Instruction Sheet for Appeals Template

The attached appeals template was developed to help patients request an appeal of a denied insurance claim for ARISTADA™ (aripiprazole lauroxil).

To use the template, simply copy and paste the contents into a blank page containing office letterhead. Bolded and/or bracketed words/phrases should be replaced with the relevant clinical information before the customized letter is sent to the patient's insurance provider. Modify the information listed to best match each patient's specific circumstances.

This is not a guarantee of payment, coverage, or reimbursement. Alkermes does not provide any advice, recommendation, guarantee, or warranty relating to coverage, reimbursement, or coding for any product or service. Healthcare providers are responsible for determining coverage and reimbursement information and ensuring the accuracy and completeness of claim submissions for their patients. Coding, coverage, and reimbursement vary significantly by payer, patient, and setting of care and are subject to change. Additional information may exist. Actual coverage and reimbursement decisions are made by individual payers.

Tips for completing the request for appeal or reconsideration:

- Include accurate information about the original claim, including patient's name, date of service, and diagnosis for provided care
- List the insurance company name that denied the claim and include the reason for denial, such as the denial code and description

Tips for completing the disease and medical history fields:

- Include specific billing codes where appropriate
- List previous treatment, including duration of use and outcomes (eg, specify reasons for unsuccessful results)
- Clearly state the rationale for the recommendation of ARISTADA treatment and why it is appropriate for the patient

INDICATION

ARISTADA is indicated for the treatment of schizophrenia.

IMPORTANT SAFETY INFORMATION

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ARISTADA is not approved for the treatment of patients with dementia-related psychosis.

Please see additional Important Safety Information on the following pages and accompanying full Prescribing Information, including Boxed Warning.

Tips for completing the enclosed materials field:

- List and enclose documents that support the rationale for the recommended medically necessary treatment:
  - Summary of patient's medical records
  - Copies of peer-reviewed articles
  - Copies of medical correspondence
  - Specific information about the recommended treatment (Prescribing Information, Food and Drug Administration approval letter, and/or evidence-based treatment guidelines)
- Be sure to include all the listed documents with the letter when sending to your patient's insurance provider
- Remember to include the healthcare professional's information for the insurer, including phone number with area code

This is not a guarantee of payment, coverage, or reimbursement. Alkermes does not provide any advice, recommendation, guarantee, or warranty relating to coverage, reimbursement, or coding for any product or service. Healthcare providers are responsible for determining coverage and reimbursement information and ensuring the accuracy and completeness of claim submissions for their patients. Coding, coverage, and reimbursement vary significantly by payer, patient and setting of care and are subject to change. Additional information may exist. Actual coverage and reimbursement decisions are made by individual payers.

Alkermes, Inc.

For more information about ARISTADA™ (aripiprazole lauroxil), call 1-866-ARISTADA (1-866-274-7823) or go to ARISTADA.com.

Please see additional Important Safety Information on the following pages and accompanying full Prescribing Information, including Boxed Warning.

Appeals Template

Payer Contact Name:

Title:

Name of Health Insurance Company:

Address:

City, State, ZIP Code:

Patient Information

Patient Name:

Insured Name:

Policy Number:

Group Number:

Diagnosis codes:
- ICD-9-CM (use ICD-9 codes for dates of service prior to Oct 1, 2015)
- ICD-10-CM (use ICD-10 codes for dates of service on or after Oct 1, 2015)

Claim Number:

Dear [Name of contact]:

This letter serves as a request for reconsideration of payment for a claim representing charges for ARISTADA™ (aripiprazole lauroxil) administered to [Patient's name] on [Date of service]. [Patient's name] has been under my treatment for [his/her] diagnosis of [Diagnosis]. You have indicated ARISTADA is not covered by [Name of health insurance company] because [Reason for denial].

ARISTADA is indicated for the treatment of schizophrenia. Because of [Insert relevant patient information—history, diagnosis, specifics of medical necessity versus other therapy alternative] I have administered ARISTADA as a medically necessary part of this patient's treatment and request your reconsideration of the [Date of service] claim for [Patient's name]. Please contact me at [Healthcare professional's area code and telephone number] if you require additional information.

Thank you in advance for your immediate attention to this request.

Sincerely,

[Healthcare professional's name]
[Healthcare professional's practice name]
[Healthcare professional's practice address]

Attachments: May include original claim form and Letter of Medical Necessity, denial, Explanation of Benefits, additional supporting documents

INDICATION

ARISTADA is indicated for the treatment of schizophrenia.

IMPORTANT SAFETY INFORMATION

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ARISTADA is not approved for the treatment of patients with dementia-related psychosis.

Contraindication: Known hypersensitivity reaction to aripiprazole. Reactions have ranged from pruritus/urticaria to anaphylaxis.

Cerebrovascular Adverse Reactions, Including Stroke: Increased incidence of cerebrovascular adverse reactions (eg, stroke, transient ischemic attack), including fatalities, have been reported in placebo-controlled trials of elderly patients with dementia-related psychosis treated with risperidone, aripiprazole, and olanzapine. ARISTADA is not approved for the treatment of patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome (NMS): A potentially fatal symptom complex sometimes referred to as NMS may occur with administration of antipsychotic drugs, including ARISTADA. Clinical manifestations of NMS include hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; 2) intensive symptomatic treatment and medical monitoring; and 3) treatment of any concomitant serious medical problems for which specific treatments are available.

Tardive Dyskinesia (TD): The risk of developing TD (a syndrome of abnormal, involuntary movements) and the potential for it to become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic increase. The syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. Prescribing should be consistent with the need to minimize TD. Discontinue ARISTADA if clinically appropriate. There is no known treatment for established TD, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn.

Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes that include:

- **Hyperglycemia/Diabetes Mellitus:** Hyperglycemia, in some cases extreme and associated with ketoacidosis, coma, or death, has been reported in patients treated with atypical antipsychotics. There have been reports of hyperglycemia in patients treated with oral aripiprazole. Patients with diabetes should be regularly monitored for worsening of glucose control; those with risk factors for diabetes should undergo baseline and periodic fasting blood glucose testing. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia, including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia should also undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients require continuation of antidiabetic treatment despite discontinuation of the suspect drug.
- **Dyslipidemia:** Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics.
- **Weight Gain:** Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Orthostatic Hypotension: Aripiprazole may cause orthostatic hypotension which can be associated with dizziness, lightheadedness, and tachycardia. Monitor heart rate and blood pressure, and warn patients with known cardiovascular or cerebrovascular disease and risk of dehydration and syncope.

Please see additional Important Safety Information on next page and accompanying full Prescribing Information, including Boxed Warning.

IMPORTANT SAFETY INFORMATION *(continued)*

Leukopenia, Neutropenia, and Agranulocytosis: Leukopenia, neutropenia, and agranulocytosis have been reported. Patients with a history of clinically significant low white blood cell count (WBC)/absolute neutrophil count (ANC) and history of drug-induced leukopenia/neutropenia should have frequent complete blood count (CBC) during the first few months of receiving ARISTADA. Consider discontinuation of ARISTADA at the first sign of a clinically significant decline in WBC count in the absence of other causative factors. Monitor patients with clinically significant neutropenia for fever or other symptoms or signs of infection and treat promptly if such symptoms or signs occur. Discontinue ARISTADA in patients with severe neutropenia (absolute neutrophil count <1000/mm^3) and follow their WBC until recovery.

Seizures: ARISTADA should be used with caution in patients with a history of seizures or with conditions that lower the seizure threshold.

Potential for Cognitive and Motor Impairment: ARISTADA may impair judgment, thinking, or motor skills. Patients should be cautioned about operating hazardous machinery, including automobiles, until they are certain ARISTADA does not affect them adversely.

Body Temperature Regulation: Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Advise patients regarding appropriate care in avoiding overheating and dehydration. Appropriate care is advised for patients who may exercise strenuously, may be exposed to extreme heat, receive concomitant medication with anticholinergic activity, or are subject to dehydration.

Dysphagia: Esophageal dysmotility and aspiration have been associated with antipsychotic drug use; use caution in patients at risk for aspiration pneumonia.

Concomitant Medication: Decreasing the ARISTADA dosage is recommended in patients taking strong CYP3A4 inhibitors and/or strong CYP2D6 inhibitors for longer than 2 weeks. Increasing the ARISTADA dosage is recommended in patients taking CYP3A4 inducers for longer than 2 weeks. No ARISTADA dosage changes are recommended for patients taking CYP450 modulators for less than 2 weeks.

Most Commonly Observed Adverse Reaction: The most common adverse reaction (≥5% incidence and at least twice the rate of placebo in patients treated with ARISTADA) was akathisia.

Injection-Site Reactions: Injection-site reactions were reported by 4%, 5%, and 2% of patients treated with 441 mg ARISTADA, 882 mg ARISTADA, and placebo, respectively. Most of these were injection-site pain and associated with the first injection and decreased with each subsequent injection. Other injection-site reactions (induration, swelling, and redness) occurred at less than 1%.

Dystonia: Symptoms of dystonia, prolonged abnormal contractions of muscle groups, may occur in susceptible individuals during the first days of treatment and at low doses.

Pregnancy/Nursing: May cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure. Advise patients to notify their healthcare provider of a known or suspected pregnancy. Inform patients that there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to ARISTADA during pregnancy. Aripiprazole is present in human breast milk. The benefits of breastfeeding should be considered along with the mother's clinical need for ARISTADA and any potential adverse effects on the infant from ARISTADA or from the underlying maternal condition.

Please see **FULL PRESCRIBING INFORMATION**, including **Boxed Warning** for ARISTADA.