somatostatin analogs:<br>• A1c or fasting glucose<br>• Electrocardiography<br>• Monitor for cholelithiasis and discontinue if complications of |

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|---|---|---|
| | Long-Acting Release:<br>○ Prescribed by, or in consultation with, an endocrinologist<br>○ Member has one of the following:<br>▪ Persistent disease following radiotherapy and/or pituitary surgery<br>▪ Surgical resection is not an option as evidenced by one of the following:<br>➢ Majority of tumor cannot be resected<br>➢ Member is a poor surgical candidate based on comorbidities<br>➢ Member prefers medical treatment over surgery, or refuses surgery<br>○ Baseline insulin-like growth factor-1 (IGF-1) meets one of the following criteria:<br>▪ Greater than or equal to 2.5 times the upper limit of normal for age<br>▪ Remains elevated despite a 6-month trial of maximally tolerated dose of cabergoline (unless member cannot tolerate, or has contraindication to cabergoline)<br>• **Carcinoid Tumor or Vasoactive Intestinal Polypeptide Secreting Tumor (VIPomas)**<br>Somatuline Depot, Sandostatin Long-Acting Release - To reduce frequency of short-acting somatostatin analog rescue therapy:<br>○ Prescribed by, or in consultation with, an oncologist or endocrinologist<br>• **Cushing's Syndrome**<br>Signifor, Signifor Long-Acting Release:<br>○ Member has persistent disease after pituitary surgery, or surgery is not an option<br>○ Member had inadequate response, intolerable side effects, or contraindication to | cholelithiasis are suspected<br>• Thyroid-stimulating hormone<br>• Response to therapy<br>**Documentation of additional requirements per indication or drug:**<br>• Acromegaly:<br>○ Decreased or normalized insulin-like growth factor-1 (IGF-1) levels<br>• Cushing's:<br>○ Decreased or normalized cortisol levels<br>• Somavert: |

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|---|---|---|
| | cabergoline<br>• **Gastro-entero-pancreatic neuroendocrine tumor**<br>Somatuline Depot, Sandostatin Long-Acting Release:<br>○ Prescribed by, or in consultation with, an oncologist or endocrinologist<br>○ Member has persistent disease after surgical resection, or is not a candidate for surgery | ○ Liver function tests<br>○ A1c or fasting glucose<br>○ Response to therapy<br>• Signifor:<br>○ Liver function tests<br>**Quantity Level Limits:**<br>• Signifor: 2 vials per day<br>• Signifor (LAR): 1 vial per 28 days<br>• Somavert: Maximum dose 30mg per day after loading dose<br>• Somatuline Depot: |

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|---|---|---|
| | | 1 syringe per 28 days |
| **Spiriva Respimat[xix] (Long-acting Muscarinic Agents [LAMA])** | **Incruse Ellipta** is the formulary preferred agent for the treatment of chronic obstructive pulmonary disease (COPD) and does not require prior authorization<br>**Spiriva Respimat may be authorized when:**<br>• Member is 6 years of age or older with a diagnosis of asthma<br>• Member is currently taking an inhaled corticosteroid (ICS), and will continue with an inhaled corticosteroid (ICS) when Spiriva is initiated<br>• There was a trial and failure with at least two formulary agents:<br>  ○ Inhaled corticosteroid<br>  ○ Inhaled corticosteroid with a long-acting beta-2 agonist<br>  ○ Montelukast or zafirlukast<br>NOTE: Spiriva HandiHaler, and Incruse Ellipta are not Food and Drug Administration (FDA) approved for asthma | **Initial Approval:**<br>12 months<br>**Renewal Approval:**<br>12 months<br>***Requires:***<br>Member is currently taking an inhaled corticosteroid (ICS), and will continue to take the inhaled corticosteroid (ICS) along with Spiriva Respimat |
| **Wakefulness Agents[xx]**<br>Armodafinil | **Excessive daytime sleepiness associated with narcolepsy:**<br>• Member is at least 17 years of age<br>• Prescribed by, or in consultation with, a sleep specialist<br>• A multiple sleep latency test (MSLT), or maintenance of wakefulness test (MWT) was performed after polysomnography supports diagnosis of narcolepsy<br>**Excessive daytime sleepiness associated with Obstructive Sleep Apnea:** | **Initial Approval:**<br>6 months<br>**Renewal Approval:**<br>1 year<br>***Requires:*** |

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|---|---|---|
| | • Member is at least 17 years of age<br>• Prescribed by, or in consultation with, a sleep specialist<br>• Polysomnography has confirmed the diagnosis of Obstructive Sleep Apnea<br>• Member remains symptomatic despite optimization of Continuous Positive Airway Pressure (CPAP), or Bilevel Positive Airway Pressure (BIPAP) therapy, with compliance for at least 1 month<br>• Continuous Positive Airway Pressure (CPAP), or Bilevel Positive Airway Pressure (BIPAP) is continued after modafinil or armodafinil is started<br>• Daytime fatigue is significantly impacting, impairing, or compromising the ability to function normally<br>**Excessive daytime sleepiness associated with Shift-Work Disorder:**<br>• Member is at least 17 years of age<br>• Prescribed by, or in consultation with a sleep specialist<br>• A sleep log and actigraphy monitoring have been completed for at least 14 days and show a disrupted sleep and wake pattern<br>• Disruption is not due to another sleep disorder, medical condition, poor sleep hygiene, or substance abuse disorder<br>• Symptoms have been present for 3 or more months<br>• The sleepiness is significantly impacting, impairing, or compromising the ability to function normally | • Response to treatment<br>• For Obstructive Sleep Apnea (OSA): member must be compliant with Continuous Positive Airway Pressure (CPAP) or Bilevel Positive Airway Pressure (BIPAP)<br>• For Shift-Work Disorder (SWD): member must still be a shift-worker |

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[i] **Anthelmintics references**

1. Biltricide [package insert]. Bayer Healthcare Pharmaceuticals, Inc., Whippany, NJ; 2019. https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/018714s018lbl.pdf. Accessed Sept 12, 2019.
2. Lexicomp [database online]. Available at: https://online.lexi.com/lco/action/home. Accessed September 12, 2019
3. Center of Disease Control and Prevention – Parasites. https://www.cdc.gov/parasites/ Accessed November 15, 2019
4. Praziquantel prescribing information. Par Pharmaceutical Chestnut Ridge, NY 10977 U.S.A. last revised 2017
5. Albendazole prescribing information. Amedra Pharmaceuticals LLC Horsham, PA 19044 U.S.A last revised 2016
6. Gold Standard, Inc. Clinical Pharmacology [database online]. Available at: http://www.clinicalpharmacology.com. Accessed November 15, 2019.

[ii] **Anticoagulants - Oral References**

1. Xarelto® [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; August 2021. http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/XARELTO-pi.pdf. Accessed November 4, 2021.
2. Eliquis® [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; April 2021. https://packageinserts.bms.com/pi/pi_eliquis.pdf. Accessed November 4, 2021.
3. Pradaxa® [package insert]. Ridgefiled, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; June 2021. https://docs.boehringer-ingelheim.com/Prescribing%20Information/PIs/Pradaxa/Pradaxa.pdf. Accessed November 4, 2021.
4. Savaysa® [package insert]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; March 2021. https://dsi.com/prescribing-information-portlet/getPIContent?productName=Savaysa&inline=true. Accessed November 4, 2021.
5. Oral Anticoagulants: Drug Class Review. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc. 2021. Retrieved from https://www.clinicalkey.com/pharmacology/resources/overviews?id=1479109. Accessed November 4, 2021.
6. January CT, Wann LS, Calkins H, et al. 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation; Guidelines Made Simple – Focused Update Edition. Journal of the American College of Cardiology. https://www.acc.org/~/media/Non-Clinical/Files-PDFs-Excel-MS-Word-etc/Guidelines/2019/2019-Afib-Guidelines-Made-Simple-Tool.pdf. Accessed July 20, 2020.
7. Lip GYH, Banjeree A, Boriani G, et al. Antithrombotic Therapy for Atrial Fibrillation: CHEST Guideline and Expert Panel Report. *Chest*. https://journal.chestnet.org/article/S0012-3692(18)32244-X/fulltext. Accessed July 20, 2020.
8. Kearon C, Akl EA, Ornelas J, et al. Antithrombotic Therapy for VTE Disease: CHEST Guideline and Expert Panel Report. *Chest*. https://journal.chestnet.org/article/S0012-3692(15)00335-9/fulltext. Accessed July 20, 2020.
9. Falck-Ytter Y, Francis CW, Johanson NA, et al. Prevention of VTE in Orthopedic Surgery Patients: Antithrombotic therapy and prevention of thrombosis, 9th ed: American College of Chest Physicians evidence-based clinical practice guidelines. Chest. 2012; 141(Suppl 2):e2788-e325S.

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1/9/2022, 2/1/2022, 5/23/2022, 6/7/2022, 7/8/2022, 8/1/2022, 2/1/2023, 2/10/2023
Current Version Effective: 2/23/2023

10. Streiff MB, Agnelli G, Connors JM, et al. Guidance for the Treatment of Deep Vein Thrombosis and Pulmonary Embolism. Journal of Thrombosis and Thrombolysis. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4715858/. Accessed July 20, 2020.
11. Guyatt GH, Akl EA, Crowther M, et al. Executive summary: Antithrombotic therapy and prevention of thrombosis, 9th ed: American College of Chest Physicians Evidence-based Clinical Practice Guidelines. Chest. 2012; 141(Suppl 2):e7S-e47S.
12. Walter A, Gallus A, et al. Oral Anticoagulant Therapy: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest. 2012; 141(Suppl 2): e44s-e88s..

[iii] **Cablivi**

1. Cablivi [package insert]. Genzyme Corporation. Cambridge, MA 02142. February 2019
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
3. George JN et al. Acquired TTP: Clinical manifestations and diagnosis. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com. Accessed on May 9, 2019.
4. National Heart, Lung, and Blood Institute. U.S. Department of Health & Human Services. Available at https://www.nhlbi.nih.gov/health-topics/thrombotic-thrombocytopenic-purpura. Accessed September 11, 2019
5. Scully M et al., Caplacizumab Treatment for Acquired Thrombotic Thrombocytopenic Purpura. NEJM. 2019;380:335-346. Available at https://www.nejm.org/doi/10.1056/NEJMoa1806311. Accessed September 11, 2019.
6. Coppo P, Schwarzinger M, Buffet M, et al. Predictive features of severe acquired ADAMTS13 deficiency in idiopathic thrombotic microangiopathies: the French TMA Reference Center experience. PLoS One 2010;5(4):e10208-e10208.

[iv] **Sensipar References**

1. Sensipar® [package insert]. Thousand Oaks, CA: Amgen Inc.; Revised December 2019. https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/sensipar/sensipar_pi_hcp_english.pdf. Accessed May 24, 2021.
2. KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease–Mineral and Bone Disorder (CKD-MBD). *Kidney International Supplements (2017) 7, 1–59 1*.
3. Quarles, L.D., & Berkoben, M. (2018). Management of secondary hyperparathyroidism in adult dialysis patients. In S. Goldfarb (Ed.), *UpToDate*. Retrieved May 24, 2021, from: https://www.uptodate.com/contents/management-of-secondary-hyperparathyroidism-in-adult-dialysis-patients.

[v] **Calcitonin Gene-Related Peptide (CGRP) Receptor Agents References**

1. Aimovig® [package insert]. Amgen Inc. Thousand Oaks, CA 91320-1799; Revised April 2020. https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/aimovig/aimovig_pi_hcp_english.ashx. Accessed September 14, 2020.

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1/9/2022, 2/1/2022, 5/23/2022, 6/7/2022, 7/8/2022, 8/1/2022, 2/1/2023, 2/10/2023
Current Version Effective: 2/23/2023

2. Emgality® [package insert]. Indianapolis, IN: Eli Lilly and Company; Revised December 2019. http://uspl.lilly.com/emgality/emgality.html#pi. Accessed September 14, 2020.
3. Ajovy® [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; Revised January 2020. https://www.ajovy.com/globalassets/ajovy/ajovy-pi.pdf. Accessed September 14, 2020.
4. Vyepti™ [package insert]. Lundbeck Seattle Pharmaceuticals, Inc; Revised February 2020.
5. https://www.lundbeck.com/upload/us/files/pdf/Products/Vyepti_PI_US_EN.pdf. Accessed September 14, 2020.
6. Ubrelvy™ [package insert]. Allergan USA, Inc; Revised June 2020. https://media.allergan.com/products/Ubrelvy_pi.pdf. Accessed September 14, 2020.
7. Nurtec™ ODT [package insert]. Biohaven Pharmaceuticals Inc; Revised March 2020. https://www.nurtec.com/pi. Accessed September 14, 2020.
8. E.W. Loder and M.S. Robbins. Monoclonal antibodies for migraine prevention: Progress, but not a panacea. JAMA. Vol. 319, August 15, 2019, p.1985. doi: 10.1001/jama.2018.4852.https://www.ncbi.nlm.nih.gov/pubmed/29800193
9. L.H. Lassen et al. CGRP may play a causative role in migraine. Cephalalgia. Vol. 22, February 1, 2002, p. 54. doi:10.1046/j. 1468-2982.2002.00310.x http://journals.sagepub.com/doi/abs/10.1046/j.1468-2982.2002.00310.x?journalCode=cepa
10. Smith, J.H., (2020). Preventive treatment of migraine in adults, In J.W. Swanson (Ed.), UpToDate. Retrieved September 15, 2020, from https://www.uptodate.com/contents/preventive-treatment-of-migraine-in-adults.
11. May, A. Cluster Headache: Treatment and Prognosis. Waltham, MA. UpToDate. Last Modified March 11, 2019. https://www.uptodate.com/contents/cluster-headache-treatment-and-prognosis. Accessed August 15, 2019.
12. Smith, J.H. (2020). Acute treatment of migraine in adults. In J.W. Swanson (Ed.), UpToDate. Retrieved March 25, 2020 from: https://www.uptodate.com/contents/acute-treatment-of-migraine-in-adults.
13. Headaches in over 12s: diagnosis and management. National Intitute for Health and Care Excellence (NICE). Last updated November 2015. https://www.nice.org.uk/guidance/cg150. Accessed August 15, 2019.
14. (2019), The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. Headache: The Journal of Head and Face Pain, 59: 1-18. doi:10.1111/head.13456.

[vi] **Direct Renin Inhibitors References**

1. James PA, Oparil S, Carter BL, et al. 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults: Report From the Panel Members Appointed to the Eighth Joint National Committee (JNC 8). JAMA. 2014;311(5):507-520. doi:10.1001/jama.2013.284427.
2. Tekturna [package insert]. Noden Pharma USA Inc, Boston, MA; November 2017. http://www.tekturna.com/wp-content/uploads/2017/11/Tekturna_PCR-1.pdf.Accessed October 17, 2019

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1/9/2022, 2/1/2022, 5/23/2022, 6/7/2022, 7/8/2022, 8/1/2022, 2/1/2023, 2/10/2023
Current Version Effective: 2/23/2023

3. Tekturna HCT [package insert]. Noden Pharma USA Inc, Boston, MA; November 2016. http://www.tekturna.com/wp-content/uploads/2017/11/TekturnaHCT_PCR-1.pdf. Accessed October 17, 2019.
4. Flynn JT, Kaelber DC, Baker-Smith CM, et al. Clinical Practice Guideline for Screening and Management of High Blood Pressure in Children and Adolescents. Pediatrics. September 2017, Volume 140 Issue 3. 10.1542/peds.2017-1904. http://pediatrics.aappublications.org/content/early/2017/08/21/peds.2017-1904#T47.
5. Whelton PK, Carey RM, Aronow WS, et al. **2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Journal of the American College of Cardiology. 2018; 71(19):127-248. doi:**10.1016/j.jacc.2017.11.006.
6. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc., URL: http://www.clinicalpharmacology-ip.com/. Updated 2017. Accessed October 17, 2019.
7. Aliskiren, Jacobs, TF, Terrell, JM. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK507868/. Accessed November 20, 2019.

**Dry Eye Medications[vii] References**

1. Cequa™ (cyclosporine ophthalmic solution) 0.09% [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; September 2019. https://cequapro.com/pdf/CequaPI.pdf. Accessed July 27, 2021.
2. Restasis® (cyclosporine ophthalmic emulsion) 0.05% [package insert]. Irvine, CA: Allergan, Inc; July 2017. https://media.allergan.com/actavis/actavis/media/allergan-pdf-documents/product-prescribing/RESTASIS_pi.pdf. Accessed July 27, 2021.
3. Xiidra® (lifitegrast 5% ophthalmic solution) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2020. https://www.novartis.us/sites/www.novartis.us/files/xiidra.pdf. Accessed July 27, 2021.
4. Tryvaya™ (varenicline solution) [package insert]. Princeton, NJ: Oyster Point Pharma Inc., October 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213978s000lbl.pdf. Accessed November 11, 2021.
5. Baer AN, Akpek EK. Treatment of dry eye in Sjögren's syndrome: General principles and initial therapy. July 2020. In Romain PL (Ed), retrieved from https://www.uptodate.com/contents/treatment-of-dry-eye-in-sjogrens-syndrome-general-principles-and-initial-therapy . Accessed July 27, 2021.
6. American Academy of Ophthalmology Retina Panel. Preferred Practice Pattern® Guidelines. Dry Eye Syndrome. San Francisco, CA: American Academy of Ophthalmology; November 2018. https://www.aao.org/preferred-practice-pattern/dry-eye-syndrome-ppp-2018. Accessed July 27, 2021.
7. Foulks GN, Forstot SL, Donshik PC, et al. Clinical guidelines for management of dry eye associated with Sjögren disease. Ocul Surf 2015; 13:118. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/25881996 . Accessed July 27, 2021.

**[viii] Egrifta References:**

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1/9/2022, 2/1/2022, 5/23/2022, 6/7/2022, 7/8/2022, 8/1/2022, 2/1/2023, 2/10/2023
Current Version Effective: 2/23/2023

1. Egrifta® [package insert]. Theratechnologies, Inc., Montreal, Quebec, Canada; July, 2018. https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/022505s011lbl.pdf. Accessed September 6, 2019.
2. Clinical Pharmacology. http://www.clinicalpharmacology-ip.com/Default.aspx. Accessed September 6, 2019.
3. Treatment of HIV-associated lipodystrophy. UpToDate. https://www.uptodate.com. Accessed September 11, 2019.
4. Stanley T, Falutz J, Marsolais C, et al. Reduction in visceral adiposity is associated with an improved metabolic profile in HIV-infected patients receiving tesamorelin. Clin Infect Dis. 2012 Jun;54(11):1642-51. Accessed September 12,2019
5. Clinical Review Report: Tesamorelin (Egrifta) [Internet]. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; 2016 Aug. https://www.ncbi.nlm.nih.gov/books/NBK539131/ Accessed September 6, 2019

[ix] **Epidiolex®**

1. Epidiolex® [package insert]. Greenwich Biosciences, Inc, Carlsbad, CA; Revised December 2018. https://www.epidiolex.com/sites/default/files/EPIDIOLEX_Full_Prescribing_Information.pdf. Accessed Novermber 14, 2019.
2. Gold Standard, Inc. Epidiolex. Clinical Pharmacology [database online]. Available at: http://www.clinicalpharmacology.com. Accessed November 14, 2019.
3. Wilfong A. Epilepsy Syndromes in Children. Waltham, MA: UpToDate. Last modified: September 27, 2019. https://www.uptodate.com/contents/epilepsy-syndromes-in-children. Accessed December 10, 2019.
4. Nascimento FA, Andrade DM. Dravet Syndrome: Management and Prognosis. Waltham, MA. UpToDate. Last modified February 1, 2019. https://www.uptodate.com/contents/dravet-syndrome-management-and-prognosis. Accessed December 10, 2019.

[x] **Griseovulvin References**

1. Griseofulvin [package insert]. Actavis Pharma, Inc. Parsippany, NJ; Revised December 2018. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=af318d5d-cc39-4a63-a590-b87c50f2694f&type=display. Accessed December 10, 2019.
2. Gold Standard, Inc. Griseofulvin. Clinical Pharmacology [database online]. Available at: http://www.clinicalpharmacology.com. Accessed December 10, 2019.
3. Goldstein, A.O., Goldstein, B.G., (2019). Dermatophyte (tinea) infections, In Ofori, A.O. (Ed), UpToDate. Retrieved December 10, 2019 from https://www.uptodate.com/contents/dermatophyte-tinea-infections.
4. Treat, J.R., (2019). Tinea capitis, In Ofori, A.O. (Ed), UpToDate. Retrieved December 10, 2019 from https://www.uptodate.com/contents/tinea-capitis.

[xi] **Intravaginal Progesterone Products References**

1. Crinone [package insert]. Actavis Pharma, Inc., Parsippany, NJ; Revised November 2017. https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=7def92fe-d521-41c0-b419-48e028f59f15. Accessed December 13, 2019.

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1/9/2022, 2/1/2022, 5/23/2022, 6/7/2022, 7/8/2022, 8/1/2022, 2/1/2023, 2/10/2023
Current Version Effective: 2/23/2023

2. Endometrin [package insert]. Ferring Pharmaceuticals., Parsippany, NJ; Revised September 12, 2019. https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=2ba50fa9-b349-40cb-9a4b-1af8faa4ec09. Accessed December 13, 2019.
3. First-progesterone suppositories [package insert]. Cutis Pharm, Wilmington, MA; May 2015.
4. The American College of Obstetricians and Gynecologists. Committee on Practice Bulletins – Obstetrics, Practice Bulletin: Prediction and Prevention of Preterm Birth. *Obstetrics & Gynecology*. Oct 2012; 120;4: 964-973.
5. National Institute for Health and Care Excellence. Preterm labour and birth (NG25): NICE guideline. Aug. 2019.
6. O'brien, J.M., DeFranco, E.A., Adair, C.D., Lewis, D.F., Hall, D.R., How, H., Bsharat, M., and Creasy, G.W. Effect of progesterone on cervical shortening in women at risk for preterm birth: secondary analysis from a multinational, randomized, double-blind, placebo-controlled trial. *Ultrasound Obstet Gynecol* 2009; 34:653-659.
7. Coomarasamy, A., Williams, H., Truchanowicz, E., et al. A randomized trial of progesterone in women with recurrent miscarriages. *N Engl J Med*. 2015;373:2141-8.
8. Gold Standard, Inc. Progesterone. Clinical Pharmacology [database online]. Available at: http://www.clinicalpharmacology.com. Accessed December 13, 2019.
9. Norwitz, E.R. (2019). Progesterone supplementation to reduce the Risk of spontaneous preterm birth. In C.J. Lockwood (Ed), *UpToDate*. Retrieved December 13, 2019 from https://www.uptodate.com/contents/progesterone-supplementation-to-reduce-the-risk-of-spontaneous-preterm-birth.
10. Corrine, K.W., & Barbieri, R.L. (2018). Evaluation and management of secondary amenorrhea. In W.F. Crowley & M.E. Geffner (Ed), *UpToDate*. Retrieved December 13, 2019, from https://www.uptodate.com/contents/evaluation-and-management-of-secondary-amenorrhea.

[xii] **Multaq References**

1. Multaq® [package insert]. Sanofi-Aventis U.S. LLC, Bridgewater, NJ; January 2017. http://products.sanofi.us/multaq/multaq.html. Accessed December 11, 2019.
2. 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation: Executive Summary. *Circulation*. 2014; 130:2071-2104.
3. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS. European Heart Journal (2016) 37, 2893–2962 doi:10.1093/eurheartj/ehw210.
4. Teme, Tonye, Goldberger, Jeffrey J. Efficacy and tolerability of dronedarone for patients with atrial fibrillation. *Cardiology Journal*. 2013. 20(5): 486-490.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc., URL: http://www.clinicalpharmacology-ip.com/. Updated periodically. Accessed December 11, 2019.
6. CORDARONE Amiodarone tablets [Prescribing Information]. Pfizer Wyeth Pharmaceuticals Inc. Philadelphia, PA. March 2015.
7. January CT, Wann S, Alpert JS, et al. 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. Journal of the American College of Cardiology. 2014;64(21). doi.org/10.1016/j.jacc.2014.03.022.
8. Passman, R., Giardina, E.G., (2018), Clinical uses of dronedarone, In B.C. Downey (Ed), UpToDate. Retrieved October 31, 2018 from

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1/9/2022, 2/1/2022, 5/23/2022, 6/7/2022, 7/8/2022, 8/1/2022, 2/1/2023, 2/10/2023
Current Version Effective: 2/23/2023

9. Kumar, K.K., (2017), Antiarrhythmic drugs to maintain sinus rhythm in patients with atrial fibrillation: Recommendations, In G.M. Saperia (Ed), UpToDate. Retrieved October 31, 2018 from https://www.uptodate.com/contents/antiarrhythmic-drugs-to-maintain-sinus-rhythm-in-patients-with-atrial-fibrillation-recommendations

[xiii] **Oxervate References**

15. Oxervate [package insert]. Boston, MA: Dompe U.S. Inc.; October 2019. https://oxervate.com/wp-content/uploads/2020/05/OXERVATE_Prescribing_Information_102019.pdf. Accessed September 7, 2021.

[xiv] **Platelet Inhibitors References**

1. Vandvik, Per Olav, Lincoff, Michael A, Gore, Joel M, et al. Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *CHEST Journal*. February 2012; 141(2_suppl)
2. O'Gara, Patrick, Kushner, Frederick et al. 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction: Journal of the American College of Cardiology http://www.onlinejacc.org/content/accj/61/4/e78.full.pdf?_ga=2.16281206.1583954993.1522813721-1795673358.1522813721 Accessed April 03, 2018.
3. Levine, Glenn N., Bates, Eric R., Bittl, John A., et al. 2016 ACC/AHA Guideline Focused Update on Duration of Dual Antiplatelet Therapy in Patients with Coronary Artery Disease. A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines http://www.onlinejacc.org/content/accj/68/10/1082.full.pdf?_ga=2.139399226.861223083.1560897735-963373453.1560897735. Accessed June 18, 2019.
4. Bonaca MP1, Gutierrez JA2, Creager MA2, et al. Acute Limb Ischemia and Outcomes with Vorapaxar in Patients with Peripheral Artery Disease: Results from the Trial to Assess the Effects of Vorapaxar in Preventing Heart Attack and Stroke in Patients With Atherosclerosis-Thrombolysis in Myocardial Infarction 50 (TRA2°P-TIMI 50). Circulation. 2016 Mar 8;133(10):997-1005. doi: 10.1161/CIRCULATIONAHA.115.019355. Epub 2016 Jan 29. https://www.ncbi.nlm.nih.gov/pubmed?term=26826179. Accessed June 19, 3019.
5. BRILINTA (ticagrelor) [package insert]. Wilmington, DE: AstraZeneca LP. Revised November 2020. Retrieved from https://www.azpicentral.com/brilinta/brilinta.pdf#page=1. Accessed July 22, 2021.
6. S C Johnston, P Amarenco, H Denison, S. Evans. Ticagrelor and Aspirin or Aspirin Alone in Acute Ischemic Stroke or TIA. N Engl J Med 2020; 383:207-217. https://www.nejm.org/doi/full/10.1056/nejmoa1916870. Accessed July 22, 2021.
7. ZONTIVITY (vorapaxar) [package insert]. Kenilworth, NJ: Merck & Co., Inc. Revised November 2019. Retrieved from https://www.zontivityhcp.com/files/Zontivity_Prescribing_Information.pdf. Accessed July 22, 2021.
8. Franchi F, Rollini F, Rivas A, Wali M, et al. Platelet Inhibition with Cangrelor and Crushed Ticagrelor in Patients With ST-Segment-Elevation Myocardial Infarction Undergoing Primary Percutaneous Coronary Intervention. Circulation. 2019;139(14):1661. https://www.ncbi.nlm.nih.gov/pubmed?term=30630341. Accessed June 19, 2019.

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1/9/2022, 2/1/2022, 5/23/2022, 6/7/2022, 7/8/2022, 8/1/2022, 2/1/2023, 2/10/2023
Current Version Effective: 2/23/2023

9. Berger, JS, Davies, MG., (2019). UpToDate. Overview of lower extremity peripheral artery disease In Collins, KA, (Ed)., Retrieved from https://www.uptodate.com/contents/overview-of-lower-extremity-peripheral-artery-disease?search=Overview%20of%20lower%20extremity%20peripheral%20artery%20disease&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1. Accessed June 19, 2019.
10. Lincoff, A.M., Cutlip, D. (2019) UpToDate. Antiplatelet agents in acute ST-elevation myocardial infarction In GM Saperia (Ed)., Retrieved from https://www.uptodate.com/contents/antiplatelet-agents-in-acute-st-elevation-myocardial-infarction?search=Antiplatelet%20agents%20in%20acute%20ST-elevation%20myocardial%20infarction&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1. Accessed June 19, 2019.

[xv] **Duration of Therapy Limits for Proton Pump Inhibitors (PPIs) References**

1. Vilcu AM, Sabatte L, Blanchon T, et al. Association between acute gastroenteritis and continuous use of proton pump inhibitors during winter periods of highest circulation of enteric viruses. *JAMA Netw Open*. 2019;2(11):e1916205. doi:10.1001/jamanetworkopen.2019.16205
2. Maes ML, Fixe DR, Linnebur SA. Adverse effects of proton-pump inhibitor use in older adults: a review of the evidence .*Ther Adv Drug Saf* .**297-273:(9)8;2017** . doi**2042098617715381/10.1177**:
3. Rotman SR, Bishop TF. Proton pump inhibitor use in the U.S. ambulatory setting, 2002-2009. *PLoS One*. 2013;8(2):e56060. doi:10.1371/journal.pone.0056060
4. Farrell B, Pottie K, ThompsonW, et al. Deprescribing proton pump inhibitors: evidence-based clinical practice guideline. *Can Fam Physician*. 2017;63(5):354-364.
5. Heidelbaugh JJ, Kim AH, Chang R, Walker PC. Overutilization of proton pump inhibitors: what the clinician needs to know. *Therap Adv Gastroenterol* 2012;5(4):219-32

[xvi] **High Dose Proton Pump Inhibitors (PPIs) References**

[xvii] **Reyvow References**

1. Reyvow™ [package insert]. Indianapolis, IN: Lilly USA, LLC; Revised January 2021. http://uspl.lilly.com/reyvow/reyvow.html#pi. Accessed July 2021.
2. Oswald JC, Schuster NM. Lasmiditan for the treatment of acute migraine: a review and potential role in clinical practice. J Pain Res. 2018;11:2221. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6181111/. Accessed July 23, 2021
3. The American Headache Society Position Statement on Integrating New Migraine Treatments into Clinical Practice. Headache: The Journal of Head and Face Pain, 59: 1-18. (2018). https://headachejournal.onlinelibrary.wiley.com/doi/full/10.1111/head.13456. Accessed July 23, 2020.
4. Smith, J.H. (2020). Acute treatment of migraine in adults. *UpToDate*. In J.W. Swanson (Ed.), UpToDate. Retrieved July 22, 2021 from: https://www.uptodate.com/contents/acute-treatment-of-migraine-in-adults.

[xviii] **Somatostatin Analogs**

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1/9/2022, 2/1/2022, 5/23/2022, 6/7/2022, 7/8/2022, 8/1/2022, 2/1/2023, 2/10/2023
Current Version Effective: 2/23/2023

1. Sandostatin Long Acting Release (LAR) Depot (octreotide acetate) [package insert]. Novartis Pharmaceuticals Corporation; April 2019Revised March 2021. https://www.novartis.us/sites/www.novartis.us/files/sandostatin_lar.pdf. Accessed April 27, 2020July 28, 2021.
2. Sandostatin (octreotide acetate) [package insert]. West Hartford, CT: Novartis Pharmaceuticals Corporation; April 2019Revised May 2021. https://www.novartis.us/sites/www.novartis.us/files/sandostatin_inj.pdf. Accessed April 27, 2020July 28, 2021.
3. Signifor LAR (pasireotide) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; https://www.signiforlar.com/pdf/signifor-lar-pi.pdf. April 2019Revised June 2020.
4. Somatuline Depot (lanreotide) [package insert]. Signes, France: Ipsen Pharma Biotech; June 2019. https://www.ipsen.com/websites/Ipsen_Online/wp-content/uploads/2019/08/30162316/Somatuline_Depot_Full_Prescribing_Information_7.22.19.pdf. Accessed April 27, 2020July 28, 2021.
5. Signifor [package insert]. Lebanon, NJ: Recordati Rare Diseases Inc; March 2020. https://www.recordatirarediseases.com/sites/www.recordatirarediseases.com/files/inline-files/SIGNIFOR_Prescribing_Information.pdf. Accessed April 27, 2020July 28, 2021.
6. Somavert [package insert]. New York, NY: Pfizer Inc; September 2019. http://labeling.pfizer.com/ShowLabeling.aspx?id=3213. Accessed May 27, 2020July 28, 2021.
7. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; Retrieved from https://www.clinicalkey.com/pharmacology. Accessed April 27, 2020.
8. Melmed, S Bronstein MD, Chanson P, et al. A Consensus Statement on acromegaly therapeutic outcomes. Nature Reviews/Endocrinology. 2018; 14 :552-561.
9. Strosburg JR, Halfdanarson RT, and Blizzi AM, et al. The North American Neuroendocrine Tumor Society Consensus Guidelines for Surveillance and Medical Management of Midgut Neuroendocrine Tumors. Pancreas. 2017; 46: 707-714.
10. Melmed S. Treatment of acromegaly. Waltham, MA; UptoDate. http://www.uptodate.com/contents/treatment-of-acromegaly?source=search_result&search=acromegaly&selectedTitle=2%7E84. Accessed August 17, 2017.
11. National Comprehensive Cancer Network. NCCN Clinical Practice Guideline in Oncology: Neuroendocrine Tumors. http://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf Version 2.2021 - June 18, 2021Version 1.2015. Accessed August 17, 2017July 28, 2021.
12. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab, 2014;99(11):3933–3951.
13. Skagen C, Einstein M, Lucey MR, et al. Combination treatment with octreotide, midodrine, and albumin improves survival in patients with Type I and Type 2 hepatorenal syndrome. J Clin Gastroenterol 2009;43:680-685.
14. Nieman, L.K. (2017). Overview of the treatment of Cushing's syndrome. In KA Martin (Ed). UpToDate. Retrieved from https://www.uptodate.com/contents/overview-of-the-treatment-of-cushings-syndrome?search=cushings%20syndrome&source=search_result&selectedTitle=3~150&usage_type=default&display_rank=3#H609003423. Accessed June 11, 2019July 28, 2021.

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1/9/2022, 2/1/2022, 5/23/2022, 6/7/2022, 7/8/2022, 8/1/2022, 2/1/2023, 2/10/2023

Current Version Effective: 2/23/2023

15. Melmed, S., Katznelson L., (201921). Treatment of acromegaly. In KA Martin, (Ed). UpToDate. Retrieved from https://www.uptodate.com/contents/treatment-of-acromegaly?search=acromegaly&source=search_result&selectedTitle=3~90&usage_type=default&display_rank=3#H33. Accessed April 24, 2020July 28, 2021.
16. Bergsland, E., VIPoma: Clinical manifestations, diagnosis, and management (20192021) In S. Grover (Ed.), UpToDate. Retrieved from https://www.uptodate.com/contents/vipoma-clinical-manifestations-diagnosis-and-management?sectionName=Somatostatin%20analogs&search=somatostatin%20analogues&topicRef=2579&anchor=H7&source=see_link#H1664653297. Accessed June 12, 2019July 28, 2021.
17. Liddle, R.A., Physiology of somatostatin and its analogues. (20192021). In S. Grover (Ed.), UpToDate. Retrieved from https://www.uptodate.com/contents/physiology-of-somatostatin-and-its-analogues?search=somatostatin%20analogues&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1#H667400. Accessed Junely 12, 201928, 2021.

[xix] **Spiriva Respimat**

1. Spiriva Handihaler® [package insert]. Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT; Revised February 2018. https://docs.boehringer-ingelheim.com/Prescribing%20Information/PIs/Spiriva/Spiriva.pdf. Accessed October 28, 2021.
2. Spiriva Respimat® [package insert]. Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT; Revised October 2020. https://docs.boehringer-ingelheim.com/Prescribing%20Information/PIs/Spiriva%20Respimat/spirivarespimat.pdf. Accessed October 28, 2021.
3. Yupelri® [package insert]. Mylan Specialty LP, Morgantown, WV; Revised May 2019. https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210598s000lbl.pdf. Accessed October 28, 2021.
4. Global Strategy for Asthma Management and Prevention. Global Initiative for Asthma (GINA) 2021. https://ginasthma.org/wp-content/uploads/2021/05/GINA-Main-Report-2021-V2-WMS.pdf. Accessed October 28, 2021.
5. Szefler SJ, Murphy K, Harper T 3rd, et al. A phase III randomized controlled trial of tiotropium add-on therapy in children with severe symptomatic asthma. Journal of Allergy and Clinical Immunology. 2017;140(5):1277-1287.[PubMed 28189771]10.1016/j.jaci.2017.01.014

[xx] **Wakefulness Agents References**

1. Nuvigil® [prescribing information]. North Wales, PA; TEVA Pharmaceuticals/Cephalon, Inc. November 2018. https://www.nuvigil.com/globalassets/nuvigil-consumer/nuv-40995-nuvigil-pi-nuv-010-11-2018-digital2.pdf. Accessed November 30, 2021.
2. Provigil® [prescribing information]. North Wales, PA; TEVA Pharmaceuticals/Cephalon, Inc. November 2018. http://www.provigil.com/pdfs/prescribing_info.pdf. Accessed November 30, 2021.

Previous Version Effective: 6/1/2018, 8/1/2018, 10/1/2018, 12/1/2018, 2/4/2019, 4/1/2019, 6/3/2019, 8/1/2019, 12/2/2019, 4/1/2020, 6/8/2020, 8/3/2020, 8/18/2020, 9/1/2020, 6/28/2021, 8/1/2021, 9/13/2021, 1/9/2022, 2/1/2022, 5/23/2022, 6/7/2022, 7/8/2022, 8/1/2022, 2/1/2023, 2/10/2023
Current Version Effective: 2/23/2023

3. Sunosi™ [prescribing information]. Palo Alto, CA; Jazz Pharmaceuticals. October 2021. https://pp.jazzpharma.com/pi/sunosi.en.USPI.pdf. Accessed November 30, 2021.
4. Wakix® [prescribing information]. Plymouth Meeting, PA; Harmony Biosciences, LLC. March 2021. https://wakixhcp.com/assets/pdf/WAKIX%20(pitolisant)%20tablets%20PI.pdf. Accessed November 30, 2021.
5. Gold Standard, Inc. Clinical Pharmacology [database online]. http://www.clinicalpharmacology.com. Accessed August 6,2020.
6. Chervin RD. Approach to the Patient with Excessive Daytime Sleepiness. Waltham, MA. UpToDate. Last Modified 2021. https://www.uptodate.com/contents/approach-to-the-patient-with-excessive-daytime-sleepiness. Accessed November 30, 2021.
7. Morgenthaler TJ, Kapur VK, Brown T, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. Sleep 2007;30(12):1705-11.
8. Epstein LJ, Kristo D, Strollo PJ Jr, et al. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. J Clin Sleep Med. 2009;5(3):263–276.
9. Cheng P, Drake CL. Sleep-wake Disturbances in Shift Workers. Waltham, MA. UpToDate. Last Modified 2021. https://www.uptodate.com/contents/sleep-wake-disturbances-in-shift-workers. Accessed November 30, 2021.
10. Pepin JL, (2021). Evaluation and management of residual excessive sleepiness in adults with obstructive sleep apnea; UpToDate; In (Ed.), G Finlay, Retrieved from https://www.uptodate.com/contents/evaluation-and-management-of-residual-excessive-sleepiness-in-adults-with-obstructive-sleep-apnea?search=Wakefulness%20Agents&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1#H563912926. Accessed November 30, 2021.