

Sandostatin® LAR Depot (octreotide acetate) for injectable suspension and Sandostatin® (octreotide acetate) Injection



When requesting Sandostatin® LAR Depot (octreotide acetate for injectable suspension) or Sandostatin® (octreotide acetate injection) for non-oncology indication(s), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Non-oncology Indications

- Treatment of acromegaly

Coverage Guidelines

Acromegaly:

The patient must meet ONE of the following criteria for approval (A or B):

- A) Initial Therapy: The patient meets ALL of the following criteria (i, ii, and iii)
- i) The patient meets ONE of the following criteria (a, b, or c):
 - a) The patient has had an inadequate response to surgery and/or radiotherapy;
OR
 - b) The patient is not an appropriate candidate for surgery and/or radiotherapy,
OR
 - c) The patient is experiencing negative effects due to tumor size (e.g., optic nerve compression); AND
 - ii) Prescribed by or in consultation with an endocrinologist; AND
 - iii) The patient has (or had) a pretreatment (baseline) insulin growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory.
- B) Patient is Currently Receiving Octreotide: The patient has responded to octreotide (e.g., decrease/normalization of IGF-1 level, decrease in growth hormone level, improvement in metabolic abnormalities ([e.g., diabetes mellitus]), as determined by the prescriber.

Approval Duration (initial): 3 months

Approval Duration (renewal): 12 months

Dosing Recommendations

- In patients currently receiving octreotide subcutaneous injection, the recommended initial dose for switching to Sandostatin LAR Depot is 20mg once every 4 week interval for 3 months.
- This dose may be increased to 30mg IM every 4 weeks and 40mg every 4 weeks in patient who have not normalized GH and/or age and sex adjusted IGF-1 levels after 3 months of initial treatment. The dose may also be decreased to 10 mg every 4 weeks if the GH and IGF-1 levels are controlled.
- Patients not currently receiving octreotide subcutaneous injection should begin therapy with that short-acting agent first. Patients should be maintained on

octreotide subcutaneous injection for at least 2 weeks to determine tolerance to octreotide. Patients who are considered “responders” based on GH and IGF-1 levels can be switched to Sandostatin LAR Depot.

- In patients with renal failure requiring dialysis and in patients with established cirrhosis of the liver, the starting dose should be 10 mg every 4 weeks.

References

1. Sandostatin® LAR Depot for injectable suspension [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2016.
2. Katznelson L, Laws ER Jr, Melmed S, et al; Endocrine Society. Acromegaly: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2014; 99:3933-3951.