Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

PALSONIFY® (paltusotine) PA CRITERIA:

PALSONIFY® (paltusotine) is a somatostatin receptor agonist used for the treatment of acromegaly in adults who had an inadequate response to surgery and/or for whom surgery is not an option.

Prior authorization is required for PALSONIFY® (paltusotine). Prior authorization approval will be considered when the following criteria are met. Along with the Universal PA Form, please submit any supporting clinical documentation.

Initial Authorization: 6 Months

1. The patient is 18 years of age or older; **AND**
2. The patient has a confirmed diagnosis of acromegaly, supported by both an elevated insulin-like growth factor 1 (IGF-1) level above the upper limit of normal for age and sex using laboratory reference ranges, and clinical symptoms consistent with acromegaly (e.g., enlarged hands/feet, headaches, arthralgias, hyperhidrosis); **AND**
3. The patient has had pituitary surgery with inadequate biochemical or clinical response, or the patient is not a surgical candidate; **AND**
4. The medication is prescribed by, or in consultation with, an endocrinologist; **AND**
5. The patient has at least a six-month trial and had an inadequate response, intolerance, or contraindication to both of the following long-acting injectable somatostatin analogs: octreotide LAR and lanreotide; **AND**
6. The patient has at least a six-month trial and had an inadequate response, intolerance, or contraindication to MYCAPSSA® (oral octreotide); **AND**
7. The prescribed dose does not exceed 60 mg once daily.

Re-Authorization: 1 Year

1. Documentation of positive clinical response, defined as IGF-1 within the normal range or a clinically meaningful reduction from baseline, and an improvement or stabilization of acromegaly-related symptoms, has been provided; **AND**
2. The prescribed dose does not exceed 60 mg once daily.

PALSONIFY® Dosing: The recommended starting dosage is 40 mg once daily; may temporarily reduce to 20 mg once daily if needed based on tolerability, then resume 40 mg once daily once adverse effects have resolved. After 2 to 4 weeks on 40 mg once daily, may increase to 60 mg once daily based on IGF-1 levels.

Formulation: PALSONIFY® is available as a 20 mg and 30 mg oral tablet.