

Octreotide Acetate Long-acting Products (Sandostatin LAR Depot, generic)

When requesting an octreotide acetate long -acting product (Sandostatin LAR Depot, generic) for non-oncology indications, the individual requiring treatment must be diagnosed with the following FDA-approved indication or one of the following approved off-label compendial uses and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Non-Oncology Indication

Octreotide acetate long acting product is 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.

Approved Off-label Compendial Uses

- Enterocutaneous fistulas
- Pancreatic fistulas
- Small Bowel Bleeds/Angiodysplasia Related Bleeding

Coverage Guidelines

Acromegaly

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

- Meets one of the following:
 - Had an inadequate response to surgery and/or radiotherapy; OR
 - Is not an appropriate candidate for surgery and/or radiotherapy; OR
 - 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.

Pancreatic fistulas

The individual must meet the following criterion for approval:

- Is being treated for operative trauma, pancreatic resection, acute or chronic pancreatitis, or pancreatic infection.

Small Bowel Bleeds/Angiodysplasia Related Bleeding

The individual must meet the following criterion for approval:

- Has chronic, recurrent gastrointestinal bleeds lasting ≥ 3 months;
- Octreotide is prescribed by or in consultation with a gastroenterologist.

Approval Duration: Acromegaly 12 months; Enterocutaneous fistulas 3 months; Pancreatic fistulas 2 months; Small bowel bleeds/angiodysplasia related bleeding 6 months

Dosing Recommendations

Acromegaly

The recommended dose is 20 mg administered intramuscularly every 4 weeks for 3 months.

Enterocutaneous Fistulas/Pancreatic Fistulas

The recommended dose is up to 40 mg administered intramuscularly every 4 weeks.

Small Bowel Bleeds/Angiodysplasia Related Bleeding

The recommended dose is up to 40 mg administered intramuscularly every 4 weeks.

References

1. Sandostatin® LAR Depot intramuscular injection [prescribing information]. East Hanover, NJ: Novartis; July 2024.
2. Kong X, Cao Y, Yang D, Zhang X. Continuous irrigation and suction with a triple-cavity drainage tube in combination with sequential somatostatin-somatotropin administration for the management of postoperative high-output enterocutaneous fistulas: Three case reports and literature review. *Medicine*. 2019;98(46):e18010.
3. Tian W, Zhao R, Luo S, et al. Effect of postoperative utilization of somatostatin on clinical outcome after definitive surgery for duodenal fistula. *Eur J Med Res*. 2023;28(1):63.
4. Alghamdi AA, Jawas AM, Hart RS. Use of octreotide for the prevention of pancreatic fistula after elective pancreatic surgery: a systematic review and meta-analysis. *Can J Surg*. 2007;50(6):459-466.
5. Veillette G, Dominguez I, Ferrone C, et al. Implications and management of pancreatic fistulas following pancreaticoduodenectomy: the Massachusetts General Hospital experience. *Arch Surg*. 2008;143(5):476-481.
6. Sundaram S, Patra BR, Choksi D, et al. Outcomes and predictors of response to endotherapy in pancreatic ductal disruptions with refractory internal and high-output external fistulae. *Ann Hepatobiliary Pancreat Surg*. 2022;26(4):347-354.
7. Noori I. Postoperative enterocutaneous fistulas: Management outcomes in 23 consecutive patients. *Ann Med Surg*. 2021;66:102413.
8. Gerson LB, Fidler JL, Cave DR, Leighton JA. ACG clinical guideline: diagnosis and management of small bowel bleeding. *Am J Gastroenterol*. 2015;110(9):1265-1288.
9. Goltstein LCMJ, Grooteman KV, Bernts LHP, et al. Standard of care versus octreotide in angiodysplasia-related bleeding (the OCEAN Study): a multicenter randomized controlled trial. *Gastroenterology*. 2024;166(4):690-703.