Alabama Medicaid
Preferred Drug and Prior Authorization Program

Prior Authorization (PA) Criteria Instructions

This document contains detailed instructions on completing the Medicaid Prior Authorization Form, Form 369. Separate PA forms for the opioid use disorder agents, smoking cessation agents, and growth failure agents can be found on the Alabama Medicaid Agency website. Additionally, separate prior authorization (PA) forms and instructions for the Targeted Immunomodulators (TIMs)/Biologics/DMARDs, Synagis, and hepatitis C antiviral agents can be found on the Agency website.

Effective October 1, 2003, as a result of legislation passed in June 2003, the Alabama Medicaid Agency implemented a mandatory Preferred Drug List (PDL). Brand name preferred drugs, generics (unless otherwise specified), and over-the-counter (OTC) drugs for classes reviewed by the Pharmacy and Therapeutics (P&T) Committee and covered by Medicaid are available on the preferred drug list. If, however, a non-preferred drug is prescribed, the practitioner will need to obtain prior authorization (PA). If approval is given to dispense the non-preferred drug, an authorization number will be assigned.

Table of Contents

Section One
PA Form: General Information

PDL Drug Classes to Require PA

The following classes of drugs are on the mandatory preferred drug list.

- Alzheimer's Agents
  - Alzheimer's Agents Attachment A
- Analgesics and Antipyretics
  - Opioid Agonists/ Narcotic Analgesic Agents
  - Opioid Partial Agonists/ Opioid Use Disorder Agents
  - Analgesics and Antipyretics, Misc
- Androgens
- Antidepressant Agents
- Antidiabetic Agents
- Antiemetic Agents
- Antigout Agents
- Antihistamines (First Generation)
- Antihypertensive Agents
- Anti-infective Agents
- Antihyperlipidemic Agents
- Anxiolytics/Sedatives/Hypnotics
- Cardiac Agents
- Calcitonin Gene-Related Peptide (CGRP) Antagonists
- Cerebral Stimulants/Agents used for ADHD
- Targeted Immunomodulators (TIMs)
- EENT Antiallergic Agents
- EENT Antibacterial Agents
- EENT Vasoconstrictor Agents
- Estrogens
- Genitourinary Smooth Muscle Relaxants
- Growth Hormone Agents
  - Adults
  - AIDS Wasting
  - Children
- Hereditary Angioedema Agents
- Intranasal Corticosteroids
- Multiple Sclerosis (MS) Agents
- Oral Anticoagulants
- Platelet-Aggregation Inhibitor Agents
- Prenatal Vitamins
- Antiulcer and Acid Suppressants
- Respiratory Agents
- Selective Serotonin Agonists
- Skeletal Muscle Relaxants
- Skin and Mucous Membrane Agents
- Wakefulness Promoting Agents

Other drug classes may be added as they are reviewed and approved.

Non-PDL Drugs and/or Drug Classes to Require PA

The following drugs or classes of drugs are not included on the mandatory preferred drug list and do require PA:

- Antihistamines (Second Generation)
- Antipsychotic Agents
- H2 Antagonists
- NSAIDs
- Phosphodiesterase Inhibitors
- Smoking Cessation
- Specialized Nutritionals
- Sustained Release Oral Opioid Agonists
- Vyjuvek
- Xenical

Definitions

Approval Timeframes

- The approval timeframe is the maximum period of time for which a PA can be approved. This varies from class to class. Refills within the approved timeframe will not require a new PA request.

Appropriate Diagnosis

- Some classes require diagnosis(es) that justifies the drug requested. Diagnosis(es) **or** ICD-10 code(s) may be used. Use of ICD-10 codes provides specificity and legibility and will usually expedite review.

Medical Justification

- Medical justification is documentation to support the physician's choice for the requested course of treatment and may include documentation from the patient record or peer-reviewed literature. Documentation from the patient record (history and physical, tests, past or current medication/treatments, patient's response to treatment, etc) should illustrate and support the physician's request for the drug specified. For example, if a recommended therapy trial is contraindicated by the patient's condition or the patient has a history of allergy to a first-line drug, and the physician wants to prescribe a non-preferred drug, documentation from the patient record would support that decision. Medical justification may be provided under the Clinical Information Section on the request form or included as an attachment.

Prior Treatment Trials

- Prior authorization requires that a designated number of prescribed generic, OTC, or brand name drugs have been utilized unsuccessfully relative to efficacy and/or safety within a specified timeframe prior to requesting the PA. For prior therapy requirements for a specific class, refer to the class specific section of the criteria booklet.

- One prior therapy is acceptable in those instances when a class has only one preferred agent, either brand, generic, or OTC, for a specific indication.

- The PA request must indicate that the prescribed generic, OTC, or brand drugs have been utilized for a specified period of time **unless** there is an adverse/allergic response or contraindication. See class specific section for the specified number of days of therapy required to meet prior treatment trials.

- If the prescribing practitioner feels there is a medical reason for which the patient should not be on a preferred generic, OTC, or brand medication, medical justification may be submitted in lieu of previous drug therapy.

- The classes below require prior treatment trials. Those classes denoted with an asterisk (*) require that the failed treatment trials be **prescribed and preferred** agents. Those without an asterisk require that the failed therapies be **prescribed**.

- Alzheimer's Agents*
- Androgens*
- Antidepressant Agents*
- Antidiabetic Agents*
- Antiemetic Agents
- Antigout Agents*
- Antihistamines (First Generation)*
- Antihistamines (Second Generation)
- Antihypertensive Agents*
- Anti-infective Agents*
- Antilipemic Agents*
- Anxiolytics/Sedatives/Hypnotics*
- Cardiac Agents*
- Calcitonin Gene-Related Peptide (CGRP) Antagonists*
- Cerebral Stimulants/ADHD*
- Targeted Immunomodulators (TIMs)*
- EENT Antiallergic Agents*
- EENT Antibacterial Agents*
- EENT Vasoconstrictor Agents*
- Estrogens
- Genitourinary Smooth Muscle Relaxants*
- Growth Hormone Agents*
- H2 Antagonist Agents
- Hereditary Angioedema Agents
- Intranasal Corticosteroids Agents*
- Multiple Sclerosis (MS) Agents*
- Narcotic Analgesic Agents*
- NSAID Agents
- Opioid Use Disorder Agents*
- Oral Anticoagulants*
- Platelet-Aggregation Inhibitor Agents*
- Prenatal Vitamins*
- Antiulcer and Acid Suppressants*
- Respiratory Agents*
- Selective Serotonin Agonists*
- Skeletal Muscle Relaxants*
- Skin and Mucous Membrane Agents*
- Wakefulness Promoting Agents*

Stable Therapy

- Stable therapy applies in some classes for patients who have been stable on the same drug and the same strength. Stable therapy applies for all classes listed in the chart on the following page. The application of stable therapy for adults is limited to the specific classes listed under the heading "Stable therapy for all ages". Consecutive therapy allows approval for patients who have been determined to be stable on the medication for a specified timeframe and who continue to require therapy. For stable therapy timeframe for a specific class, refer to the class specific section of the criteria booklet.

- Documentation of stable therapy is not required for renewal requests if claims history supports stable therapy. For all other requests, documentation must be provided in order to meet stable therapy requirements. Examples of acceptable documentation include pharmacy profile printouts, prescription copies, copies of the medical record medication list or progress notes documenting strength and quantity consistent with consecutive therapy timeframes. The use of medication samples or manufacturer vouchers does not count towards stable therapy requirements.

- The chart on the following page outlines the stable therapy guidelines.

Stable Therapy Guideline Chart

Drug Class	Stable Therapy for All Ages	18 years old and younger
Alzheimer's Agents	√	
Analgesics and Antipyretics, Misc		
Androgens		√
Antidepressants	√	
Antidiabetic Agents	√	
Antiemetic Agents		√
Antigout Agents		√
Antihistamines (First Generation)		√
Antihistamines (Second Generation)		√
Antihypertensive Agents	√	
Antilipemic Agents		√
Anti-infective Agents	√	
Anxiolytics/Sedatives/Hypnotics		√
Cardiac Agents	√	
Cerebral Stimulants/Agents used for ADHD	√	
Targeted Immunomodulators (TIMs)	√	
EENT Antiallergic Agents		√
EENT Antibacterial Agents		√
EENT Vasoconstrictor Agents		√
Estrogens		√
Genitourinary Smooth Muscle Relaxants		√
Hereditary Angioedema Agents	√	
Intranasal Corticosteroids		√
Multiple Sclerosis (MS) Agents	√	
Narcotic Analgesics		√
NSAIDs		√
Oral Anticoagulants	√	
Platelet-Aggregation Inhibitors	√	
Prenatal Vitamins		√
Prevacid NapraPAC®		√
Antiulcer and Acid Suppressants		√
Respiratory Agents		√
Selective Serotonin Agonists		√
Skeletal Muscle Relaxants*	√	
Skin and Mucous Membrane Agents		√
Sustained-release Opioid Agonist (SROA) Agents		√
Wakefulness Promoting Agents	√	

**For Skeletal Muscle Relaxants, stable therapy only applies if the patient has a chronic condition associated with spasticity.*

Verbal Requests

PA requests for drugs that meet previous drug usage requirements will be accepted verbally. Verbal PA requests may be initiated by pharmacists, physicians, or their authorized representative. Any drug requiring additional information or medical justification must be submitted on the required PA form.

Drugs that may be requested verbally are:

- Alzheimer's Agents
- Androgens
- Antidepressants
- Antidiabetic Agents
- Antiemetic Agents
- Antigout Agents
- Antihistamines (First Generation)
- Antihistamines (Second Generation)
- Anti-infective Agents
- Antilipemic Agents
- Anxiolytics/Sedatives/Hypnotics
- Cardiac Agents
- Calcitonin Gene-Related Peptide (CGRP) Antagonists
- Cerebral Stimulants/ADHD
- EENT Antiallergic Agents
- EENT Antibacterial Agents
- EENT Vasoconstrictor Agents
- Estrogens
- Genitourinary Smooth Muscle Relaxants
- Growth Hormone Agents
- H2 Antagonists
- Hereditary Angioedema Agents
- Intranasal Corticosteroids
- Multiple Sclerosis (MS) Agents
- Narcotic Analgesics
- NSAIDs
- Oral Anticoagulants
- Platelet-Aggregation Inhibitors
- Prenatal Vitamins
- Antiulcer and Acid Suppressants
- Respiratory Agents
- Selective Serotonin Agonists
- Skeletal Muscle Relaxants
- Skin and Mucous Membrane Agents
- Wakefulness Promoting Agents

Paper Requests

Page One (1) of the Prior Authorization Request Form may be submitted alone unless the medication requested is listed on Page Two (2). DMARDs/biological injectable agents, Synagis, hepatitis C antiviral agents, growth failure agents, smoking cessation agents, and opioid use disorder agents all have separate PA forms.

Check the appropriate box at the top of the form to indicate whether one or both pages are being submitted. Acknowledgement of transmission of the second page will ensure that the reviewer has completed all material needed to review the request.

Drugs listed on Page 2 of PA form are:

- Antipsychotic Agents
- Erectile Dysfunction Drugs
- Specialized Nutritionals
- Sustained Release Oral Opioid Agonists
- Xenical

A separate form will need to be completed for each drug/nutritional requested.

Once the form is completed, the paper request can be submitted via fax or mail.

Electronic Requests

Electronic claims are submitted from the pharmacy and electronic requests may be submitted online by the pharmacy or physician.

Electronic Prior Authorization Program (EPA) – Certain classes of drugs are included in the EPA Program. Once the pharmacy sends an electronic claim for a drug in the EPA program, the system reviews medical and pharmacy claims history for the patient. If the criteria are met, the claim is automatically assigned an authorization number and is approved. If the PA criteria are not met, a message is returned to the pharmacy instructing the submitter to submit a manual (paper or online) request.

- An EPA rejected claim does not constitute a PA denial, only a notice to the pharmacy that a manual PA request is needed.

Drug classes included in the EPA program:

- Alzheimer's Agents
- Androgens
- Antidepressants
- Antidiabetic Agents
- Antiemetic Agents
- Antigout Agents
- Antihistamines (First Generation)
- Antihistamines (Second Generation)
- Antihypertensive Agents
- Antilipemics
- Antipsychotic Agents
- Analgesics and Antipyretics, Misc
- Anxiolytics/Sedatives/Hypnotics
- Cardiac Agents
- Cerebral Stimulants/ADHD
- EENT Antiallergic Agents
- EENT Vasoconstrictor Agents
- Estrogens
- Genitourinary Smooth Muscle Relaxants
- Hereditary Angioedema Agents
- Intranasal Corticosteroids
- Multiple Sclerosis (MS) Agents
- NSAIDs
- Opioid Use Disorder Agents
- Oral Anticoagulants
- Platelet-Aggregation Inhibitors
- Respiratory Agents
- Selective Serotonin Agonists
- Skeletal Muscle Relaxants
- Skin and Mucous Membrane Agents
- Sustained Release Oral Opioid Agonists
- Wakefulness Promoting Agents

Online Form Submission

From the Medicaid website (www medicaid.alabama.gov), a link can be found for a PA Request Form that can be completed and submitted electronically online. The form can also be found on Acentra Health's website at almedicaid.acentra.com.

Online requests, once submitted, are processed like paper requests and are subject to paper request requirements.

Section Two
PA Form: Patient Information

Below are fields to be completed on the PA Form.

Form States	Your Response
Patient name	Record the patient's name as it appears on their Medicaid card.
Patient Medicaid #	Record patient's Medicaid number.
Patient DOB	Record patient's date of birth.
Patient phone # with area code	Record the patient's phone number including area code.
Nursing home resident	If patient is nursing home resident, indicate yes.

Section Three
PA Form: Prescriber Information

Below are fields to be completed on the PA Form.

Form States	Your Response
Prescribing practitioner	Record the prescribing practitioner's name.
NPI/License number	Record the prescribing practitioner's NPI or license number.
Phone number with area code	Record the prescribing practitioner's phone number with area code.
Fax number with area code	Record prescribing practitioner's fax number with area code.
Address (optional)	Prescribing practitioner's mailing address is optional
Prescribing practitioner signature/date	The prescriber should sign and date in this section on the prescribing practitioner signature line.*

**By signing in the designated space, the practitioner verifies that the request complies with Medicaid's guidelines and that he/she will be supervising the patient during treatment with the requested product.*
The practitioner further certifies that documentation is available in the patient record to justify the requested treatment.

Section Four
PA Form: Clinical Information

(***This information is required for all requests.)***

Below are fields to be completed on the PA Form.

Form States	Your Response
Drug requested	Record the name of the drug being requested.
Strength	Record the strength of the drug.
J Code	Enter the J code if the drug requested is to be administered using office medications.
Quantity	Enter the quantity of the drug being requested.
Days supply	Enter the days supply for the quantity requested.
PA refills	Circle the number of refills requested.
Diagnosis or ICD-10 Code	Record diagnosis(es) that justifies the requested drug. Diagnosis(es) **or** ICD-10 code(s) may be used. Use of ICD-10 codes provides specificity and legibility and will usually expedite review.
Initial/Renewal Request	Indicate if this is an initial request or a renewal request.
Type of therapy requested	For H2 Antagonists and PPIs, specify if therapy is acute or maintenance.
Medical justification	Explain the reason this drug is required, and attach any additional medical justification necessary.*

**Medical justification is documentation to support the physician's choice of the requested course of treatment and may include documentation from the patient record or peer-reviewed literature. Documentation from the patient record (history and physical, tests, past or current medication/treatments, patient's response to treatment, etc) illustrates and supports the physician's request for the drug specified. For example, if a recommended therapy trial is contraindicated by the patient's condition or a history of allergy to a first-line drug, and the physician wants to order a non-preferred drug, documentation from the patient record would support that decision.*

Section Five
PA Form: Drug Specific Information

Below are fields to be completed on the PA Form.

Form States	Your Response
Drug class requested	Check the appropriate box for the drug class for the PA being requested.
Previous drug usage	Record the name of the discontinued medication. If there is no previous drug usage, additional medical justification must be provided.
Reason for d/c	Record the reason the medication was discontinued.
Therapy start date	Record the start date of the discontinued medication.
Therapy end date	Record the end date of the discontinued medication.

PA Criteria for Drugs/Drug Classes

The following section outlines class specific information regarding PA criteria.

PDL Drug Classes to Require PA:

- Alzheimer's Agents
  - Alzheimer's Agents Attachment A
- Analgesics and Antipyretics
  - Opioid Agonists/ Narcotic Analgesic Agents
  - Opioid Partial Agonists/ Opioid Use Disorder Agents
  - Analgesics and Antipyretics, Misc
- Androgens
- Antidepressant Agents
- Antidiabetic Agents
- Antiemetic Agents
- Antigout Agents
- Antihistamines (First Generation)
- Antihypertensive Agents
- Anti-infective Agents
- Antilipemic Agents
- Anxiolytics/Sedatives/Hypnotics
- Cardiac Agents
- Calcitonin Gene-Related Peptide (CGRP) Antagonists
- Cerebral Stimulants/Agents used for ADHD
- TIMs/Biologics/DMARDs
- EENT Antiallergic Agents
- EENT Antibacterial Agents
- EENT Vasoconstrictor Agents
- Estrogens
- Genitourinary Smooth Muscle Relaxants
- Growth Hormone Agents
  - Adults
  - AIDS Wasting
  - Children
- Hereditary Angioedema Agents
- Intranasal Corticosteroids
- Multiple Sclerosis (MS) Agents
- Oral Anticoagulants
- Platelet-Aggregation Inhibitor Agents
- Prenatal Vitamins
- Antiulcer and Acid Suppressants
- Respiratory Agents
- Selective Serotonin Agonists
- Skeletal Muscle Relaxants
- Skin and Mucous Membrane Agents
- Wakefulness Promoting Agents

Alzheimer's Agents

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

- For Leqembi® (lecanemab-irmb) or Kisunla® (donanemab-azbt) the diagnosis must be for mild cognitive impairment (MCI) or mild dementia associated with Alzheimer's Disease and all of the criteria as outlined in Alzheimer's Agents Attachment A must be met.

Prior Treatment Trials

- The patient must also have failed 30-day treatment trials with at least one other prescribed and preferred Alzheimer's agent in this class, either generic, OTC, or brand, within the past 6 months, or have a documented allergy or contraindication to all preferred agents in this class.

Stable Therapy

- Stable therapy for this class is defined as a 90-day or greater timeframe. Approval may be given for those who have documented stable therapy on the requested medication for 90 consecutive days or greater.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval for Leqembi® (lecanemab-irmb) may be given for up to 6 months with a follow-up MRI required prior to the 3rd, 5th, 7th, and 14th infusions. Approval for Kisunla® (donanemab-azbt) may be given for up to 6 months with a follow-up MRI required prior to the 2nd, 3rd, 4th, and 7th infusions. Evidence of the patient NOT having disease progression and documentation of ARIA monitoring is required.

- Approval for other agents may be given for up to 12 months.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Narcotic Analgesics

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

- For agents indicated for opioid use disorder, see separate PA form.

- Methadone for the treatment of pain is indicated only for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Prior Treatment Trials

- The patient must also have failed 30-day treatment trials with at least 2 prescribed and preferred narcotic analgesics in this class, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

Stable Therapy

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- For narcotic analgesics, medical justification must include documentation of therapeutic pain management failure with nonsteroidal anti-inflammatory drugs (NSAIDs), acetaminophen, or aspirin and a complete pain evaluation in the medical record. Type of pain (acute versus chronic) and pain intensity (mild, moderate, or severe) must be indicated in the Drug/Clinical Information section under Medical Justification. Medical justification may also include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 3 months with initial and renewal requests unless one of the qualifying diagnoses is indicated, then approval may be given for up to 6 months. If the patient is a nursing home resident, approval may be given for up to 6 months for initial requests and up to 12 months for renewal requests.

Electronic Prior Authorization (EPA)

- Not Applicable

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Opioid Use Disorder Agents

Appropriate Diagnosis

For all requests, the patient must have an appropriate diagnosis supported by documentation in the patient record. For agents indicated for opioid use disorder, the patient must have a diagnosis of opioid dependence, opioid abuse, or opioid abuse disorder.

Prior Treatment Trials

- For requests for non-preferred agents, the patient must have failed a treatment trial with at least one prescribed and preferred agent in this class, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

Stable Therapy

- Not applicable.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

- For manual requests, attestation from the prescribing physician stating that the Prescription Drug Monitoring Program (PDMP) record for the patient has been reviewed prior to prescribing an opioid use disorder medication must also be submitted with each renewal request.

PA Approval Timeframes

- Requests may be approved for 1 year.

Electronic Prior Authorization (EPA)

- Buprenorphine-containing agents can be approved electronically (i.e., at the pharmacy point of sale), with no manual PA if criteria is met with claims history. For electronic requests, claims history must be free of concurrent (within past 3 months) opioids.

- If claims history does not meet criteria, the request can be submitted to Acentra Health for a manual review.

Verbal PA Requests

- Not Applicable.

Analgesics and Antipyretics, Miscellaneous

Preferred Agents

- Requests for Journavx® must meet certain clinical criteria.
    - **Clinical criteria consists of an allowance for up to a 14-day supply every 90 days for recipients 18 years of age and older through the electronic prior authorization (PA) system, with no manual PA required. Requests outside of clinical criteria guidance will require manual PA.**

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

- For Journavx® requests not meeting the clinical criteria, a manual PA will review for:
    - The patient must be ≥18 years of age and therapy must be prescribed for moderate to severe acute pain supported by documentation in the patient record and may not exceed 14 days.
    - The patient must not be on concomitant therapy with other medications that cause drug interactions per the prescribing information.
    - The patient must not have severe hepatic impairment or renal impairment of eGFR <15 mL/min.

Prior Treatment Trials

- Not applicable.

Stable Therapy

- Not applicable.

Medical Justification

- Medical justification may include peer reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- For Journavx®, duration of therapy is 14 days every 90 days.

Electronic Prior Authorization (EPA)

- Journavx® can be approved electronically (i.e., at the pharmacy point of sale), with no manual PA if criteria is met with claims history. If claims history does not meet criteria, the request can be submitted to Acentra Health for a manual review.

Verbal PA Requests

- Not applicable.

Androgens

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

- For products indicated for use in males only, the patient must be male and have a diagnosis of hypogonadotropic hypogonadism (congenital or acquired in males) or primary hypogonadism (congenital or acquired in males).

Prior Treatment Trials

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred androgen agents in this class, either generic or brand within the past 6 months, or have a documented allergy or contraindication to all preferred agents in this class.

Stable Therapy

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- Androgens are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Antidepressants

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

Prior Treatment Trials

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred antidepressant agents in this class, either generic, OTC, or brand within the past 6 months, or have a documented allergy or contraindication to all preferred agents in this class.

- For Zurzuvae®, in lieu of prior usage requirements, approval may be obtained by meeting the following criteria:
    - Patient is ≥ 18 years of age with a diagnosis of postpartum depression (PPD) based on Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria for a major depressive episode
    - Baseline PPD severity has been assessed using a standardized, validated depression rating scale (e.g., Hamilton Rating Scale for Depression [HAM-D], Patient Health Questionnaire-9 [PHQ-9], Montgomery-Åsberg Depression Rating Scale [MADRS], Beck's Depression Inventory [BDI], Edinburgh Postnatal Depression Scale [EPDS]) and is rated as “severe”
    - Patient is not currently pregnant and is using effective contraception
    - Patient has ceased lactating or has agreed to refrain from providing breast milk to the infant prior to receiving the first dose until 7 days after the last dose
    - Prescriber attests to appropriate patient counseling, assessing for potential drug interactions, and establishing a protocol for follow-up care
    - If patient is taking another oral antidepressant medication, the dose has been stable for ≥ 30 days
    - Baseline renal and hepatic function have been assessed and dosing is appropriate according to labeling

- For Spravato® approval, the patient must meet the following:
    - Patient is ≥ 18 years of age with a diagnosis of treatment-resistant depression (TRD) in adults, as monotherapy or in conjunction with an oral antidepressant (TRD defined as patient has not responded adequately to at least two different antidepressants of adequate dose and duration) OR depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior in conjunction with an oral antidepressant (appropriate medical records confirming diagnosis).
    - Baseline severity as established by PHQ-9 score.
    - Prescribed by a psychiatrist.
    - Recipient, pharmacy, prescriber, and facility are enrolled in the Spravato® REMS program.
    - Spravato® must be administered under the direct supervision of a healthcare provider with patient observation for at least 2 hours until the

patient is safe to leave. Assess blood pressure prior to and after administration.
    - No history of clinically significant cardiac disease (i.e., aneurysm, intracerebral hemorrhage, uncontrolled hypertension, unstable coronary artery disease, congestive heart failure, tachyarrhythmias, recent myocardial infarction, etc.).
    - No history of psychosis or dissociative symptoms that may be worsened by dissociative changes.
    - Recipient's risk for abuse or misuse is assessed prior to initiating treatment and will be assessed periodically while on therapy.
    - In women of childbearing potential, negative pregnancy test and appropriate birth control precautions in place. Spravato® is not recommended during pregnancy.

Stable Therapy

- Approval may be given to those who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 12 months.

- Zuranolone treatment has not been evaluated for more than one course of treatment per pregnancy. Safety and efficacy of retreatment for a PPD episode have not been established.

- Initial approval for Spravato® (esketamine) may be given for 4 weeks. Renewals may be approved for 6 months if the criteria are met.

Electronic Prior Authorization (EPA)

- Antidepressants are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Antidiabetic Agents/ Incretin Mimetics

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

- For OSA indications for incretin mimetics, patient must be ≥18 years of age with moderate to severe obstructive sleep apnea (apnea-hypopnea index [AHI] ≥15) **and** obesity (BMI ≥30 kg/m^2) with **no** diagnosis of diabetes. The patient has been counseled to continue a reduced-calorie diet and increased physical activity and is **not** taking this medication in combination with another GLP-1 agonist. Stable therapy does not apply.

- Wegovy® is indicated in combination with a reduced calorie diet and increased physical activity for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) and either obesity or overweight in adults. Requests must include documentation to support the FDA approved indication related to MASH with **no** diagnosis of diabetes.

- Wegovy® is indicated in combination with a reduced calorie diet and increased physical activity to reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight. Requests must include documentation to support the FDA approved indication related to cardiovascular disease.
    - For Wegovy® cardiovascular renewals, prescriber must provide documentation of member weight records (dated within the last 90 days), member requires Wegovy® for cardiovascular risk reduction and the benefit of cardiovascular risk reduction outweighs the risk associated with use of GLP-1 agents, and medical records document appropriate diagnosis.

Prior Treatment Trials

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred antidiabetic agents, either generic, OTC, or brand, within the past 12 months, or have a documented allergy or contraindication to all preferred agents in this class.

- If the request is for Symlin®, the patient must also be on insulin therapy and have a hemoglobin A1c greater than 7% despite more than 90 days of insulin therapy.

- If the request is for Korlym®, the patient must be ≥18 years of age with endogenous Cushing's syndrome with type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery.

- Preferred agents in the Incretin Mimetic class are “preferred with clinical criteria” and must meet specified clinical criteria to include FDA approved indications and prior therapy trials.

Stable Therapy

- Approval may be given for those who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 12 months, with the exception of the incretin mimetics for non-diabetes indications which may have an initial approval for 6 months.

Electronic Prior Authorization (EPA)

- Antidiabetic agents, excluding Symlin®, Korlym®, and Tzield® are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Antiemetic Agents

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

Prior Treatment Trials

- The patient must also have failed 3-day treatment trials with at least two prescribed antiemetics, to include promethazine or a preferred antiemetic agent, either generic, OTC or brand, within the past 6 months, or have a documented allergy or contraindication to all preferred agents in this class.

Stable Therapy

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- Antiemetic agents are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Antigout Agents

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

Prior Treatment Trials

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred agents in this class, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

Stable Therapy

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- Antigout agents are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Antihistamines (First Generation)

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

Prior Treatment Trials

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred agents in this class, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

Stable Therapy

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- Antihistamines are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Antihypertensive Agents

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

Prior Treatment Trials

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred antihypertensive agents in this class, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

- To meet these prior usage requirements, drugs within this specific classification must be judged against others in the same class (AHFS specific). For example, to qualify for a non-preferred beta-blocker, the patient must have met prior usage requirements of 30-day treatment trials with two other preferred beta-blockers, either generic, OTC, or brand.

- For fixed-dose combination products containing drugs from 2 or more different subclasses, prior therapies must include at least 2 prescribed and preferred agents from the respective subclasses.

- For Hemangeol®, patients must be five weeks to five months of age when initiating treatment. Hemangeol® may only be approved for the treatment of proliferating infantile hemangioma requiring systemic therapy.

- For Kerendia®, the diagnosis must include adult patients with chronic kidney disease associated with type 2 diabetes OR heart failure with left ventricular ejection fraction (LVEF) ≥ 40%. For Kerendia® for CKD associated with T2DM, prior therapies must include an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) AND an antidiabetic agent. For Kerendia® for HF (LVEF ≥40%), prior therapies must include an ACEi, ARB, or angiotensin receptor neprilysin inhibitor (ARNI) AND a diuretic agent.

- For Tryvio®, patients must have hypertension despite treatment with at least three antihypertensive medications. Patients are to continue standard background antihypertensive therapy consisting of an angiotensin receptor blocker, a calcium channel blocker, and a diuretic (with or without a beta-blocker) unless there is an allergy/contraindication.

Stable Therapy

- Approval may be given for those who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- Antihypertensive agents are included in the electronic PA program.

Verbal PA Requests

- Not Applicable

Anti-infective Agents

Preferred Agents

- Requests for preferred agents in the HCV anti-infective class must meet certain clinical criteria, please see Form 415 Criteria instruction booklet.

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

Prior Treatment Trials

- The patient must also have failed two treatment trials of no less than three-days each, with at least two prescribed and preferred anti-infectives, either generic, OTC, or brand, for the above diagnosis within the past 30 days or have a documented allergy or contraindication to all preferred agents for the diagnosis submitted.

- For the HCV anti-infectives, please see separate PA forms for specific information.

Stable Therapy

- Patients on anti-infective therapy while institutionalized once discharged or transferred to another setting or patients having a 60 day consecutive stable therapy may continue on that therapy with supportive medical justification or documentation.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested. Approval may also be given, with medical justification, if the medication requested is indicated for first line therapy when there are no other indicated preferred agents available or if indicated by susceptibility testing or evidence of resistance to all preferred agents.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- Not Applicable.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Antihyperlipidemic Agents

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

Prior Treatment Trials

- For oral medications, the patient must also have failed 30-day treatment trials with at least two prescribed and preferred lipid lowering agents, either generic, OTC, or brand, within the past 6 months, or have a documented allergy or contraindication to all preferred agents in this class.

- For Zetia®, if prior usage requirements have not been met, approval may be obtained for adjunctive therapy to a current lipid lowering drug.

- For Praluent®, Repatha®, Nexletol®, or Nexlizet®, 12 weeks of prior therapy with at least 2 maximally tolerated doses of statins is required. If prior usage requirements for these agents have not been met, approval may be obtained for adjunctive therapy to a maximally tolerated statin (or a statin or ezetimibe for patients with a diagnosis of familial hypercholesterolemia).

- For Juxtapid® or Evkeeza®, 12 weeks of prior therapy with at least 2 maximally tolerated doses of statins is required. If prior usage requirements for these agents have not been met, approval may be obtained for adjunctive therapy to a maximally tolerated statin, ezetimibe, and a PCSK9 inhibitor for patients (≥5 years of age for Evkeeza® and ≥18 years of age for Juxtapid®) with a diagnosis of homozygous familial hypercholesterolemia.

- For Leqvio®, 12 weeks of prior therapy with at least 2 maximally tolerated doses of statins is required. Leqvio®, is for use as an adjunct to maximally tolerated statin therapy in those who require additional LDL-C lowering.

Stable Therapy

- Approval for the oral products may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- For oral agents, approval may be given for up to 6 months for initial request and up to 12 months for renewal requests.

- For Praluent®, Repatha®, Leqvio®, Nexletol®, Nexlizet®, Juxtapid®, or Evkeeza®, approval may only be given for 6 months and renewal requests are contingent on sufficient decrease in LDL from onset of initiation of therapy.

Electronic Prior Authorization (EPA)

- Antilipemic agents are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Anxiolytics/Sedatives/Hypnotics

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

Prior Treatment Trials

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred agents in this class, either generic, OTC, or brand within the past 6 months, or have a documented allergy or contraindication to all preferred agents in this class.

- For Hetlioz, in lieu of prior usage requirements, the patient must be ≥18 years of age diagnosed with non-24-hour sleep-wake disorder or ≥3 years of age (3 to 15 for suspension, ≥16 for capsules) diagnosed with nighttime sleep disturbances in Smith-Magenis Syndrome.

Stable Therapy

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 3 months for initial request and up to 6 months for renewal requests.

Electronic Prior Authorization (EPA)

- Anxiolytic, sedative, and hypnotic agents are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Cardiac Agents

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

Prior Treatment Trials

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred cardiac agents in this class, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

- To meet these prior usage requirements, drugs within this specific classification must be judged against others in the same class (AHFS specific).

  - For example, to qualify for a non-preferred cardiotonic, the patient must have met prior usage requirements of 30-day treatment trials with two other preferred cardiotonic agents, either generic, OTC, or brand.

  - For Ranexa®, in lieu of prior usage requirements, approval may be obtained for adjunctive therapy to a current antianginal drug.

  - For Corlanor®, previous beta-blocker usage or contraindication to beta-blocker therapy is required.

Stable Therapy

- Approval may be given for those who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- Cardiac agents are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Calcitonin Gene-Related Peptide (CGRP) Antagonists

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

- Requests for prophylactic treatment, with at least four or more migraines per month.

Prior Treatment Trials

- The patient must have failed a 30-day treatment trial with at least 2 prescribed and preferred prior therapies, within the past 6 months.

- The patient must have failed a 30-day treatment trial with at least one other prescribed and preferred CGRP antagonists, either generic, OTC, or brand, within the past 6 months if the request is for a non-preferred agent.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 6 months.

Electronic Prior Authorization (EPA)

- Not applicable.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Cerebral Stimulants/Agents Used for ADHD

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

- For agents with an FDA-approved indication of narcolepsy, the patient must have an appropriate diagnosis supported by documentation in the patient record of appropriate diagnostic testing.

Prior Therapy

- If the request is for a *short- or intermediate-acting* cerebral stimulant/agent used to treat ADHD, the patient must also have failed 30-day treatment trials with at least two prescribed and preferred short- or intermediate-acting cerebral stimulants/agents used for ADHD, either generic, OTC, or brand, within the past 6 months.

- If the request is for a *long-acting* cerebral stimulant/agent used for ADHD, the patient must also have failed 30-day treatment trials with at least two prescribed and preferred long-acting cerebral stimulants/agents used for ADHD, either generic, OTC, or brand within the past 6 months.

- If the request is for Qelbree, the patient must be 6 years of age or older AND also have failed 30-day treatment trials with at least two prescribed and preferred cerebral stimulants/agents used for ADHD OR one prescribed and preferred cerebral stimulants (short-, intermediate- or long-acting) AND atomoxetine, either generic, OTC, or brand within the past 6 months; or a history of substance abuse or a concern regarding substance abuse in the patient's household.

- In lieu of prior usage requirements, approval may be given if there is a documented allergy or contraindication to all preferred agents in this class.

Stable Therapy

- Approval may be given to those who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- Cerebral Stimulant/Agent Used for ADHD agents are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Targeted Immunomodulators (TIMs)/Biologics/DMARDs

Preferred Agents

- Requests for preferred agents in this class must meet certain clinical criteria, please see Form 373 Criteria instruction booklet.

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

Prior Treatment Trials

- For Targeted Immunomodulators (TIMs)/Biologics/DMARDs prior treatment trial requirements, please see Form 373 Criteria instruction booklet.

Stable Therapy

- Approval may be given to those who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- Not applicable.

Verbal PA Requests

- Not applicable.

EENT Antiallergic Agents

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

Prior Treatment Trials

- For ophthalmic products, the patient must also have failed 14-day treatment trials with at least two prescribed and preferred ophthalmic agents in this class, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

- For nasal products, the patient must have also failed 14-day treatment trials with at least two prescribed antiallergic agents, to include oral antihistamines, intranasal corticosteroids, or intranasal cromolyn, either generic, OTC, or brand within the past 6 months or have a documented allergy or contraindication to all preferred or acceptable agents.

Stable Therapy

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- EENT antiallergic agents are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

EENT Antibacterial Agents

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

Prior Treatment Trials

- The patient must also have failed 3-day treatment trials with at least two prescribed and preferred agents in this class, either generic, OTC, or brand, within the past 30 days or have a documented allergy or contraindication to all preferred agents in this class.

Stable Therapy

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- Not Applicable

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

EENT Vasoconstrictor Agents

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

Prior Treatment Trials

- The patient must also have failed 3-day treatment trials with at least two prescribed and preferred agents in this class, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

Stable Therapy

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- EENT vasoconstrictors are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Estrogens

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

Prior Treatment Trials

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred estrogens in this class, either generic, OTC, or brand, within the past 6 months, or have a documented allergy or contraindication to all preferred agents in this class.

Stable Therapy

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- Estrogens are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Genitourinary Smooth Muscle Relaxants

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

Prior Treatment Trials

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred agents in this class, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

Stable Therapy

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- Genitourinary smooth muscle relaxants are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Growth Hormone Agents in Adults

Appropriate diagnosis

- The patient must have one of the following primary diagnoses listed below confirmed by a board certified endocrinologist or a board certified gastroenterologist for short bowel syndrome.
    - Childhood onset of growth hormone deficiency
    - Adult onset of growth hormone deficiency with other deficiencies
    - Adult onset of growth hormone deficiency without other pituitary hormone deficiencies
    - Short Bowel Syndrome

- Example agents include Genotropin®, Humatrope®, Norditropin®, Nutropin AQ®, Nutropin®, Omnitrope®, Saizen®, Zomacton®, and Zorbtive®.

- Adult is defined for growth hormone replacement therapy as any patient with closed epiphyses.

- Preferred agents in this class are “preferred with clinical criteria” and must meet specified clinical criteria.

Prior Treatment Trials

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred agents in this class, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

Stable Therapy

- Stable therapy does not apply to agents used for growth failure.

Medical Justification

- Adults being considered for treatment with growth hormone must be screened prior to initiation of therapy to verify the absence of any malignant condition. If growth failure results from an intracranial tumor, absence of tumor growth, or tumor recurrence must be documented for at least 6 months before initiating growth hormone therapy.

- Patients must be tested for normal thyroid function.

- Patients will be denied if they have any of the following contraindications.
    - Pregnancy
    - Proliferative or preproliferative diabetic neuropathy
    - Pseudotumor cerebri or benign intracranial HTN

- For growth hormone deficiency, provocative testing and IGF-1 levels as well as dates must be included. For adults with childhood onset growth hormone deficiency or with additional pituitary hormone deficits, one stimulation test is

required. For those with suspected growth hormone deficiency with no other pituitary hormone deficits, 2 stimulation tests are required.

- As provocative testing, Insulin Tolerance Test (ITT) is **required** unless contraindicated. ITT is contraindicated in patients with seizures, CAD, abnormal EKG with history of IHD or CVD and not advised for those > age 60. If ITT is contraindicated, documentation must be provided and an alternative test performed. Results from other stimulation tests (arginine, glucagon, L-Dopa, growth hormone-releasing hormone [GHRH], and combinations of these agents, excluding clonidine), may be submitted for those patients with documented contraindication to ITT.

- For patients with short bowel syndrome, the patient must be receiving specialized nutritional support such as dietary adjustments, enteral feedings, parenteral nutrition, and/or fluid and micronutrient supplement.

- The strength, daily dose, patient's height and weight must be included with all requests.

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- For growth hormone deficiency, approval may be given for up to 6 months. For subsequent requests, the physician must submit progress reports including information regarding efficacy, adverse effect and compliance, and the results of any required lab tests. The report must include the date the patient was last seen by the physician.

- For short bowel syndrome, approval may be granted for up to 4 weeks.

Electronic Prior Authorization (EPA)

- Growth hormone agents are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Growth Hormone Agents in AIDS Wasting

Appropriate diagnosis

- The patient must have a diagnosis of HIV/AIDS.
- Example agents include Serostim®.
- Preferred agents in this class are "preferred with clinical criteria" and must meet specified clinical criteria.

Prior Treatment Trials

- Patient must be on antiretroviral therapy. The start date of the antiretroviral must be at least 120 days prior to the initiation of growth failure agent.
- Documentation of failed trial with appetite stimulants or weight gain agents (Periactin®, Marinol®, Megace®, Oxandrin®, or androgenic steroid) must be included.
- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred agents in this class, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class. One prior therapy is acceptable in those instances when a class has only one preferred agent (brand, generic or OTC) for a specific indication.

Stable Therapy

- Stable therapy does not apply to agents used for growth failure.

Medical Justification

- Adults being considered for treatment with growth hormone must be screened prior to initiation of therapy to verify the absence of any malignant condition. If growth failure results from an intracranial tumor, absence of tumor growth or tumor recurrence must be documented for at least 6 months before initiating growth hormone therapy.
- Patients will be denied if they have any of the following contraindications.
  - Pregnancy
  - Proliferative or preproliferative diabetic neuropathy
  - Pseudotumor cerebri or benign intracranial HTN
- For approval, documentation of unintentional weight loss of 10% over 12 months, 7.5% over 6 months, or loss of muscle mass (BMI < 20kg/m^2).
- Weight stabilization or weight gain must be reported to continue therapy.
- The duration of therapy, strength, daily dose, patient's height, weight, and BMI must be included with all requests.

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 6 months. For subsequent requests, the physician must submit progress reports including information regarding efficacy, adverse effect and compliance, and the results of any required lab tests. The report must include the date the patient was last seen by the physician.

Electronic Prior Authorization (EPA)

- Growth hormone agents are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Growth Hormone Agents in Children

Appropriate diagnosis

- The patient must have one of the following primary diagnoses listed below.
    - Documented Growth Hormone Deficiency
    - Turner Syndrome
    - Growth Deficiency due to Chronic Renal Insufficiency (CRI)
    - Noonan Syndrome
    - Prader-Willi Syndrome

- Example agents include Genotropin®, Humatrope®, Norditropin®, Nutropin AQ®, Omnitrope®, Saizen®, and Zomacton®.

- The diagnosis must be confirmed by a board certified endocrinologist. For CRI, diagnosis may be confirmed by a board certified pediatric nephrologist.

- Preferred agents in this class are “preferred with clinical criteria” and must meet specified clinical criteria.

Prior Treatment Trials

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred agents in this class, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class. One prior therapy is acceptable in those instances when a class has only one preferred agent (brand, generic or OTC) for a specific indication.

Stable Therapy

- Stable therapy does not apply to agents used for growth failure.

Medical Justification

- The strength, daily dose, and patient’s height must be included with all requests.

- Children being considered for treatment with growth hormone must be screened prior to initiation of therapy to verify the absence of any malignant condition. If growth failure results from an intracranial tumor, absence of tumor growth or tumor recurrence must be documented for at least 6 months before initiating growth hormone therapy (does not apply to mecasermin).

- Patients will be denied if they have any of the following contraindications.
    - Pregnancy
    - Proliferative or preproliferative diabetic retinopathy (does not apply to mecasermin)
    - Pseudotumor cerebri or benign intracranial hypertension
    - Multiple pituitary hormone deficiencies (for documented growth hormone deficiency only)
    - Severely obese or severe respiratory impairment (for Prader-Willi Syndrome only)

- Closed epiphyses (after epiphyseal closure, use Adult Growth Hormone Therapy criteria)

- For growth hormone (GH) deficiency, provocative testing (for children ≥12 months of age) and IGF-1 levels as well as dates must be included. Results from at least two (2) stimulation tests (arginine, clonidine, glucagon, insulin, L-Dopa, and growth hormone-releasing hormone [GHRH], and combinations of these agents) are required. In some circumstances, only one (1) stimulation test may be required. GH peak levels of ≤10 ng/ml after provocative testing support GH deficiency and justify treatment.

- Short stature in girls with Turner Syndrome is not due to GH deficiency, but growth failure due to intrinsic skeletal dysplasia. The decision to treat these patients is not based on provocative testing but on the diagnosis of Turner Syndrome using karyotyping. For Turner Syndrome, the date and results of karyotyping must be included.

- The following diagnosis specific information is needed for approval of growth failure agents in children:

  - **Documented Growth Hormone Deficiency**
    - Diagnosis by Board Certified Endocrinologist
    - Normal thyroid function
    - Provocative testing
    - IGF-1 level
    - Height value and growth velocity
    - Pituitary hormone levels
    - Screening for intracranial malignancy and free from recurrence for at least 6 months
    - Free from following contraindications
      - Pregnancy
      - Proliferative or preproliferative diabetic neuropathy
      - Pseudotumor cerebri or benign intracranial hypertension
      - Closed epiphyses (after epiphyseal closure, use Adult Growth Hormone Therapy criteria)

  - **Turner Syndrome**
    - Diagnosis by Board Certified Pediatric Endocrinologist
    - Normal thyroid function
    - Karotyping with 45X (XO) date and results
    - Screening for intracranial malignancy and free from recurrence for at least 6 months
    - Free from following contraindications
      - Pregnancy
      - Proliferative or preproliferative diabetic retinopathy
      - Pseudotumor cerebri or benign intracranial hypertension
      - Closed epiphyses (after epiphyseal closure, use Adult Growth Hormone Therapy criteria)

- **Growth Deficiency due to Chronic Renal Insufficiency (CRI)**
  - Diagnosis by Board Certified Pediatric Nephrologist or Board Certified Pediatric Endocrinologist
  - Normal thyroid function
  - GFR and date
  - Height value and growth velocity
  - Screening for intracranial malignancy and free from recurrence for at least 6 months
  - Free from following contraindications
    - Pregnancy
    - Proliferative or preproliferative diabetic retinopathy
    - Pseudotumor cerebri or benign intracranial hypertension
    - Closed epiphyses (after epiphyseal closure, use Adult Growth Hormone Therapy criteria)

- **Prader-Willi Syndrome**
  - Diagnosis by Board Certified Pediatric Endocrinologist
  - Normal thyroid function
  - Genetic testing date and results
  - Screening for intracranial malignancy and free from recurrence for at least 6 months
  - Free from following contraindications
    - Pregnancy
    - Proliferative or preproliferative diabetic retinopathy
    - Pseudotumor cerebri or benign intracranial hypertension
    - Closed epiphyses (after epiphyseal closure, use Adult Growth Hormone Therapy criteria)
    - Severely obese or severe respiratory impairment

- **Noonan Syndrome**
  - Diagnosis by Board Certified Pediatric Endocrinologist
  - Normal thyroid function
  - Genetic testing date and results
  - Screening for intracranial malignancy and free from recurrence for at least 6 months
  - Free from following contraindications
    - Pregnancy
    - Proliferative or preproliferative diabetic retinopathy
    - Pseudotumor cerebri or benign intracranial hypertension
    - Closed epiphyses (after epiphyseal closure, use Adult Growth Hormone Therapy criteria)

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 6 months. For subsequent requests, the physician must submit progress reports including information regarding efficacy, adverse effect and compliance, and the results of any required lab tests. The report must include the date the patient was last seen by the physician.

Electronic Prior Authorization (EPA)

- Growth hormone agents are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Complement Inhibitors for the Treatment of Hereditary Angioedema

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.
- The patient must have documentation of >1 event per month or a history of recurrent laryngeal attacks for prophylactic treatment.

Prior Treatment Trials

- The patient must have failed 30-day treatment trials with at least two prescribed and preferred agents in this class for a specific indication, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

Stable Therapy

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- Hereditary angioedema agents are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Intranasal Corticosteroids

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

Prior Treatment Trials

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred intranasal corticosteroids in this class, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

Stable Therapy

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- Intranasal corticosteroid agents are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Multiple Sclerosis (MS) Agents

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

Prior Treatment Trials

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred agents in this class, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

Stable Therapy

- Approval may be given to those who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- MS agents are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Oral Anticoagulants

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

Prior Treatment Trials

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred oral anticoagulant in this class, either generic, OTC, or brand, within the past 6 months, or have a documented allergy or contraindication to all preferred agents in this class.

Stable Therapy

- Approval may be given to those who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- Oral anticoagulants are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Platelet-Aggregation Inhibitors/Vasodilating Agents, Misc

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

Prior Treatment Trials

- The patient must also have failed 30-day treatment trials with at least 2 prescribed and preferred platelet-aggregation inhibitors in this class, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

- For Verquvo®, the patient must be symptomatic despite receiving standard of care therapy with an ACEI, ARB, or ARNI in combination with a β-blocker (carvedilol, metoprolol succinate or bisoprolol) or have a documented contraindication, allergy or intolerance to the use of these agents.

Stable Therapy

- Approval may be given to those who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Acceptable medical justification consists of specific clinical diagnoses for 1st line treatment by certain branded products in lieu of prior usage, allergy, contraindication or intolerance to the use of aspirin, cilostazol, ticlopidine, and dipyridamole.

- Clinical literature and guidelines support the use of Aggrenox®, Brilinta®, and Effient® and for specific 1st line indications; these indications include acute coronary syndrome, acute myocardial infarction (NSTEMI and STEMI), peripheral arterial occlusive disease (PAD, PVD), transient ischemia or ischemic stroke due to thrombosis/embolism, chronic heart failure and ejection fraction less than 45%, and percutaneous coronary interventions (balloon angioplasty, laser angioplasty, intra coronary stents, other catheter devices treating coronary atherosclerosis).

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- Platelet-aggregation inhibitors are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Prenatal Vitamins

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

Prior Treatment Trials

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred agents in this class, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

Stable Therapy

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- Not Applicable

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Antiulcer and Acid Suppressants

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record. Requests must indicate under the Clinical Information Section of the PA Request Form whether medication is for acute or maintenance therapy.

Prior Treatment Trials

- The patient must also have failed 30-day treatment trials with at least 2 prescribed and preferred PPIs in this class, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

Stable Therapy

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

Uncomplicated Symptomatic GERD (Nonerosive Reflux Disease)

The patient must meet prior usage requirements. Empirical therapy with a PPI is an appropriate initial management strategy for patients with typical symptoms in the absence of alarm features. A diagnosis of GERD can be made based on a history of classic symptoms and favorable response to antisecretory therapy without further testing.

For acute therapy, approval may be given for up to 8 weeks.

For maintenance therapy, documentation of appropriate testing (endoscopy, manometry, ambulatory impedance-pH, catheter pH, or wireless pH monitoring) is required for patients who have not responded to an empirical trial of PPI therapy. Approval may be given for up to 12 months. After 12 months, approval will require documentation of persistent symptoms. Retesting is not required for maintenance therapy renewals.

Complicated GERD (Erosive Esophagitis)

The patient must have an appropriate diagnosis confirmed by testing (endoscopy) and meet prior usage requirements.
For acute therapy, approval may be given for up to 8 weeks. For patients who do not heal after 8 weeks, an additional 8 weeks may be approved.

For maintenance therapy, approval may be given for up to 12 months. Retesting is not required for maintenance therapy renewals.

Positive *H. pylori* Infections
The patient must have a diagnosis of *H. pylori* infection, confirmed by testing (breath test, blood test, or tissue biopsy if endoscopic exam done) within the past 30 days, and duodenal ulcer disease, confirmed by testing within the past 12 months, and meet prior usage requirements.

For acute therapy, the patient may be approved for up to 14 days of combination therapy.

Gastric or Duodenal Ulcers
The patient must have an appropriate diagnosis confirmed by testing (barium contrast, double contrast radiography, or endoscopy) within the past 12 months and meet prior usage requirements.

For acute therapy, approval may be given for up to 8 weeks of therapy.

For maintenance of healed duodenal ulcers, maintenance therapy may be approved for up to 12 months (Prevacid®).

To reduce the risk of NSAID-associated gastric ulcers in patients at risk for developing a gastric ulcer who require the use of an NSAID, approval may be given for up to 12 weeks (Prevacid®) or 6 months (Nexium®) of therapy.

Barrett's Esophagus, Zollinger-Ellison Syndrome, or Other Pathological Hypersecretory Conditions
The patient must have an appropriate diagnosis confirmed by testing (barium contrast or double contrast radiography, or endoscopy).

For acute therapy, approval may be given for up to 12 months of treatment.

For maintenance therapy, approval may be given for up to 12 months. Retesting is not required for maintenance therapy renewals.

PA Timeframe Approval
- Approval may be given for up to 12 months for maintenance. Otherwise, please see above.

Electronic Prior Authorization (EPA)
- Not Applicable

Verbal PA Requests
- PA requests that meet prior usage requirements for approval may be accepted verbally.

Respiratory Agents

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

Prior Treatment Trials

- For a diagnosis of allergic rhinitis, the patient must also have failed 30-day treatment trials with at least two prescribed antiallergic agents, to include oral antihistamines or intranasal corticosteroids either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

- For all other diagnoses, the patient must also have failed 30-day treatment trials with at least two prescribed and preferred respiratory agents in this class, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

Stable Therapy

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- Respiratory agents are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Selective Serotonin Agonists

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

- The request must be for acute treatment, not prophylactic, therapy.

Prior Treatment Trials

- The patient must have failed 2-week treatment trials with at least two other prescribed and preferred selective serotonin agonists, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

Stable Therapy

- Approval may be given for children age 18 years and under who have been stable on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 6 months initially and up to 12 months for renewal requests.

Electronic Prior Authorization (EPA)

- Selective serotonin agonists are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Skeletal Muscle Relaxants

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

Prior Treatment Trials

- The patient must have also failed 30-day treatment trials with at least two prescribed and preferred skeletal muscle relaxants, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

Stable Therapy

- Approval may be given if the patient has been on consecutive 60 day or greater treatment if the skeletal muscle relaxant being requested is for a chronic condition associated with muscle spasticity.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- For chronic conditions associated with muscle spasticity, approval may be given for up to 6 months initially and up to 12 months for renewal requests.

- For acute conditions associated with muscle spasms, approval may be given for up to a 10-day course of medication consistent with current maximum limits when criteria are met.

Electronic Prior Authorization (EPA)

- Skeletal muscle relaxant agents are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Skin and Mucous Membrane Agents

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.
- Opzelura is approvable for the diagnosis of mild to moderate atopic dermatitis.

Prior Treatment Trial

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred skin and mucous membrane agents in this class, either generic, OTC, or brand, within the past 6 months, or one failed treatment trial, when appropriate, based on PDL preferred agents, or have a documented allergy or contraindication to all preferred agents in this class.

- To meet prior usage requirements, drugs within this specific classification must be judged against others in the same class (AHFS specific).

    - For example, to qualify for a non-preferred topical antifungal agent, the patient must have met prior usage requirements of 30-day treatment trials with two other topical antifungal agents, either generic or brand.

- For scabicides and pediculicides, the patient must have failed 14-day treatment trials with at least two prescribed and preferred skin and mucous membrane agents in this class, either generic, OTC, or brand within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

- For Eucrisa, the patient must have failed one prescribed and preferred skin and mucous membrane topical agent, either generic, OTC or brand, within the past 6 months.

- For Elidel and Protopic, prior therapies must include prescribed and preferred skin and mucous membrane corticosteroids.

- For Eucrisa, Zoryve, and Opzelura, prior therapy may be from any skin and mucous membrane class.

Stable Therapy

- Approval may be given for children age 18 years and under who have been stable on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- Skin and mucous membrane agents are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Wakefulness Promoting Agents

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

- For agents with an FDA-approved indication of idiopathic hypersomnia in children 18 and under, narcolepsy, obstructive sleep apnea, or shift work sleep disorder, the patient must have an appropriate diagnosis supported by documentation in the patient record of appropriate diagnostic testing.

Prior Therapy

- The patient must have also failed 30-day treatment trials with at least two prescribed and preferred wakefulness promoting agents, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

Stable Therapy

- Approval may be given to those who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- Wakefulness Promoting are not included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

ATTACHMENT A
ALZHEIMER'S AGENTS

For Leqembi® approval, the patient must meet the listed criteria:	Medical records documenting baseline (within the past three months) cognitive function based on Mini Mental State Exam (MMSE) score ≥22 OR a Clinical Dementia Rating (CDR) global score of 0.5 or 1.0
	Medical records documenting confirmed presence of amyloid beta pathology based on Cerebral Spinal Fluid (CSF) biomarkers OR Amyloid positron emission tomography (PET)
	Patient has had a brain magnetic resonance imaging (MRI) in the previous one year
	The prescriber is a neurologist or geriatrics specialist or there are consult notes from a neurologist or geriatrics specialist provided
For Leqembi® approval, the patient must NOT have any of the following:	Patient does NOT have ANY of the following non-Alzheimer's Disease neurodegenerative disorders: (1) Probable dementia with Lewy bodies by consensus criteria; (2) Suspected frontotemporal degeneration; (3) Dementia in down syndrome
	Patient has NOT had ANY of the following in the past year: (1) Stroke or transient ischemic attack; (2) Seizures
	Patient does NOT have an uncontrolled bleeding disorder (including platelet count <50,000 or IRN >1.5 for patients utilizing warfarin)
	Patient does NOT have ANY of the following neurological or psychiatric conditions: (1) Uncontrolled seizure disorder; (2) Uncontrolled mood disorder or psychosis
	Patient does NOT have significant cerebrovascular disease as established by brain MRI showing ANY of the following: 1. Acute or sub-acute hemorrhage 2. Prior macro-hemorrhage or prior subarachnoid hemorrhage (unless finding is not due to an underlying structural or vascular hemorrhage) 3. ≥4 microhemorrhages 4. Cortical infarct 5. >1 lacunar infarct 6. Superficial siderosis 7. History of diffuse white matter disease
	Patient does NOT have any uncontrolled clinically significant chronic medical condition (e.g., cardiovascular disease, liver disease, kidney disease, pulmonary disease, autoimmune disease requiring chronic immunosuppression, malignant neoplasm, active chronic infection [HIV, HCV], poorly controlled diabetes mellitus)

ATTACHMENT A
ALZHEIMER'S AGENTS
(continued)

For Kisunla® approval, the patient must meet the listed criteria:	Medical records documenting baseline (within the past three months) cognitive function based on Mini Mental State Exam (MMSE) score ≥20 OR a Clinical Dementia Rating (CDR) global score of 0.5 or 1.0
	Medical records documenting confirmed presence of amyloid beta pathology based on Cerebral Spinal Fluid (CSF) biomarkers OR Amyloid positron emission tomography (PET)
	Patient has had a brain magnetic resonance imaging (MRI) in the previous one year
	The prescriber is a neurologist or geriatrics specialist or there are consult notes from a neurologist or geriatrics specialist provided
For Kisunla® approval, the patient must NOT have any of the following:	Patient does NOT have significant neurological disease affecting the central nervous system other than Alzheimer's Disease, that may affect cognition or ability to complete the study, including but not limited to, other dementias, serious infection of the brain, Parkinson's disease, multiple concussions, or epilepsy or recurrent seizures (except febrile childhood seizures)
	Patient does NOT have history of schizophrenia or other chronic psychosis
	Patient does NOT have ANY of the following on MRI: 1. Presence of ARIA-E, 2. >4 cerebral microhemorrhages, 3. More than 1 area of superficial siderosis, 4. Any macrohemorrhage or severe white matter disease
	Patient does NOT have any current serious or unstable illnesses including cardiovascular, hepatic, renal, gastroenterologic, respiratory, endocrinologic, neurologic (other than Alzheimer's Disease), psychiatric, immunologic, or hematologic disease

All information in Alzheimer's Agents Attachment A can be found in the package inserts (Leqembi® [package insert]. Nutley (NJ): Eisai, Inc.; 2026 Jan.; Kisunla® [package insert]. Indianapolis (IN): Eli Lilly and Company; 2025 Jul.) and/or in clinical trial information referenced to in the package inserts.

Non-PDL Drugs and/or Drug Classes to Require PA

- Antihistamines (Second Generation)
- Antipsychotic Agents
- H2 Antagonists
- NSAIDs
- Phosphodiesterase Inhibitors
- Smoking Cessation
- Specialized Nutritionals
- Sustained Release Oral Opioid Agonists
- Vyjuvek
- Xenical

Antihistamines (Second Generation)

Appropriate Diagnosis

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

Prior Treatment Trials

- The patient must also have failed 30-day treatment trials with at least two prescribed antihistamines, either generic, OTC, or brand within the past 6 months, or have a documented allergy or contraindication to all covered OTC or generic antihistamine agents.

Stable Therapy

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- Second generation antihistamines are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Antipsychotic Agents

Appropriate Diagnosis/Prescriber Specialty

- The patient must have an appropriate diagnosis supported by documentation in the patient record, or the prescription may be written by a psychiatrist (adults), a child/adolescent psychiatrist (children), or a mid-level practitioner (CRNP or Physician Assistant) of the respective psychiatrist.

Prior Treatment Trials

- Not Applicable

Stable Therapy

- Approval may be given for children, adolescents, and adults (≥6 years of age) who have documented stable therapy on the requested medication for 60 consecutive days or greater.

- If an appropriate diagnosis is not included, requests will be approved for 3 months for adults (>18 years of age) and 6 months for children and adolescents (6 to 18 years of age). Notification (via PA approval letter) will be sent to the prescribing physician notifying him/her that an appropriate diagnosis will be required to approve subsequent requests.

- Stable therapy does not apply to antipsychotic agents for children <6 years of age.

Medical Justification

- For children, adolescents, and adults (≥6 years of age), medical justification may include peer-reviewed literature, medical record documentation, request for continuation of therapy after discharge from the hospital, or information specifically requested.

- For children <6 years of age, medical justification must include chart notes with specific symptoms that support the diagnosis, as well as peer-reviewed literature if the antipsychotic agent is being used for an off-label use.

- For children <6 years of age, the prescriber must indicate through attestation that monitoring protocols have been followed. For a list of monitoring protocols, see Attachment C on the Agency website at www.medicaid.alabama.gov.

PA Approval Timeframes

- Approval may be given for up to 12 months for adults with an appropriate diagnosis and for up to 3 months for adults without an appropriate diagnosis.

- Approval may be given for up to 6 months for children and adolescents (6 to 18 years of age) and for up to 6 months for children <6 years of age.

Electronic Prior Authorization (EPA)

- Antipsychotic agents are included in the electronic PA program.

Verbal PA Requests

- Not Applicable

H2 Antagonists

Appropriate Diagnosis

- Indicate in the clinical information section whether this request is for acute or maintenance therapy.

Prior Treatment Trials

- The patient must also have failed 30-day treatment trials with two prescribed H2 Antagonists in this class, either generic, OTC, or brand, within the past 6 months.

- Approval may be given without failed drug trials **if** a relevant diagnosis and documentation of testing with date and results are provided.

Stable Therapy

- Stable therapy does not apply to the H2 antagonist class.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval timeframes are based on acute versus maintenance therapy. Approval may be given for up to 12 months for maintenance therapy.

Electronic Prior Authorization (EPA)

- Not Applicable

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Nonsteroidal Anti-inflammatory Drugs (NSAIDs)

Appropriate Diagnosis

- For COX II Inhibitors, the patient must have an appropriate diagnosis supported by documentation in the patient record, as well as any additional diagnoses and any history preventing the use of other NSAIDs.

Prior Treatment Trials

- The patient must have failed 30-day treatment trials with at least 2 other therapies, either generic, OTC, or brand, within the past 6 months.

Stable Therapy

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

- For **Prevacid NapraPAC®** the patient must have a diagnosis of gastric ulcer, diagnosed within the past 12 months, **and** require the use of an NSAID for treatment of the signs and symptoms of rheumatoid arthritis, osteoarthritis, or ankylosing spondylitis. The patient must also have failed two 30-day treatment trials with at least two prescribed NSAIDs while on concomitant H2 or PPI therapy within the past 6 months, either generic, OTC, or brand, or have a documented contraindication to all preferred agents in this class.

PA Approval Timeframes

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- Nonsteroidal anti-inflammatory drugs (NSAIDs) are included in the electronic PA program.

Verbal PA Requests

- PA requests that meet prior usage requirement for approval may be accepted verbally.

Phosphodiesterase Inhibitors

Appropriate Diagnosis

- Phosphodiesterase inhibitors require diagnosis of pulmonary arterial hypertension (defined by a mean pulmonary arterial pressure >25 mm Hg at rest or >30 mm Hg with exercise, by a pulmonary capillary wedge pressure ≤15 mm Hg and by peripheral vascular resistance >3 mm Hg/L/min).

- Documentation must be provided of consultation with a specialist experienced in the treatment of pulmonary hypertension patients.

- A sole diagnosis of erectile dysfunction will not be approved.

Prior Treatment Trials

- Documentation must include failure of or contraindication to at least three other available oral conventional therapies.

- Previous therapies may include oral anticoagulants, calcium channel blocking agents, digoxin, diuretics and/or oxygen supplementation.

Stable Therapy

- Stable therapy does not apply to phosphodiesterase inhibitors.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 30 days for initial requests, with up to 3 months allowed for renewal requests.

Electronic Prior Authorization (EPA)

- Not Applicable

Verbal PA Requests

- Not Applicable

Smoking Cessation

Appropriate Diagnosis

- An appropriate diagnosis is not required for smoking cessation products.

Prior Treatment Trials

- Prior treatment trials do not apply to smoking cessation products.

Stable Therapy

- Stable therapy does not apply to smoking cessation products.

Medical Justification

- Medical justification includes a copy of the Department of Public Health's Alabama Tobacco Quitline Patient Referral/Consent Form signed by the recipient. The form must be faxed with the prior authorization request.
- Smoking cessation products are covered without prior approval for recipients currently enrolled in the Plan First Program.

PA Approval Timeframes

- Approval timeframe is dependent upon the duration of therapy for the approved medication.
- Only one course of therapy is allowed per calendar year.

Electronic Prior Authorization (EPA)

- Not Applicable

Verbal PA Requests

- Not Applicable

Specialized Nutritionals

Appropriate Diagnosis

- Patients who, because of illness or trauma, cannot be sustained through oral feedings and must rely on enteral nutrition therapy may qualify for coverage under Medicaid. Enteral nutrition may be administered by nasogastric, jejunostomy, or gastrostomy tubes.

- Specialized nutrition is covered for Medicaid eligible EPSDT recipients less than 21 years of age with nutritional disorders. They do not have to be tube fed, but the specialized feeding must constitute more than 50% of their nutritional needs. A qualifying diagnosis is required.

- Recipients age 21 and over who must rely on enteral feedings as their only source of nutrition may qualify for Medicaid coverage if they have a qualifying diagnosis and meet disease specific criteria.

Prior Treatment Trials

- Prior treatment trials do not apply to nutritional products.

Stable Therapy

- Stable therapy does not apply to nutritional products.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

- Additional Information
  - Current height and weight are required.
  - Current age is required.
  - Route specialized nutritional is administered, along with the duration and number of refills is required.

- Prior authorization is for the nutritional product only and does not include any equipment or supplies necessary to administer the nutrients. Supplies and equipment used in conjunction with nutritional therapy may be covered in the Medical Supplies, Appliances and Durable Medical Equipment Program. For more information on supplies and equipment, see Chapter 14 of the Medicaid Provider Manual or contact Medicaid Provider/Recipient Services at 1-334-353-4753.

PA Timeframe Approval

- Approval may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- Not Applicable

Verbal PA Requests

- Not Applicable

Sustained Release (SR) Oral Opioid Agonists

Appropriate Diagnosis

- Approval may be given for the treatment of intractable, chronic pain with oral SR opioid agonists (Avinza®, Embeda ER®, Exalgo®, Hysingla™ ER, Kadian®, MS Contin®, Opana ER®, OxyContin®, Xtampza ER, and Zohydro ER®). These medications are narcotic analgesics and Schedule II controlled substances and are not intended for use with acute pain, as a PRN analgesic, or for short-term pain management (≤10 days).

- The request form must include duration of therapy, if medication is for PRN use, type of pain, and severity of pain.

Prior Treatment Trials

- The patient must have failed 30-day trials with alternative pain management therapies and non-opioid adjuvant drugs to replace or enhance opioid analgesia, unless the primary diagnosis is an approved cancer diagnosis.

Stable Therapy

- Approval may be given for children age 18 years and under who have been stable on the requested medication for 60 consecutive days or greater who meet the diagnosis requirements.

Medical Justification

- For patients ≥65 years of age, medical justification may be provided in lieu of non-opioid adjuvant drugs.

- If the patient has a history of substance abuse or addiction, a treatment plan (a plan of action addressing continuing medical monitoring, titration, and a written signed contract for therapy) must be attached to the request, unless the patient is a nursing home resident.

- For nursing home residents with a history of substance abuse or addiction, medical justification may be submitted in lieu of a plan of action, alternate pain management choices and adjuvant therapy.

PA Approval Timeframes

- Approval timeframes are diagnosis dependent and may be given for up to 12 months.

Electronic Prior Authorization (EPA)

- Sustained release (SR) oral opioid agonists are included in the electronic PA program.

Verbal PA Requests

- Not Applicable

Vyjuvek®

Appropriate Diagnosis

- To receive prior authorization for Vyjuvek®, the patient must have a diagnosis of dystrophic epidermolysis bullosa.

- The patient must have mutation(s) in the *collagen type VII alpha 1 chain (COL7A1)* gene.

- Dosage requested must not exceed:
  - For patients <3 years old: maximum of 2 x 10^9 PFU/week or 1 mL/week.
  - For patients ≥ 3 years old: maximum of 4 x 10^9 PFU/week or 2 mL/week.

- Documentation must be provided of consultation with a specialist (e.g., dermatologist, geneticist, histopathologist).

Prior Treatment Trials

- Prior therapy does not apply to Vyjuvek®.

Stable Therapy

- Stable therapy does not apply to Vyjuvek®.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Initial approval may be given for up to 6 months.

Electronic Prior Authorization (EPA)

- Not applicable

Verbal PA Requests

- Not applicable

Xenical®

Appropriate Diagnosis

- To receive prior authorization for Xenical®, the patient must be 12 years of age or older with a BMI ≥ 27 kg/m^2 and have at least one of the following primary medical diagnoses:
  - Diabetes mellitus
  - Hypertension
  - Hyperlipidemia

- For initial requests the patient's height (in inches), weight (in pounds) and BMI are required.

- Renewal requests require the patient's previous and current weights (in pounds). Continued weight loss must be documented for renewals.

- Dosage requested must not exceed 120 mg TID.

Prior Treatment Trials

- There must be documentation in the patient record to support failure with prior physician supervised exercise/diet regimen(s) of at least 6 months duration. Documentation must also show that adjuvant therapy is planned.

Stable Therapy

- Stable therapy does not apply to Xenical®.

Medical Justification

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

PA Approval Timeframes

- Approval may be given for up to 3 months with initial request, and up to 6 months for each subsequent request to a total approval period not to exceed 2 years for the recipient.

Electronic Prior Authorization (EPA)

- Not Applicable

Verbal PA Requests

- Not Applicable

Section Six
PA Form: Dispensing Pharmacy Information

(Information in this area may be completed by the pharmacy).

Below are fields to be completed on the PA Form.

Form States:	Your Response:
Dispensing pharmacy	Enter the pharmacy name.
NPI/Provider number	Enter the pharmacy NPI or provider number.
Phone number with area code	Enter the pharmacy phone number with area code.
Fax number with area code	Enter the pharmacy fax number with area code.
NDC number	Record the NDC number of the drug requested.