

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 an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Non-Oncology Indication

Sandostatin LAR Depot and Sandostatin are indicated for the treatment of acromegaly in individuals who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy, is not an option.

Coverage Guidelines

Acromegaly

The individual must meet **all** of the following criteria for approval:

- Meets one of the following:
 - o Had an inadequate response to surgery and/or radiotherapy; OR
 - o Is not an appropriate candidate for surgery and/or radiotherapy; OR
 - o Is experiencing negative effects due to tumor size (e.g., optic nerve compression);
- Has/had a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory;
- Octreotide is prescribed by or in consultation with an endocrinologist.

Approval Duration: 12 months

Dosing Recommendations

Individuals not currently receiving Sandostatin injection subcutaneously:

The recommended dose is 50 mcg three times daily Sandostatin injection subcutaneously for 2 weeks followed by Sandostatin LAR Depot 20 mg intragluteally every 4 weeks for 3 months.

Individuals currently receiving Sandostatin injection subcutaneously:

The recommended dose is Sandostatin LAR Depot 20 mg every 4 weeks for 3 months.

After 3 months, Sandostatin LAR Depot dosage may be adjusted as follows:

- GH $\leq$ 2.5ng/mL, IGF-1 normal, and clinical symptoms controlled: maintain Sandostatin LAR Depot dosage at 20 mg every 4 weeks
- GH >2.5ng/mL, IGF-1 elevated, and/or clinical symptoms uncontrolled, increase Sandostatin LAR Depot dosage to 30 mg every 4 weeks
- GH $\leq$ 1 ng/mL, IGF-1 normal, and clinical symptoms controlled, reduce Sandostatin LAR Depot dosage to 10 mg every 4 weeks
- If GH, IGF-1, or symptoms are not adequately controlled at a dose of 30 mg, the dose may be increased to 40 mg every 4 weeks. Doses higher than 40 mg are not recommended.

References

1. Sandostatin® LAR Depot intramuscular injection [prescribing information]. East Hanover, NJ: Novartis; March 2021.